McLennan COMMUNITY COLLEGE

2021

Institutional Review Board Guidelines McLennan Community College

Research Review Committee
McLennan Community College
1/19/2021

Contents

A committee of at least five members:

a. Composition of the committee must include members with enough experience, expertise, and diversity to make informed decisions as to whether research is ethical, informed consent is sufficient, and appropriate safeguards have been put in place.

b. If the IRB works with studies that include vulnerable populations, the IRB needs to have members who are familiar with these groups.

c. The IRB should include men and women, as long as they aren't chosen specifically for their gender.

d. The IRB members must not all be from the same profession/field of study.

e. The IRB must include at least one scientist and at least one non-scientist.

f. The IRB must include at least one person who is not affiliated with the institution or in the immediate family of a person affiliated with the institution.

g. IRB members may not vote on their own projects.

h. The IRB may include consultants in their discussions to meet requirements for expertise or diversity, but only actual IRB members may vote.

Committee Members —

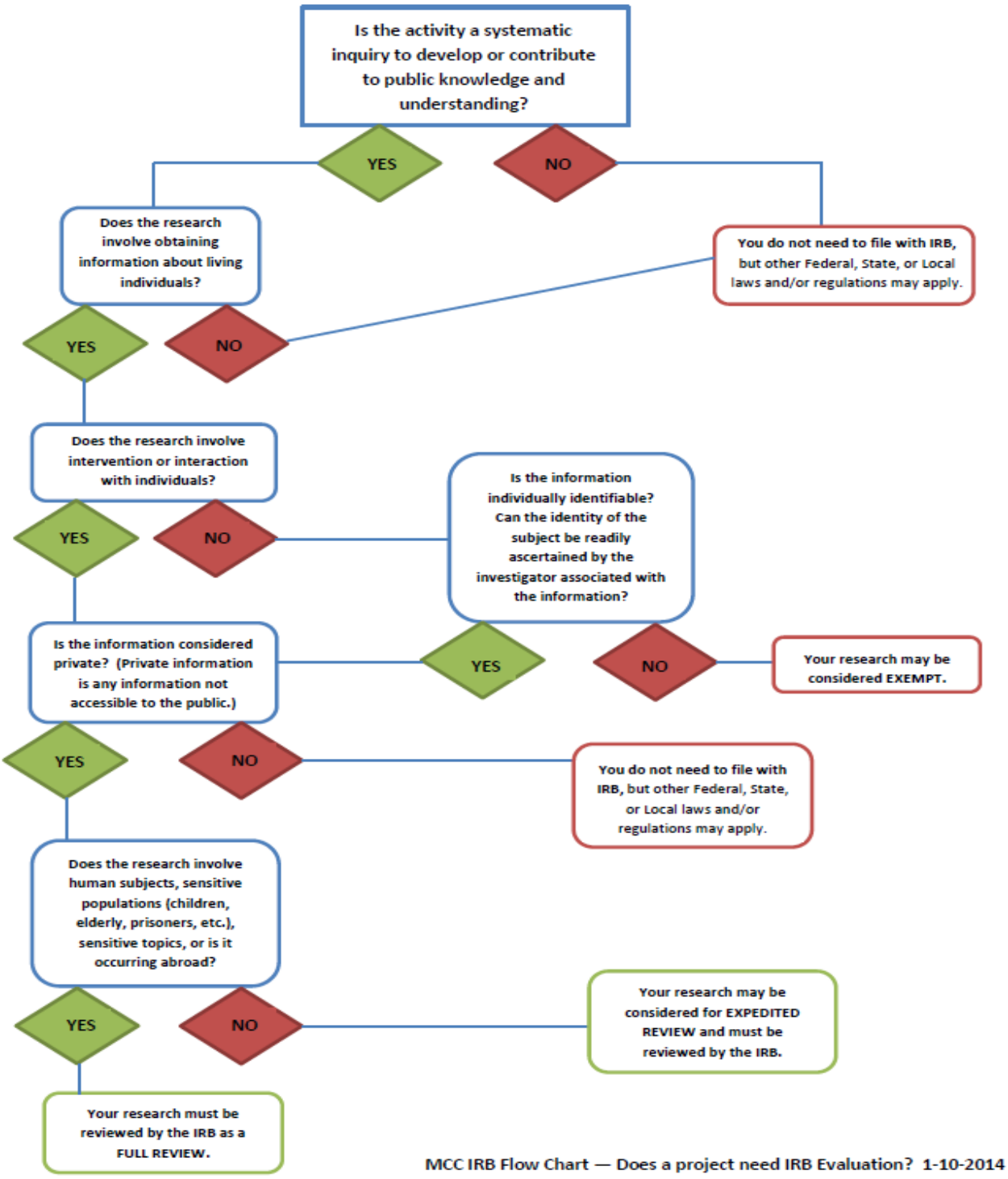
IRB Committee Members	Credentials of IRB Committee Members	Term of IRB Committee Members
Bradley Christian, Chair bchristian@mclennan.edu (254) 299-8179 S 322	**Associate Professor, Biology** Doctorate, Biology, Baylor University BS, Microbiology/Biology University Texas Arlington	Permanent term
Community Member [Vacant]		2019-2022
Cynthia McAdams cmcadams@mclennan.edu (254) 299-8304 HPN 110	**Professor, Associate Degree Nursing** Doctorate, Nursing, University of Texas at Austin MS, Nursing, Texas A&M University Corpus Christie BS, Nursing, University of Texas Arlington	2017-2021
Suzanne Baldon sbaldon@mclennan.edu (254) 299-6505 ESEC 216	**Associate Professor, Criminal Justice** Doctorate, Philosophy, California Integral Studies MA, Anthropology, University of Texas Arlington	2017-2021
Deborah Brock dbrock@mclennan.edu (254) 299-8933 MAC 328	**Associate Professor, Psychology** Doctorate, Psychology MEd, Secondary Education, Sam Houston State University	2017-2020

Ex-Officio Members —

(Non-voting and not present during Board deliberations—serve in support role as subject area specialists.)

Sue Allen suallen@mclennan.edu (254) 299-8742 RANC 127	**Program Director/Professor** **Veterinary Technician Program** AAS, Veterinary Technology, TSTC, Waco
Sharon Kenan skenan@mclennan.edu (254) 299-8343 LTC 312	**Librarian/Professor** **Library Sciences** Doctorate, Educational Studies, University of Nebraska, Lincoln MA, Baylor University MLS, University Texas Austin
Michelle Powell mpowell@mclennan.edu (254) 299-8162 MATH 122	**PT Instructor, Child Studies & Education** Doctorate, Educational Psychology, Baylor University MS, Curriculum/Instruction, Baylor University
Tom Proctor tproctor@mclennan.edu (254) 299-8619 RE 122	**Director, Program Review, Planning & Assessment** MA, American Studies & Archives, University of Massachusetts Boston
Richard Sneed rsneed@mclennan.edu	**PT Instructor, Philosophy** Doctorate, Philosophy, Florida State University MA, Philosophy, Michigan State University MDiv, Theology, Southern Methodist University
Laura Wichman lwichman@mclennan.edu (254) 299-8476 RE 119	**Director, Institutional Research** MS, Management & Leadership, Tarleton University

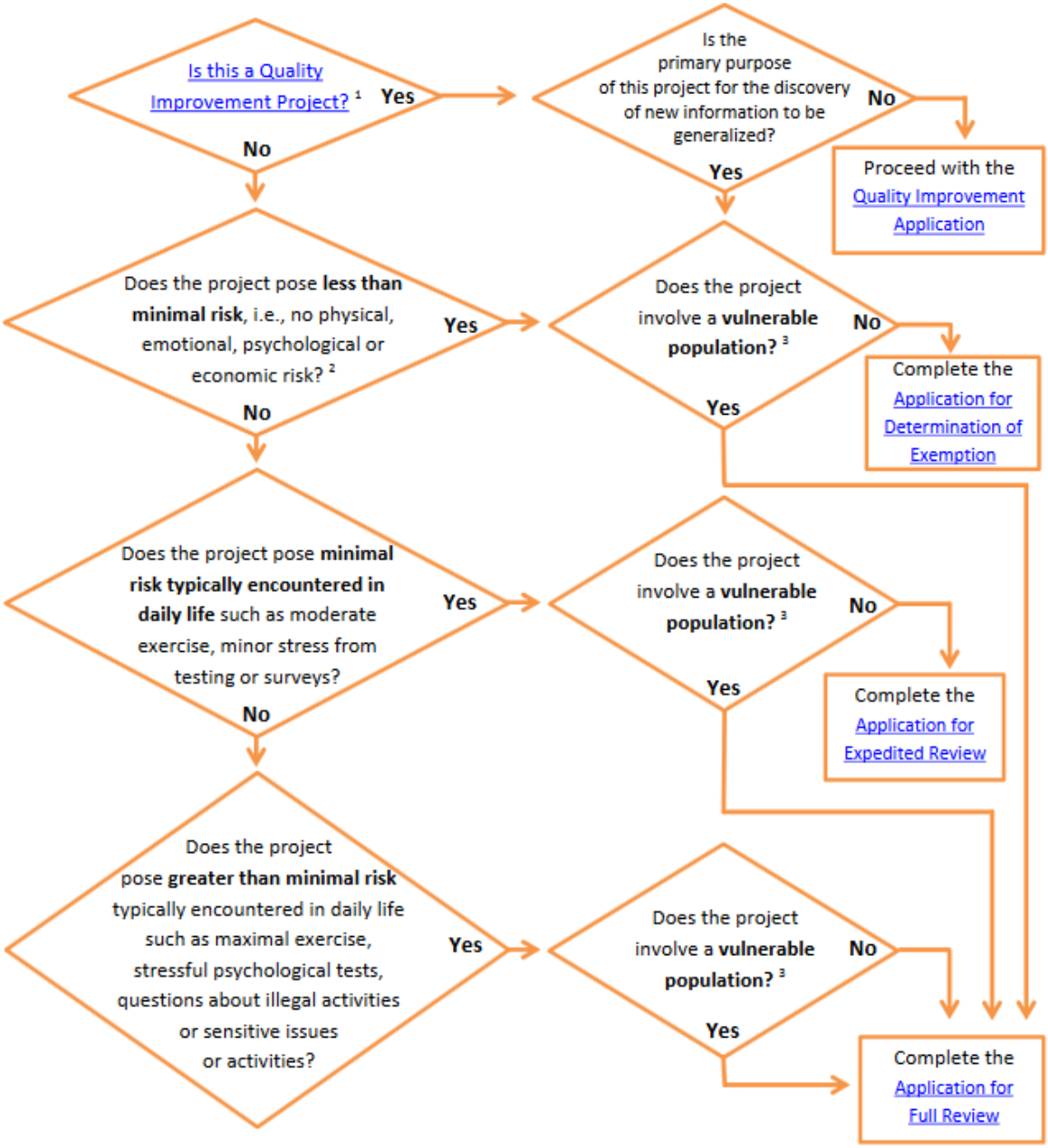
DECISION CHART — WHAT CONSTITUTES RESEARCH AT MCC?
(For detailed charts see: pp. 49-50.)



MCC IRB Flow Chart — Does a project need IRB Evaluation? 1-10-2014

IRB Application Category Decision Tree

Note: The IRB makes the final determination of the review category



[1]Quality Improvement "is specifically initiated with a goal of improving the performance of institutional practice in relationship to an established standard" [Bankert, E.A. & Amdur, R.J. (2006). Institutional review board: Management and function. Sudbury, MA: Jones and Bartlett, p.102]

[2]Minimal risk means that "the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests" Code 45 CFR 46.102 (i)

[3]Vulnerable subjects include "children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons" CFR21.1, part 56, sec. 111(b)

Checklist for Research Proposals sent to MCC's IRB:

___1. Certifications of Human Subject Protection Training
[Protecting Human Research Participants (PHRP) Training Certificate -or-
Collaborative Institutional Training Initiative (CITI)]
___2. Completed and signed application for review
___3. Research plan/proposal
___4. Samples of informed consent/assent forms
___5. Outline of information to be provided prior to subjects' agreement to participate
___6. Instruments, surveys, questionnaires, etc.
___7. Curriculum vitae of researcher/PI

Contact information for the IRB:

Bradley Christian
Chair, Institutional Review Board

Submit one electronic copy of all documents to bchristian@mclennan.edu

Frequently Asked Questions

1. **What is "human subjects research"?**

The sort of research that falls under the review of the MCC Institutional Review Board (IRB)is defined as the systematic investigation, including research development, testing, and evaluation using human subjects as participants, that is specifically designed to develop or contribute to generalizable knowledge.

A human subject means a living individual about whom the investigator conducting research obtains data by direct **intervention** or **interaction** with that individual, or by obtaining **identifiable private information** from or about that individual.

Intervention can include either physical procedures by which data are gathered, such as an exercise regimen or taking a blood sample, or the investigation of the subject's environment, which are performed for research purposes.

Interaction can include communication with or interpersonal contact between the investigator and the subject, such as a survey or an interview.

Identifiable private information may include information about behavior that occurs in a context in which the subject may reasonably expect that no observation or recording is taking place, or information that has been provided for specific purposes by the subject and which he/she can reasonably expect will not be made public, such as a health record or records of personal activities or behaviors.

2. **So, what is an Institutional Review Board?**

The MCC Institutional Review Board (IRB) exists to review all research that directly or indirectly involves human participants as study subjects and to develop institutional policies to oversee such research. Our primary role is to ensure the protection of human participants as subjects of research at MCC. We also want to ensure the safety and responsibility of student researchers and faculty mentors in following best practices for

responsible research. We do this by reviewing study proposals and by providing educational workshops and training for students and faculty. We also serve as a resource for anyone with questions or concerns about human subjects research.

The MCC IRB office is located in the Science building (S110).

3. Do I have to submit a proposal to the IRB before I start my study?

Maybe. If a research project involves human participants as described above, it must be submitted to the IRB for review and approval **before** beginning the study. This includes research involving existing data or any advertising or other recruitment procedures. Please consult the IRB Human Subjects Research Checklist (page 73) and Decision Chart (page 6) to see if your study needs to be submitted for IRB review.

4. Who can be an investigator?

At MCC, all full-time faculty and staff and full-time students may act as investigators. Under special circumstances, part-time students may act as investigators, and part-time faculty may serve as mentors, but the IRB must approve their doing so. All student investigators must have a faculty mentor.

5. Do I need any specific training to be an investigator?

Yes. All student investigators and faculty mentors must complete the free online Protecting Human Research Participants (PHRP) training course (**https://phrp.nihtraining.com/users/login.php**) prior to becoming an investigator or mentor. It is MCC IRB policy that PHRP training be renewed every two years. Alternatively, MCC recognizes the Collaborative Institutional Training Initiative (CITI) as being acceptable training to be an investigator. CITI training also may be completed online, but there is a cost involved. Once PHRP training is completed, you must print the Certificate of Completion to include with your IRB submission.

6. If I propose a project that is required for a class, do I need IRB approval?

If the project fits the definitions of "research" and "human participants" as

described above, then you may need to get IRB approval. However, if the purpose of the project is **only** to learn proper research methods, the project may not constitute human participant research. This means, however, that none of the data can be used for publication, presentation, or other research purposes. If, at a later date, you want to use the data obtained from a class project to present at Scholar Day, or some other venue, you must submit a request to the IRB. In such a case, Informed Consent must be obtained from everyone who provided the data. Such persons must consent to allow their data to be used outside the classroom and only for some specific purpose; only at this point is using prior data allowed.

7. What types of IRB review are there?

There are three types of IRB review: **Full Committee**, **Expedited**, and **Exempt**.

Full Committee review is done by the full IRB committee at its regularly scheduled meetings. Reasons for full committee review can include the use of vulnerable populations (explained below) as study subjects, projects which may involve deception, or projects which seek to obtain particularly sensitive information. This does not mean no other types of proposals will go before the full committee, nor does it mean that all others may be either expedited or exempt. The Chair of the IRB will make a determination of the type of review required.

Expedited review means that the study does not require full board review but is still subject to the same scrutiny regarding protecting human research subjects. You may not begin any research activities until you have received written approval from the IRB.

Exempt means that all of the research activities outlined in the proposal fall under one or more of the exemption categories specified by federal regulations. Exempt status does not lessen the ethical obligations toward human research subjects. You may request that your study qualify as exempt, but that does not mean your proposal will be granted exempt status; the IRB Chair will review all requests for exempt status and will notify you of the decision.
If the Chair determines that your study does not qualify as exempt, you will be required to submit the regular IRB application. Even if your proposal is

exempt, you still must submit all supporting documentation, such as surveys, and you still are required to complete PHRP training and submit a Certificate of Completion.

8. What happens if my study needs Full IRB review?

Full board review means that, for any number of reasons, the decision was made to have the full board take a look at your proposal. This does not mean you did something wrong or improper; it could mean that the study seeks to investigate an issue that the Chair is not familiar with and wishes the rest of the board to look at it. (The IRB has some very talented and knowledgeable members, but we are not all experts in everything.)

It can sometimes happen that the board wants to talk to you about your study, usually to clarify some point or method. In such cases, the IRB Chair will notify you to attend an IRB meeting and will explain to you why you are being asked to attend. If this occurs, **DON'T PANIC!** In nearly all cases, we may only need some point clarified. When you arrive, we will invite you to come in and talk to us about your project. You will be given the opportunity to ask the board any question you like. The only rules are that you keep confidential what is discussed, and you are not permitted to be present during any deliberation or voting.

9. Can I make changes to my study after it has been approved?

Yes. There is an Amendment form that may be used for most purposes to make changes to an approved study. This form is found on the IRB Forms link or in this document, pages 78-79. The IRB Chair must approve any changes made to an approved study **before** the changes are implemented.

Also, remember that a study is approved only for one year from the date of approval; if you want to continue the study beyond one year, you must fill out a Renewal Form, see pages 80-81. Amending your study does **not** change its anniversary date, which is one year from the date of the initial approval.

10. What do I do when I have completed my study?

There is a Closure Form, see pages 97-98 that must be submitted to the IRB to officially close a study. Once you have received notification that the study is closed, you may not continue to recruit new study subjects or collect new data; however, you may continue to analyze the data you already obtained and to prepare that analysis for presentation/publication.

If you want to reopen a study which has been closed, you must submit a new proposal to the IRB.

11. My study involves deception. Are there any special considerations?

Yes. Deception in human subjects research is not prohibited by either federal regulations or by MCC. The use of deception in research can be very useful in obtaining data not possible otherwise, but it also can be seen as a violation of the trust that the participant puts in the researcher. It is important to be able to justify using deception. Investigators need to be able to describe to the IRB the method of the research, including a clear statement that no other study method would be able to yield equally valid data, and there must be a process for the study participants to be informed at the end of their participation that deception was a component of the study.

Participants subject to deception in a study must be fully debriefed when their participation is over, and it must be explained to them very clearly why it was necessary that they be deceived. Great care should be taken not only in crafting a study where deception is a component but also in the debriefing of participants afterward. Remember, most people do not take kindly to being intentionally deceived. You must be very careful about how you inform study participants that deception was a part of the study. A script of the debrief must be included with your IRB application, and the IRB will examine it with special attention.

12. What is a "vulnerable population"?

A vulnerable population refers to members of a group who may have a diminished capacity to give informed consent. **Informed consent** means

that the subject:

- Is fully informed of and understands the purpose and method of the study;
- Has been informed about all foreseeable benefits and risks;
- Has been able to ask questions and given answers regarding the study;
- Is free to volunteer to participate or not; and
- Is aware that s/he can discontinue their participation at any time without any penalty or loss of rights to which they might otherwise be entitled.

Persons who are unable to meet this standard of consent still may be study subjects, but because of their diminished capacity to give informed consent, special considerations are necessary to ensure that they receive the fullest protections possible.

Federal regulations do not clearly specify all vulnerable groups. The MCC IRB considers minors (meaning, by law, anyone under the age of 18), prisoners or those under court-ordered restrictions, the mentally and/or cognitively challenged, persons over the age of 65, and persons who are being recruited because they have suffered from various types of addiction or abuse, as requiring greater considerations.

Often studies involving vulnerable populations require full committee review; this is to ensure that the fullest protections are in place for their rights to be secured. This is not to discourage targeting a vulnerable population as study subjects, however, the IRB wants be very careful that the participants are treated with the utmost respect and consideration.

13. What is informed consent?

Much of the justification for the existence of institutional review boards has to do with studies that were conducted in which the participants were forced to participate, were not told what exactly what was going to be done to them, were lied to about the purpose of the study they were participating in, or were never told they were even subjects in a study. Examples include accounts of "medical" experiments conducted in Nazi and Japanese prisoner of war camps and the Tuskegee Syphilis Study in the U.S. The need for medical studies using live human participants must be balanced by issues of respect for the participants, the balance of risks

and benefits, and simple justice regarding the selection of study subjects.

The Belmont Report, issued in 1979, provided a summary of these considerations. As a result of this report, federal legislation was passed requiring that all studies involving human subjects undergo review to ensure the fullest protections for the rights of the study participants. (See: http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html). One result was the creation of institutional review boards, or IRBs, to independently review all research proposals that involve human participants, to ensure informed consent, especially of risks and benefits, and the prevention of conflicts of interest.

IRB-approved research, unless it is exempt, must include informed consent forms. Study participants must sign an Informed Consent form prior to the initiation of your study. Guidelines for obtaining informed consent are available on the IRB Forms link. There are separate forms for children (Assent) and for their parents/guardians (Parental Consent), see pages 104-105. All are available on the IRB site.

14. Can I do a study entirely online? How do I get informed consent if my study is conducted online?

Informed consent is a standard, not a document. It can sometimes be the case that the recruitment, consent, and the study itself, all are designed to be completed entirely online. The IRB application allows you to obtain consent without an actual written and signed document.

15. Do I always need to obtain informed consent? How is it different from a "waiver of written consent"?

There is a separate form called the "Waiver of Written Informed Consent" which is used to allow for obtaining unsigned consent under certain circumstances; these can include implied and verbal consent. Consent will still be obtained from participants; the difference is that they will not be required to sign the consent form. Examples in which the IRB may waive the requirement to obtain a signed consent form can be where the only record linking the research participant to the research would be the consent document itself, and the only risk would be potential harm resulting from a breach of confidentiality or that the research presents no more than minimal risk of harm to participants.

You can request a waiver of informed consent; this means that you are requesting to omit obtaining consent. Examples of types of studies in which some or all elements of consent can be waived include retrospective literature reviews or studies that involve no more than minimal risk and where waiving consent will in no way affect the rights of the study subjects. If you are not sure, it is best to try to get informed consent. You can contact the IRB to help clarify this point.

A waiver of written consent means that you still obtain consent, just not in the form of a written and signed document. Again, though, it remains your responsibility to ensure that participants are fully informed about your study, whether they have to sign a document or not.

16. I am not collecting any personally identifying information. Do I still need to obtain informed consent?

Yes. You can do this by informing the participant about all of the elements of consent, but the signature line on the consent form is replaced with a statement saying that the completion and return of the study instrument(s) is considered to be tacit, or implied, consent.

Implied consent is the agreement to participate in research by engaging in research activities. By completing the research activities, such as a survey or questionnaire, the subject has demonstrated that he/she has agreed to be a participant in the study. An example could be an online survey; when a study participant clicks the option to begin or continue, they are by doing so agreeing to participate in the study. If it is clearly stated what the study is about, what their participation will require, and that clicking to begin or continue means they agree to participate, the standard of informed consent is met.

17. Can I conduct research off campus? Does it require IRB approval?

If you are an MCC faculty, staff, or student, and you are the Principal Investigator (PI), you will need IRB approval to conduct your research regardless of where the research takes place. If the study site has its own review committee (an IRB or something similar), we may require that this other committee send us their approval for you to do your study. If the site is a school, or other organization, we will require that they provide permission

for you to do your research on their site. Written permission is best, but an email that identifies the local authority can work.

18. If I have approval from another IRB, will I still need to get MCC IRB approval?

You may do collaborative research under the authority of another IRB, but the IRB must be informed. In cases where the other IRB recruits local study participants or Co-PIs, some version of an inter-institutional Authorization Agreement must be submitted; this effectively cedes control and responsibility for the oversight of the research and the researchers to the other IRB. The MCC participants and/or researchers are still obliged to abide by the ethical research guidelines of MCC, regardless of who is in charge of the study.

The IRB will require documentation of the other IRB's approval of the study, and the approved IRB form from that institution; in some cases, we may require the completion of an MCC IRB study proposal application, regardless of the study being approved by another IRB. Such decisions are made by the IRB Chair and may involve full board review and approval. In either case, no research activities may begin until the MCC IRB has reviewed and approved the study.

19. Does the IRB provide any other training for investigators?

Yes. We can schedule training sessions for both students and faculty. The Chair of the IRB is available to meet with individuals and classes, as requested, to do presentations on the application process, as well as more general presentations about human subjects research. Contact the IRB Chair, Bradley Christian, bchristian@mclennan.edu to schedule training or presentations.

20. What do I do if an unanticipated problem involving risks to participants or to others arises?

A serious adverse event usually means injury or death to a study subject or a researcher, even if the event was not directly related to the research itself.

Though very rare, in such cases the research activities will be suspended until an investigation into the adverse event has been completed. If a serious adverse event occurs, it must be reported to the IRB Chair immediately, and the PI must submit a written report within 24 hours of the PI becoming aware of the event. In these cases, it is likely that research activities will be suspended, pending the outcome of an investigation.

Less serious unanticipated problems, such as the loss of data security or violations of confidentiality, should be reported by the PI to the IRB Chair within 7 days of first becoming aware of the problem. Prompt reporting is important, since unanticipated problems may require the modification of study procedures, protocols, and/or informed consent. Any modifications to an approved study will require submitting the proper form and are subject to the review and approval of the IRB.

21. How long can I keep my data?

As long as you want to keep it, provided it has been "de-identified." This means that all potentially personally identifiable information has been erased or deleted. This can include names, dates of birth, addresses, hometown, high school attended, college major, and identifying medical conditions; in short, you can only keep data results if they are stripped of anything that might identify any of the participants.

Data that contains identifiable information may only be kept for the approved duration of the study. If you want to keep the data longer, this amounts to a continuation of the study itself, so you will be required to submit the Renewal Form (see pages, 95-96) and specify why you want to keep your identifiable data longer.

By law, Informed Consent forms are to be kept under secure storage for a minimum of three years; after that, you can destroy them. Just throwing them in the trash is **not** an acceptable way of disposal. You may bring the consent forms to the IRB office, and we will dispose of them properly.

(For very low risk information, this may mean simply deleting electronic files or using a desk shredder for paper documents. However, these types of destruction methods can be undone, by a determined and motivated individual, making these methods inappropriate for more sensitive data. For more sensitive data, stronger methods of destruction at a more

granular level may need to be employed to assure that the data are truly irretrievable.)

Defining the work of an IRB

A. An IRB Obtains:

- Trial protocols/amendments
- Written informed consent form(s) and consent form updates the investigator proposes for use in the trial
- Written information to be provided to subjects
- Investigator's brochure
- Available safety information
- Information about payments/compensation to subjects
- Investigator's current vitae and other documentation evidencing qualifications to carry out the study

B. An IRB Reviews proposals within a reasonable amount of time and documents its views in writing, clearly identifying the trial, the documents reviewed, and the dates for the following**:**

- Approval
- Modifications required prior to approval
- Disapproval
- Termination/suspension of any prior approval

INSTITUTIONAL REVIEW BOARD GUIDELINES

INTRODUCTION

It is the mission of McLennan Community College (MCC) to provide collegiate education and training to adults of all ages and backgrounds, helping them achieve their individual goals and contribute as citizens and workers to the vitality of an increasingly global community. Towards this goal, the college encourages and supports the scholarly efforts of its students and faculty.

The charge of the MCC Institutional Review Board (IRB) is to protect the rights and welfare of human subjects in research projects by minimizing risks and ensuring informed and voluntarily participation. It is the goal of the IRB to provide a climate for research and scholarly activity that is fertile and flexible while protecting the well-being of human subjects. The fundamental principle of human subject protection is that people should not (in most cases) be involved in research without their informed consent and that subjects should not incur increased risk of harm from their research participation beyond the normal risks inherent in everyday life.

The Institutional Review Board at McLennan Community College has the responsibility to oversee procedures for carrying out the College's commitment to protect human subjects in research. The IRB is authorized to review, approve, require modifications in, or disapprove human subject research activities conducted by or through the College. The IRB does not assume the role of evaluating the soundness of the proposed research study, the merits of the research design, or the potential contribution of the research to scholarly literature. Rather, **the IRB is charged with evaluating each project's compliance with ethical standards in regard to issues such as informed consent, confidentiality, and any risk to the participants.**

It is the role of the McLennan Community College IRB to review proposed research projects that involve human subjects; ensure that the individuals involved in the project are treated ethically; ensure that all subjects are provided with substantial information about the study and that they consent to be a subject in the study; and that all private information is handled appropriately. MCC's IRB is not authorized to grant access to McLennan Community College's data. Requests for access to MCC's data must be submitted to the Institutional Research Office at MCC and are reviewed on a case-by-case basis (see Priority List for Requests, p. 185).

STATEMENT OF PRINCIPLES

UNDERLYING PRINCIPLES

McLennan Community College has adapted the ethical principles for protection of human subjects as stated in the Code of Federal Regulations: 45CFR46. Created by the

National Research Act in 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was established to enact these regulations. The Commission published The Belmont Report, which set forth the following basic ethical principles for the conduct of research involving human subjects:

- **Respect for Persons** - Acknowledgment of the autonomy of the individual and the responsibility to provide special protection for individuals with reduced autonomy.
- **Beneficence** - A responsibility to do no harm, to maximize possible benefits, and to minimize possible harm.
- **Justice** – An expectation of fairness in distribution of benefits realized from research as well as its burdens.

APPLICATION

As stated in the Federal Code of Regulations, 45 CFR 46. 101, it is the charge of the IRB to ensure that in the conduct of research

- risks are minimized and reasonable in relation to anticipated benefits
- subjects give informed consent
- rights and welfare of the subjects are maintained

McLennan Community College applies the following principles to all human subject research with no distinctions between the monitoring of projects being drawn between funded and unfunded, sponsored and non-sponsored, among various funding sources, or between projects carried out by students, faculty or other MCC employees either on or off campus. Additionally, these principles apply to any human research conducted by others on the MCC campuses or with MCC students or employees.

- Subjects' legal rights will be respected; their rights to privacy, dignity, and comfort will also be considered in approving proposed research.
- Risks to subjects must be reasonable in relation to anticipated benefits.
- No subject in a research activity shall be exposed to unreasonable risk to health or well-being.
- Appropriate professional attention and facilities shall be provided to ensure the protection of the individual as a research subject.
- Adequate provisions should be made for recruiting a subject population that represents the population base in terms of gender and ethnicity unless scientifically justified.
- Research involving human subjects must be supervised by qualified persons as approved by the IRB.
- Participation of a human subject in research must be voluntary, and the right to withdraw at any time must be provided. Information provided to gain

subject's consent must be adequate, appropriate, and presented in lay language appropriate to the subject population.
• Any request by a subject for withdrawal from a research activity will be honored promptly with no penalty.
• All research programs that involve human subjects must be reviewed by and must receive approval of a formally constituted Board prior to project initiation or prior to initiating any changes to the protocol. Continuing research programs are subject to periodic review, to be carried out no less often than once a year.

THE MCC INSTITUTIONAL REVIEW BOARD

PURPOSE

The purpose of the McLennan Community College Institutional Review Board is to ensure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research studies conducted by or with McLennan Community College employees or students or on MCC campuses.

AUTHORIZING REGULATIONS

1. Federal Register 56 (June 18, 1991): 28002-28032 [Federal Policy for the Protection of Human Subjects; Notices and Rules] (The Common Rule)
2. Title 45 Part 46 of the Code of Federal Regulations
    a. Codification of the Federal Policy for each of the departments and agencies adopting it is as follows:
        1. CFR Part 1c [Department of Agriculture]
        2. 10 CFR Part 745 [Department of Energy]
        3. 14 CFR Part 1230 [National Aeronautics and Space Administration]
        4. 15 CFR Part 27 [Department of Commerce]
        5. 16 CFR Part 1028 [Consumer Product Safety Commission]
        6. 22 CFR Part 225 [International Development Cooperation Agency] [Agency for International Development]
        7. 24 CFR Part 60 [Department of Housing and Urban Development]
        8. 28 CFR Part 46 [Department of Justice]
        9. 32 CFR Part 219 [Department of Defense]
        10. 34 CFR Part 97 [Department of Education]
        11. 38 CFR Part 16 [Department of Veterans Affairs]
        12. 40 CFR Part 26 [Environmental Protection Agency]
        13. 45 CFR Part 46 [Department of Health and Human Services]
        14. 45 CFR Part 690 [National Science Foundation]
        15. 49 CFR Part 11 [Department of Transportation]

b. FDA regulations pertaining to research with human subjects are codified at
    1. 21 CFR Part 50 [Protection of Human Subjects]
    2. 21 CFR Part 56 [Institutional Review Boards]

IRB MEMBERSHIP

IRB MEMBERSHIP: 45CFR §46.107

1. Members will be invited to join the board by the Vice President of Instruction and Vice President of Research, Effectiveness and Information Technology.

2. The IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members, and the diversity of the members, including consideration of race, gender, and cultural backgrounds and sensitivity to community issues, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. In addition to possessing the professional competence necessary to review specific research activities, the IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments and regulations, applicable law, and standards of professional conduct and practice. The IRB shall, therefore, include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a vulnerable category of subjects, such as children, prisoners, or physically or mentally disabled persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these subjects.

3. Every effort will be made to ensure that the IRB will not consist entirely of men or entirely of women, including the institution's consideration of qualified persons of both sexes, so long as no selection is made to the IRB on the basis of gender. The IRB may not consist entirely of members of one discipline.

4. The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.

5. The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.

6. No IRB member may participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.

7. The IRB may, at its discretion, invite individuals with competence in special areas to assist in the review of issues requiring expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

8. A majority of the members must participate in each board action.

TRAINING AND EDUCATION

1. All IRB members are required to undergo formal training at the time of their initial appointment.

Approved training includes:

a. The National Institutes of Health Human Participant Protections Education for Research Teams Course. http://phrp.nihtraining.com/users/overview.php
b. OHRP Mini-Tutorials. https://www.hhs.gov/ohrp/education-and-outreach/online-education/mini-tutorials/index.html
c. Approved Trainings Hosted by MCC or other IRB Institutions.
d. Other Educational Materials:
    1. OHRP Educational Videos
    https://www.hhs.gov/ohrp/education-and-outreach/online-education/videos/index.html#
    2. OHRP Educational Webinars
    https://www.hhs.gov/ohrp/education-and-outreach/online-education/webinars/index.html
    3. Resources
    https://www.hhs.gov/ohrp/education-and-outreach/resources/index.html

e. Other Education Opportunities:
    1. Research Community Forums https://www.hhs.gov/ohrp/education-and-outreach/educational-collaboration-with-ohrp/research-community-forums/index.html
    2. Educational Workshops: https://www.hhs.gov/ohrp/education-and-outreach/educational-collaboration-with-ohrp/workshops/index.html

2. The IRB Chair will maintain a log of training completion dates.

3. Continuing education of IRB members is accomplished through participation in regional IRB training, review of various online tutorials, and through MCC provided IRB training activities.

4. IRB members must complete the *Documentation of Education on Human Subject Protection* form once every three years.

CONFLICT OF INTEREST

An IRB member is said to have a conflicting interest whenever that IRB member, member's spouse, or member's dependent child:

1. is an investigator or sub-investigator on the project;
2. has a "significant financial interest" in the sponsor or agent of the sponsor of a study being reviewed by the IRB, whereby the outcome of the study could influence the value of the financial interest;
3. acts as an officer or a director of the sponsor or an agent of the sponsor of a study being reviewed by the IRB; or
4. has identified himself or herself for any other reason as having a conflicting interest.

It is the responsibility of each IRB member to identify and avoid any situations in which he or she, either personally or by virtue of his or her position, might have a conflict of interest, or may be perceived by others as having a conflict of interest, arising in connection with a matter before an IRB of which he or she is a member. If assigned as a reviewer for a matter with which the IRB member feels that he or she may have a conflict of interest, the IRB member must notify the IRB Chair immediately so the matter may be reassigned to another reviewer.

BOARD MEMBERS' RESPONSIBILITIES

It is each board member's responsibility to:

1. Participate in required trainings and submit evidence of training to the Board Chair.
2. Review all materials on each application including the full proposal.
3. Protect the interests and welfare of research subjects.
4. Help researchers comply with ethical requirements and with federal and state regulations.
5. Help protect McLennan Community College and it's researchers from any potential liabilities to which they may be exposed.
6. Attend and actively participate in board actions and determinations. (More than two, unexcused, absences will result in dismissal from the committee.)

IRB CHAIR'S RESPONSIBILITIES

It is the responsibility of the IRB Chair to:

1. Ensure all review submission materials are collected for board determination.
2. Initiate all board reviews.

3. Ensure a majority of members participate in all board decisions with a majority of those present in agreement of determination.
4. Sign and submit the IRB determination letter to the Principle Investigator (PI).
5. Ensure all records are maintained as required by Title 45 Part 46 of the Code of Federal Regulations. (See reporting requirements.)
6. Assist in decisions on IRB applications.

IRB OFFICE MANAGER RESPONSIBILITIES

It is the responsibility of the IRB Manager to:

1. Oversee all IRB activities.
2. Monitor the IRB email.
3. Verify that all required materials are in the application packets.
4. Distribute applications to Chair and members at the direction of the Chair
5. Set up all IRB meetings.
6. Distribute Determination letters to PI and OHRP at the direction of the Chair.
7. Maintain required records and minutes of Board activities.
8. Submit documentation to OHRP.
9. Assist with faculty workshops.

IRB AUTHORITY

CHARGE

The MCC IRB is accountable to the U.S. Department of Health and Human Services Office of Human Research Protections for the oversight of all human subject research to ensure the ethical treatment of all human subjects.

The MCC IRB must review and approve any funded or non-funded research related to human subjects whether or not it is funded internally or externally by private or government funds if the research is

1. Sponsored by MCC,
2. Performed by or involves MCC faculty, staff and/or students regardless of where the study is performed, or
3. Conducted using college-owned facilities or equipment.

§46.112 REVIEW BY INSTITUTION

Research covered by this policy that has been approved by an IRB may be subject to further appropriate review and approval or disapproval by officials of the institution. However, those officials **may not** approve the research if it has not been approved by an IRB.

REPORTING REQUIREMENTS

The institution or, when appropriate, the IRB must prepare and maintain adequate documentation of IRB activities [Federal Policy §46.115]. In addition to the written IRB procedures and membership lists required by the assurance process [Federal Policy §46.103], such documentation must include copies of all research proposals reviewed, minutes of IRB meetings, records of continuing review activities, copies of all correspondence between the IRB and investigators, and statements of significant new findings provided to subjects (as required by Federal Policy §46.116(b)(5)).

Minutes of IRB meetings must be kept in sufficient detail to record the following information: attendance at each meeting, actions taken by the IRB, the vote on actions taken (including the number of members voting for, against, and abstaining), the basis for requiring changes in or disapproving research, and a written summary of the discussion of controversial issues and their resolution [Federal Policy §46.115(a)(2)].

IRB records must be retained for at least three years: records pertaining to research that is conducted must be retained for three years after completion of the research project. All records must be accessible for inspection and copying by authorized representatives of the department or agency supporting or conducting the research at reasonable times and in a reasonable manner [Federal Policy §46.115(b)].

REQUIRED ASSURANCES

Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule.

Institutions must have an Assurance of Compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency. [Office for Human Research Protections OMB No. 0990-0263.]

ACTIONS

A majority of the IRB members must participate in all decisions and actions of the board. Final approval of all actions shall require a majority of the members present or participating in the action. Meetings may be conducted in person or through a real-time telephone conference arrangement.

The IRB may take one of five actions in regard to proposed human subject research:

1. Exempt from full review
2. Approve
3. Approve contingent on requested changes
4. Disapprove and/or make recommendations of required changes for resubmission.
5. Suspend or terminate as per §46.113

The IRB shall have authority to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval shall include a statement of the reasons for the IRB's action and shall be reported promptly to the investigator, appropriate institutional officials, and the department or agency head.

Furthermore, the IRB may sanction the Principle Investigator as the board deems necessary to ensure continued human subject protection. All actions will be reported to the Office for Human Research Protections.

THE IRB REVIEW

REQUIRED CONSIDERATIONS:

The *HHS Office of Human Research Protections IRB Guidebook* requires that IRBs

1. Consider the qualifications and professional development of the principal investigator and relate them to the degree of protocol complexity and risk to human subjects;
2. Consider requiring that less experienced research investigators be sponsored by seasoned researchers;
3. Consider directing that proposals requiring skills beyond those held by the principal investigator be modified to meet the investigator's skills, have additional qualified personnel added, or be disapproved;
4. Instruct investigators to prepare protocols, with complete descriptions of the proposed research. The research plan must include provisions for the adequate protection of the rights and welfare of prospective subjects and ensure that pertinent laws and regulations are observed. Samples of informed consent must be included with protocols. Investigators are responsible for obtaining informed consent and ensuring that no human subject will be involved in the research before consent is obtained;
5. Ensure that the research plan address quality assurance standards set by the institution as well as applicable external standards;

6. Ensure that appropriate reviews for scientific merit be conducted before the research is approved;
7. Ensure that mechanisms be in place for monitoring the progress of the research.

For non-exempt research, the IRB must

1. Review the proposal at a convened meeting.
2. Evaluate the procedures
    a. How are subjects recruited?
    b. Are subjects equitably selected?
    c. What are the risks and are they minimized?
    d. Do the benefits outweigh the risks?
3. Evaluate the consent *process*
    a. Will subjects be fully informed of procedures and risks?
    b. Is consent written in appropriate understandable language?
    c. Is the subject's voluntary consent and withdrawal explained fully?
    d. How is informed consent obtained?
4. Evaluate the informed consent *document* (see informed consent)

Changes to the Exempt Determination Process (2018)

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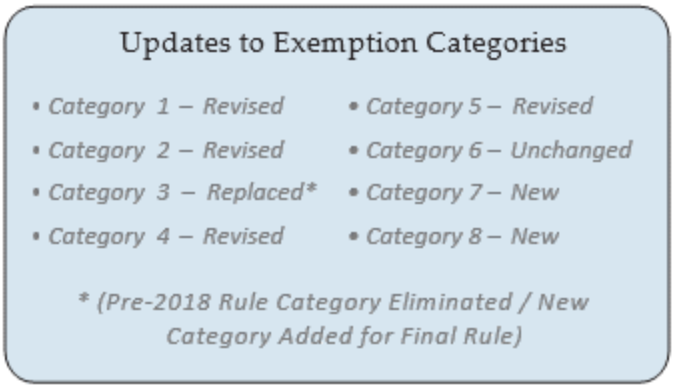
The Final Rule (45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" [the Common Rule]) revised and expanded the categories for exempt research. New categories were added, and two new processes were introduced: **limited IRB review** and **broad consent**. This material will review the exempt determination processes and the new exemption categories.

How is research determined to be exempt?

The Final Rule did not specify or restrict who can determine if research is exempt. The institution usually has a policy on who has the authority to determine if research is exempt, but the Final Rule, like the pre-2018 rule, did not specify. Due to the potential for conflict of interest, however, the Office for Human Research Protections (OHRP) continues to recommend that investigators not be given the authority to make an independent determination that their own human subjects research is exempt. Limited IRB review as a condition of exemption must be conducted by an IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB.



Summary of Changes:

The pre-2018 rule had six exempt categories in 46.101(b). The revised rule gave exempt categories an entire section in 46.104, and now includes eight categories in 46.104(d)(1-8).

Below is a summary of the changes to each of the exempt categories from 46.104(d). Because one of the major emphases of the Final Rule revisions was to address concerns associated with social and behavioral research, this resource will highlight the changes that are most relevant for researchers in the social and behavioral sciences.

It is important to note that "exempt" does not always mean exempt from all of the requirements of the Common Rule (HHS 2017). For example, the new Exempt Category 7

includes specific regulatory requirements of broad consent and limited IRB review as a condition of being exempt from other regulatory requirements.

Category 1: Research in Established or Commonly Accepted Educational Settings

This category has been amended from the pre-2018 rule to include a condition that the research is not likely to have adverse impacts on students learning required educational content or assessment of educators who provide instruction (HHS 2017). The exemption may only be used for studies about normal educational practices.

Category 2: Educational Tests, Surveys, Interviews, Observations of Public Behavior

During the time of the pre-2018 rule, this was the category most used by researchers in the social and behavioral sciences. Under the pre-2018 rule, research in this category may be exempt if the identity of the subjects could not be readily ascertained either directly or indirectly and if the disclosure of identifiable data would not cause harm.

The new regulation allows for exemption as long as one of the three criteria is met:

(1) Information obtained is not identifiable

(2) Disclosure outside of the research would not put subjects at risk of harm

(3) Information obtained can be identifiable but the IRB has done a limited IRB review in keeping with 46.111(a)(7), which relates to there being adequate provisions for protecting privacy and maintaining confidentiality

Importantly, the revised Common Rule eliminated the "and" – instead there is an "or." That is, research could be exempt that is any of the following:

(1) Not Identifiable

(2) Does not pose any risk if there is disclosure (regardless if identifiable or not)

(3) Does not pose any risk if there is limited IRB review in keeping with the 46.111(a)(7) criteria

Also, the Final Rule revised this category to include visual or auditory recording as research methods. Surveys also cannot include collection of biospecimens or interventions, as those additional activities would disqualify the research from this category.

When the research is subject to Subpart D and includes children, Category 2 still does not allow surveys or interviews or the observer participating with children (public behavior observation without intervention is permitted).

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information From Adult Subjects

This is a new category. Benign behavioral interventions are defined as "brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the

subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing" (HHS 2017).

An example provided is having subjects solve puzzles under various noise conditions.

Research using deception is not eligible for exemption in this category unless the subjects prospectively agree that they will be unaware of or misled regarding the nature and purpose of the research.

As with research in Category 1, exemption is permitted if the data are recorded in such a way that the identities of the subjects cannot be readily ascertained either directly or indirectly or if the identities can be ascertained, a disclosure of the subjects' responses outside the research setting would not reasonably place the subjects at risk of harm. Alternatively, if the subjects' identities can readily be ascertained and if a disclosure of subjects' responses has potential to harm subjects, the exemption is permitted if the IRB conducts a limited review and determines that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

Category 4: Secondary Research for Which Consent is Not Required

This category covers secondary research uses of identifiable private information or identifiable biospecimens. The Final Rule revised and clarified the pre-2108 rule category for the use of secondary use of data. Category 4 does not require informed consent if at least one of the criteria listed below is met.

There are four available options for use of the exemption:

1. Use of publicly available identifiable private information or identifiable biospecimens.

2. Information recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

3. Research use of identifiable health information when that use is regulated by HIPAA as health care operations, research, or public health activities and purposes as those terms are defined in HIPAA.

4. Analysis of data on behalf of a federal agency or department – as opposed to an investigator-initiated analysis of federally supplied data – if the requirements of certain federal laws are met.

It is important to note that data do not need to be existing ("on the shelf") at the time of the research study, as was previously required by the pre-2018 rule. The data can be collected prospectively and still be used for exempt research under Category 4 in the Final Rule.

Category 5: Research and Demonstration Projects that Are Conducted or Supported by a Federal Department or Agency

The category has been revised to: allow research supported by a federal agency (not just conducted) to qualify for this exemption; provide examples of the types of public benefit and service programs covered by the exemption; and clarify the federal components for which the exempt research is subject to approval (for example, delegated subordinate agencies).

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies

This is the only unchanged category.

Category 7: Storage or Maintenance for Secondary Use for Which Broad Consent is Required

This is a new category. This category is for the storage of identifiable biospecimens and identifiable private information, prior to secondary analysis. The storage and maintenance may be exempt if the IRB conducts a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data, and if broad consent is obtained.

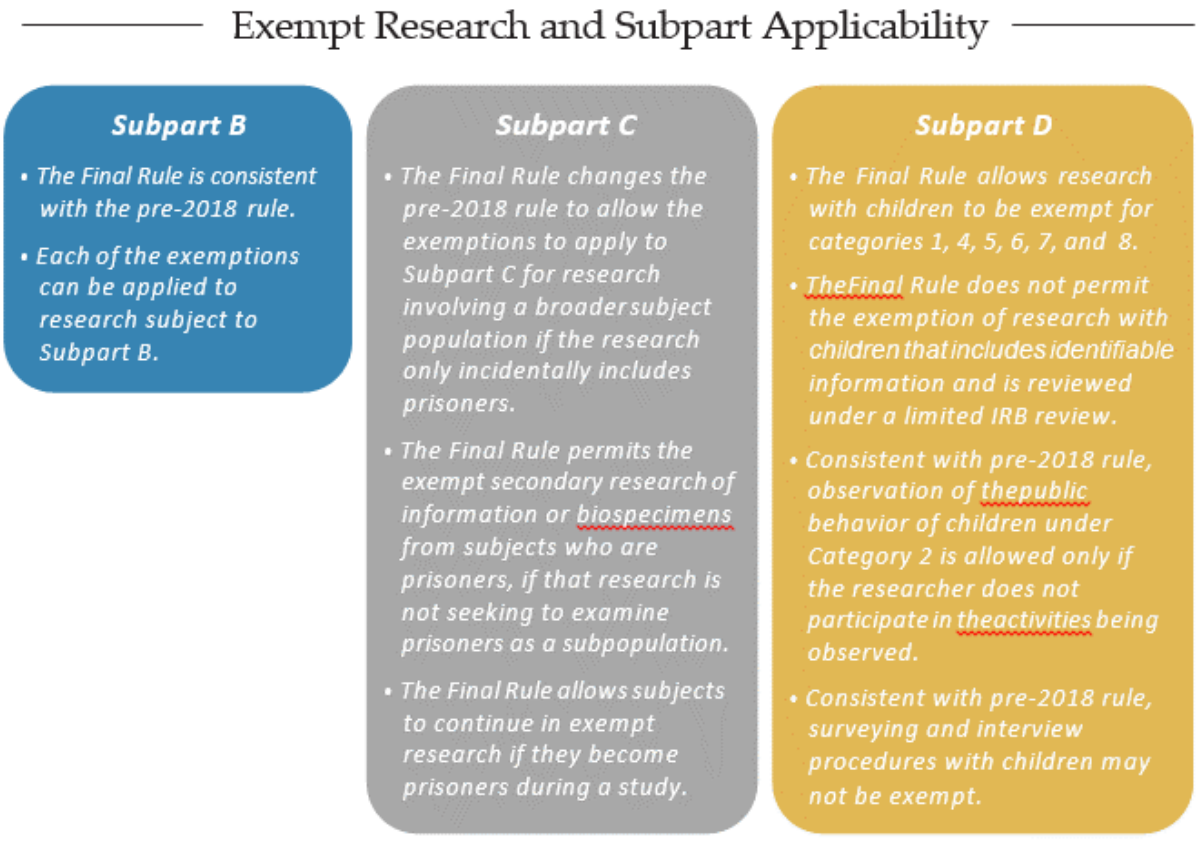
Institutions can create their own templates for broad consent (which may be electronic). Broad consent includes at least seven and possibly nine elements of consent. It includes five standard elements of consent such as providing information to subjects (or legally authorized representatives) in languages understandable to the research subjects (or the legally authorized representatives). Broad consent also includes elements particular to secondary analysis, such as a general description of the data and of the types of research that may be conducted. Additional elements may be needed, if for example, the research involves whole genome sequencing.

This category may be more widely used by biomedical researchers to allow them to use data gathered during the practice of research and medicine either by another researcher or through another study. However, social and behavioral researchers may also use identifiable private information for secondary analysis.

Category 8: Secondary Research for Which Broad Consent is Required

This is also a new category. Category 8 allows the secondary analysis of existing private identifiable data and identifiable biospecimens provided broad consent was secured and the documentation of consent was either secured or waived. The IRB must also conduct a limited IRB review to determine that there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data as noted in 46.111(a)(7), and that the use is within the scope of the broad consent. Category 8 also requires that the investigator does not include returning individual research results to subjects as part of the study plan; however, the exemption does not prevent investigators from returning results if required by law.

Similar to Category 7, this category may be more widely used by biomedical researchers. However, social and behavioral researchers may also use identifiable private information for secondary analysis.



Broad Consent for Exempt Research

Broad consent will be an optional alternative that an investigator may choose instead of, for example, conducting the research on nonidentified information and nonidentified biospecimens, having an Institutional Review Board (IRB) waive the requirement for informed consent, or obtaining consent for a specific study.

(Final Rule Preamble, HHS 2017)

The Final Rule allows the use of broad consent from subjects for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens. As noted above, it is an alternative informed consent process with required elements. Broad consent was developed to balance public concerns about the use of information or biospecimens for research without consent. Broad consent aims to respect subjects' autonomy and provide appropriate privacy safeguards, and reduce burden on investigators that would result from requiring specific consent for each secondary research study.

It remains to be seen how broad consent will be used by researchers in the social and behavioral sciences, humanities, or education; however, it will be an available option for consent.

Where does data come from?

Researchers in the social and behavioral sciences, humanities, and education may collect:

- De-identified data
- Data with informed consent
- Data from research approved without informed consent
- Data for secondary analysis when informed consent was secured by the original data collector

Can broad consent be altered or waived?

The IRB cannot omit or alter any of the elements of broad consent. However, the IRB can waive the requirement of documentation (signature). The IRB must determine that broad consent is appropriately documented or that the requirement of documentation has been waived in accordance with 46.117.

Further, if a subject refused to provide broad consent, the IRB cannot waive consent for the storage, maintenance, or secondary research use of the subject's identifiable private information or identifiable biospecimens. This is meant to respect a subject's autonomy.

Limited IRB Review as a Condition of Certain Exempt Research

The Final Rule introduced a new concept of limited IRB review as a condition of exemption for four of the exempt categories listed above.

When is limited IRB review required?

For Categories 2 and 3, it is only sometimes an option.

- A limited IRB review is only required if the research involves identifiable information (the regulation states "information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects" [HHS 2017]). Then, the IRB must conduct a limited IRB review to determine if there are adequate provisions in place to protect privacy and confidentiality as defined under 46.111(a)(8).

For Categories 7 and 8, it is always required. These are the broad consent exempt categories.

- Category 7 requires limited IRB review for secondary research involving storage or maintenance of identifiable private information or identifiable biospecimens to determine if conditions of 46.111(a)(8) are met. This includes if broad consent was obtained and documented (or waiver of documentation was obtained) in accordance with the requirements for broad consent, and if there are any changes made for research purposes to the way information or biospecimens are stored or maintained, there are adequate protections for privacy and confidentiality.

"Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information" (46.102(e)(5)).

"An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen" (46.102(e)(6)).

- Category 8 is also for secondary research, and requires a limited IRB review to determine if broad consent was obtained and documented (or waiver of documentation was obtained) in accordance with the relevant regulatory requirements, and there are adequate provisions in place to protect privacy and confidentiality. Category 8 also stipulates that the researcher does not include returning individual research results to subjects as part of the study plan (except where legally required).

How is limited IRB review applicable to research in the social and behavioral sciences, education, and the humanities?

For research in these areas, a limited review may be required when the research involves benign behavioral interventions in conjunction with the collection of information from adult subjects (Category 3) and when it involves educational tests, surveys, interviews, or observations of public behavior (Category 2). A limited review must be conducted for exempt research in these categories when information is recorded in a manner in which the identity of the subjects can be readily ascertained and a disclosure of the data could pose a risk of harm (limited review does not need to be conducted if the identifiable data would not reasonably place the subjects at risk).

Who may be a limited IRB reviewer?

An IRB may use the expedited review procedure to review research for which limited IRB review is a condition of exemption.

"Under an expedited review procedure, the review may be carried out by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB" (HHS 2017).

There is only one criterion for limited review for these categories: "When appropriate, there are adequate provisions to protect the privacy of the subjects and to maintain the confidentiality of the data" (46.111(a)(7)).

The regulation does not provide guidance on what are adequate provisions to protect privacy and maintain confidentiality. The Final Rule's preamble listed some considerations for IRBs.

IRB Considerations for Privacy and Confidentiality Safeguards (Final Rule Preamble)

- Extent to which identifiable private information is or has been de-identified and the risk that such de-identified information can be re-identified
- Use of the information
- Extent to which the information will be shared or transferred to a third party or otherwise disclosed or released
- Likely retention period or life of the information
- Security controls that are in place to protect the confidentiality and integrity of the information
- Potential risk of harm to individuals should the information be lost, stolen, compromised, or otherwise used in a way contrary to the contours of the research under the exemption

References

- *U.S. Department of Health and Human Services (HHS). 2017. "Federal Policy for the Protection of Human Subjects." Federal Register 82(12):7149-274.*
- *U.S. Department of Health and Human Services (HHS). 2018. "Federal Policy for the Protection of Human Subjects: Six Month Delay of the General Compliance Date of Revisions While Allowing the Use of Three Burden-Reducing Provisions During the Delay Period." Federal Register 83(118):28497-520.*

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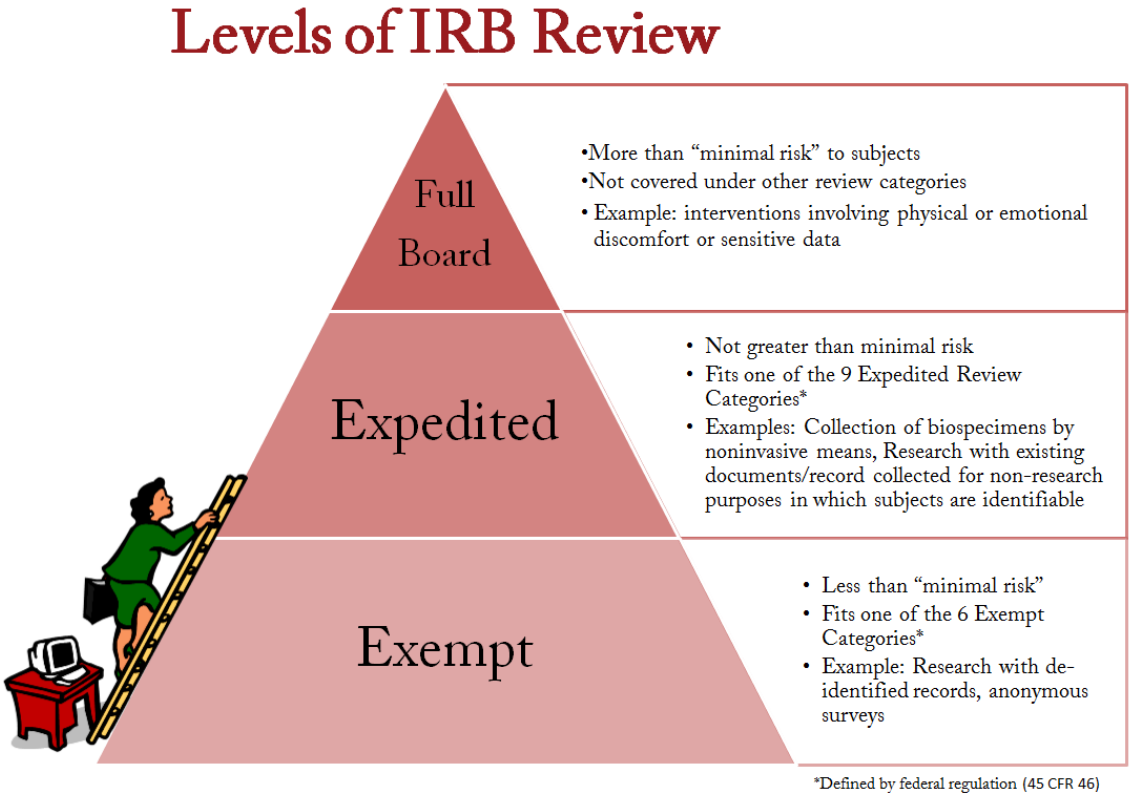


TYPES OF IRB REVIEW

1. **Exempt Review**

a. A research protocol can be submitted for an exempt review if the chair deems the project qualified.
b. If the chair anticipates that there will be no or few questions about a proposal and that the proposal is appropriate for consideration for exemption, he/she may call for an exempt review.
c. The IRB chair will distribute the application materials electronically, via mail, or by fax for each member to review and convene the Board.
d. If a majority of members approve the exempt status, the research is approved as exempt.
e. If a majority of members have doubts of the project's qualification as exempt, the chair may call for full board review of the proposal.
f. The term "exempt" refers to the requirement for continuing IRB review, but not the general requirements for informed consent and protection of subjects. Thus,

even if the project is exempt, the PI must inform potential subjects of the proposed procedures and of their rights as subjects.
g. Exempted approvals expire one year after Board review. For projects that lasting longer than a year, see: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/2018-requirements-faqs/index.html. Additionally, the PI must ensure that progress reports and/or review applications are submitted more frequently if mandated by the IRB.

2. **Expedited Review**

a. A research protocol may be considered for expedited review if

1. The research has been reviewed and approved by another IRB;
2. It is a continuation review of research previously approved by the convened IRB as follows:

(a) where

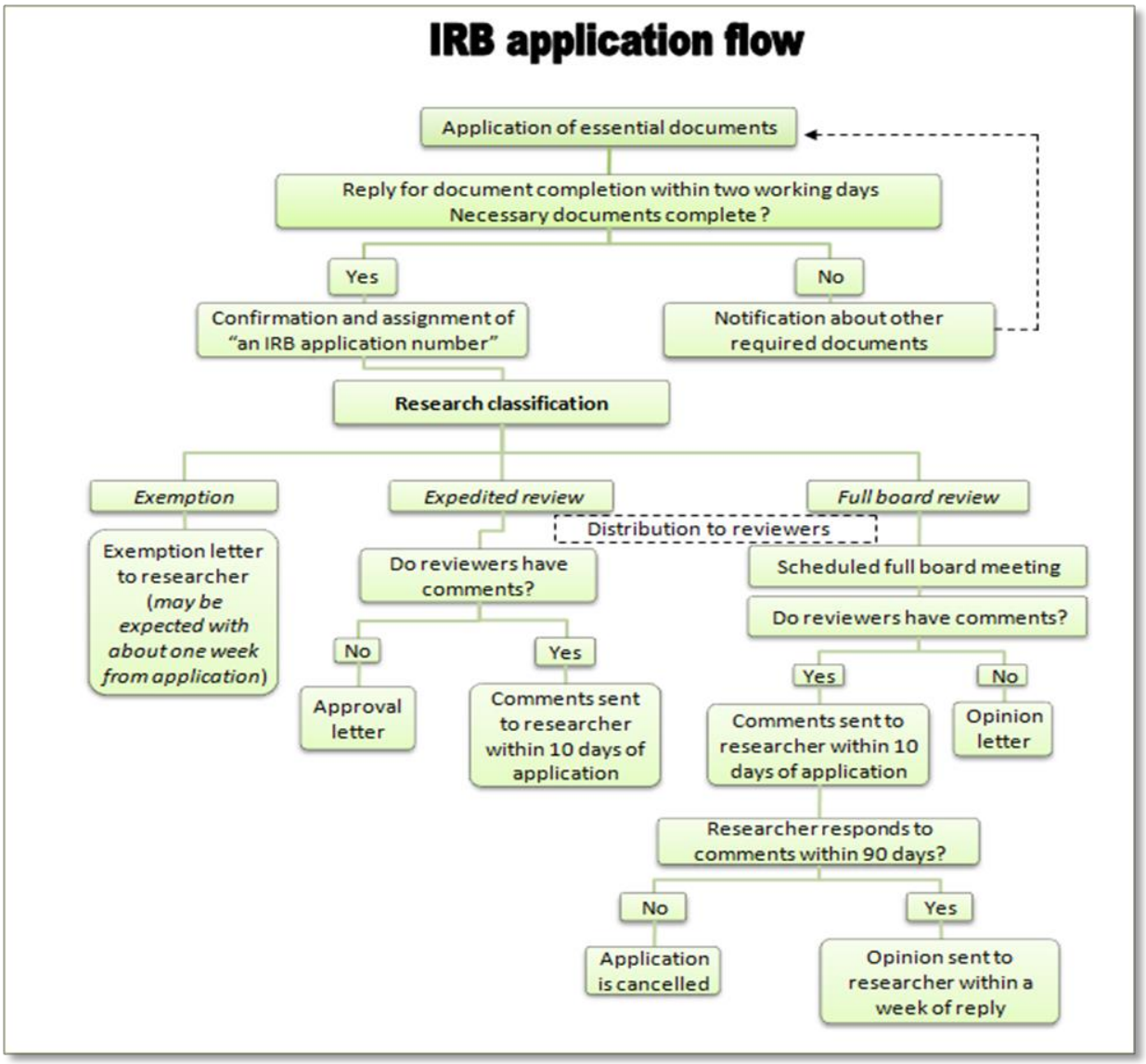
(i) the research is permanently closed to the enrollment of new subjects;
(ii) all subjects have completed all research-related interventions, or
(iii) the research remains active only for long-term follow-up of subjects, or

(b) where no subjects have been enrolled and no additional risks have been identified; or
(c) where the remaining research activities are limited to data analysis.

3. An expedited review will be conducted by two board members selected by the chair. Both reviewers must approve the proposal.
4. In an expedited review, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved **only** after review in accordance with the non-expedited procedure set forth in §46.108(b).

3. **Full Board Review**

a. All proposed human subject research that does not meet the criteria for exemption or an expedited review, must be reviewed by a majority of the IRB members at a convened meeting referred to as a "full board review."
c. Prior to the review meeting, the full board review application is previewed by the chair or designee to determine if further documentation is needed.
d. Once all materials are collected, the application is submitted to the full board for review requiring a majority of members to review proposal.
e. A majority of board members reviewing the proposal must agree on the board's determination.



CRITERIA FOR IRB APPROVAL OF RESEARCH §46.111

REQUIREMENTS

In order to approve research covered by this policy, the IRB shall determine that all of the following requirements are satisfied:

1. Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii)

whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

2. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB should consider only those risks and benefits that may result from the research (as distinguished from risks and benefits the subjects would receive even if not participating in the research). The IRB should not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibilities.

3. Selection of subjects is equitable. In making this assessment the IRB should consider the purposes of the research and the setting in which the research will be conducted and should be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons.

4. Informed consent is sought from each prospective subject or the subject's legally authorized representative, in accordance with, and to the extent required by §46.116.

5. Informed consent is documented, in accordance with, and to the extent required by §46.117.

6. When appropriate, the research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects.

7. When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

OTHER CONSIDERATIONS

1. The MCC IRB will make every effort to ensure that both the mental and physical well-being of the subjects are adequately protected and establish procedures to ensure the maintenance of proper records, the protection of anonymity, and the confidentiality of all data collected.

2. The MCC IRB will determine whether risks to subjects are reasonable relative to the anticipated benefits. The IRB shall not allow the use of human subjects in poorly designed projects that are unlikely to elicit meaningful results.

3. Ensure informed consent of subjects will be obtained through appropriate methods. The IRB will ensure that written consent is obtained from all subjects unless waived in accordance with CFR §46.117 (c) (1) or (2).

4. As per CFR §46.117 (c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either (1) that the consent document is the only record linking the subject and the research and potential harm could result from a breach of confidentiality. In this case, each subject will be asked whether he or she wants documentation linking the subject with the research, and the subject's wishes will govern; or (2) that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. If the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

5. All projects using or collecting data about MCC students, faculty, or employees must have oversight by a designated MCC faculty member or administrator.

VULNERABLE SUBJECTS

When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, mentally disabled persons, or economically or educationally disadvantaged persons, the IRB must ensure that additional safeguards have been included in the study to protect the rights and welfare of these subjects.

REVIEW INTERVAL

1. The review interval will be determined by the IRB at the time of approval.
2. The maximum interval for IRB review is one year.
3. A request for continuation must be submitted at least two months prior to expiration date.
4. Even when subject activities are complete, but data is still being analyzed or any other aspect of the study is ongoing, the study must have IRB approval to continue.

INVESTIGATOR'S RESPONSIBILITIES

PRINCIPAL INVESTIGATOR'S RESPONSIBILITIES

1. For any project involved with live human subjects/participants, it is the responsibility of the Principle Investigator (PI) to apply to the MCC Institutional Review Board for **Human Subject Research Determination.**
2. Should it be determined that a project meets the OHRP definition of Human Subject Research, no activity with the subjects may begin until IRB approval as been issued.
3. Prior to submission for IRB review, the PI must complete IRB training to include at a minimum, a MCC IRB Human Subject Protection Orientation and the

National Institutes of Health Human Participant Protections Education for Research Teams on-line course. https://phrp.nihtraining.com/users/login.php
4. The PI must ensure that all researchers working with the subjects and the project director of a human subject research project complete the MCC IRB Human Subject Protection Orientation. It is at the discretion of the PI as to what other training may be required.
5. No contact with human subjects may be conducted until the PI's IRB training is complete and the *Documentation of Training in Human Subject Protection* form has been submitted to the MCC's IRB Chair. (See forms.)
6. If it is determined that the study is human subject research, the PI should submit the appropriate applications to the IRB one (1) month prior to the anticipated start date of the project. No contact with human subjects may begin prior to IRB approval.
7. All application materials must be submitted no later than one (1) week prior to the regularly scheduled IRB review meeting to be considered at that meeting.
8. All work on the project must stop on the IRB approval expiration date unless continuation has been formally approved.
9. Records of all PI and researchers IRB training must be maintained in the MCC Office.
10. The Principal Investigator must maintain records of all human subject research projects for a minimum of three (3) years after completion of the project.
11. The PI must ensure that the records are well organized and easily accessible by the IRB and the appropriate funding agent.

IRB PROCEDURES/STEPS (THE APPROVAL PROCESS)

STEPS

1. The PI completes and submits electronically the *Human Subject Research Determination* form and proposal to MCC's IRB.
    a. These are distributed to the IRB chair or their designees.
    b. If it is determined that the project is human subject research, the PI must submit his/her *Documentation of Training in Human Subject Protection* form (see forms) with the certification of completion. This certification must accompany all IRB applications for review.
2. If the proposal is determined a human subject research project, the PI completes the appropriate IRB review application form:
    a. Application for Exempt Review
    b. Application for Expedited or Continuation Review
    c. Application for Full Board Review

3. The PI gathers all required documentation as per the application checklist.
4. The PI electronically submits the application packet to the IRB email address.

5. IRB reviews are conducted as necessary, but no less than at least once in the Fall and Spring semesters. Deadline for submission of application and materials is one (1) week prior to the regularly scheduled IRB review.
6. The application packets are sent to the IRB chair for review and distribution.
7. The IRB takes action within one month or less of application submission.
8. THE IRB MUST APPROVE THE RESEARCH PROJECT ***BEFORE*** THE RESEARCHER MAKES ANY CONTACT WITH THE SUBJECTS.
9. Approval is for a maximum of one year from the date of the IRB meeting considering the application.
10. If any work or data analysis is to continue after the approval expiration date, the PI MUST submit a continuance application for board review **two months prior** to expiration date.
11. A project that requires a full board review for the original application must apply for a full board review for continuation unless it meets the criteria for expedited review.
12. Upon completion of the project, the PI should submit to the IRB the *Close Out Report* form. No approval is required by the IRB.

CHECKLIST

1. PI Certifications of Human Subject Protection Training
2. Completed and signed application for review
3. Research plan/proposal
4. Samples of informed consent/assent forms
5. Outline of information to be provided prior to subjects' agreement to participate
6. Instruments, surveys, questionnaires, etc.
7. Curriculum vitae of researcher/PI

DETERMINATION AS RESEARCH

CODE OF FEDERAL REGULATIONS

As defined in the Code of Federal Regulations, *research* means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. §46.102

It is generally accepted practice and discussed in the *Office of Human Research Protection IRB Guidebook* that the above is interpreted comprehensively to include as research any project in which any part of the project is to be a contribution to

"generalized knowledge" and/or its results are intended to probably be made public in some way, such as in a presentation at a conference or other professional meeting or if a model is designed that will be distributed to other organizations, or if the data or strategies could be utilized in some way by another institution.

FACTORS TO BE CONSIDERED

- Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? 45 CFR 46.102(d)
- Does research involve obtaining information about living individuals? 45 CFR 46.102 (f)
- Does the research involve intervention or interaction with the individuals? 45 CFR 46.1029f)(1)(2)
- Is the information individually identifiable? 45 CFR 46.102 (f)(2)
- Is the information private? (The designation of private would include behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place or which the individual can reasonably expect will not be made public.) 45CFD 46.102(f)(2)

DETERMINATION AS HUMAN SUBJECTS

HUMAN SUBJECTS

Human subjects are individuals whose physiologic or behavioral characteristics and responses are the object of study in a research project. Under federal regulations, human subjects are defined as living individual(s) about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information [Federal Policy §46.102(f)].

Intervention includes both physical procedures by which data are gathered (for example, drawing blood) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and subject. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. This can include information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Data is considered *identifiable* if the identity of the subject is associated with the information or may readily be ascertained by the investigator. §46.102

EXEMPTIONS

EXEMPTED RESEARCH ACTIVITIES

The Final Rule (45 CFR 46, Subpart A - "Federal Policy for the Protection of Human Subjects" [the Common Rule]) revised and expanded the categories for exempt research. New categories were added, and two new processes were introduced: **limited IRB review** and **broad consent**.

Category 1: Research in Established or Commonly Accepted Educational Settings.

Category 2: Educational Test, Surveys, Interviews, Observations of Public Behavior.

Category 3: Benign Behavioral Interventions in Conjunction with the Collection of Information from Adult Subjects.

Category 4: Secondary Research for Which Consent is Not Required.

Category 5: Research and Demonstration Projects that are Conducted or Supported by a Federal Department or Agency.

Category 6: Taste and Food Quality Evaluation and Consumer Acceptance Studies.

Category 7: Storage or Maintenance for Secondary Use for which Broad Consent is Required.

Category 8: Secondary Research for which Broad Consent is Required.

(See pp. 32-39.)

*These exemptions do **NOT** apply when (a) **deception** of subjects may be an element of the research; (b) subjects are **under the age of eighteen**; (c) the activity may **expose the subject to discomfort or harassment** beyond levels encountered in daily life; or (d) **fetuses, pregnant women, human** **in vitro** **fertilization, children, individuals who are mentally impaired, or individuals involuntarily confined or detained in penal institutions** are subjects of the activity.*

Federal department or agency heads retain final judgment as to whether a particular activity is covered by this policy. 45 CFR 46.101 (c)

The term "exempt" refers to the requirement for continuing IRB review, but not the general requirements for informed consent and protection of subjects. Thus, even if the project is exempt, the PI must inform potential subjects of the proposed procedures and of their rights as subjects and obtain informed consent.

INFORMED CONSENT

INFORMED CONSENT DEFINITION

Informed consent is a person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights or release or appear to release, the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].

IRB CONSIDERATIONS

Investigators may seek consent only under circumstances that provide the prospective subject or his or her representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. Furthermore, the information must be written in language that is understandable to the subject or representative. The consent process may not involve the use of exculpatory language through which the subject or representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, sponsor, institution, or agents from liability for negligence [Federal Policy §46.116].

FEDERAL REGULATIONS

Federal regulations require that certain information must be provided to each subject [Federal Policy
§46.116(a)]:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(3) A description of any benefits to the subject or to others which may reasonably be expected from the research;
(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; (6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

The regulations further provide that the following additional information be provided to subjects, where appropriate [Federal Policy §46.116(b)]:

(1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
(2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
(3) Any additional costs to the subject that may result from participation in the research;
(4) The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
(5) A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
(6) The approximate number of subjects involved in the study.

As per CFR §46.117 (c), the IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern;

or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

ASSENT

Assent is defined as an "agreement by an individual not competent to give legally valid informed consent (e.g., a child or cognitively impaired person) to participate in research." *IRB Guidebook:* http://wayback.archive-it.org/org-745/20150930182832/http://www.hhs.gov/ohrp/archive/irb/irb_glossary.htm. Assent is generally required if

1. Subjects are minors between the ages of 7 and 17. Children below the age of 7 are generally not asked to provide assent.

2. Subjects 18 or older are intellectually or emotionally impaired and not legally competent to give their informed consent.

In the case where the minor subjects are able to read and understand the informed consent document, they may provide assent on a form with a separate signature line for their parents/guardians.

The assent form must include:

1. Study Title
2. Study Purpose. Provide a brief explanation of the purpose of the study.
3. Procedures. Describe what the subject is being asked to do.
4. Withdrawal Privilege. Describe how a subject can stop participation later even if he/she agrees to start.
5. Voluntary Participation. Include a statement that the subject does not have to participate.
6. Confidentiality Statement. Indicate that the experimenter will not tell anyone (parents, teachers) what the subject says or does in the study.
7. Signature Lines. Include a signature line for the subject and for the investigator.
8. Date Line.

It is important that the form is written using language that is appropriate for the age level and mental capacity of subjects.

ADVERSE EVENTS

Adverse Events are events or circumstances that were unintended and unanticipated at the time the project was approved by the IRB. Any illness, injury, or trauma that required medical or psychological treatment must be reported to the IRB, to the funding agency, and in the Progress Report. (See forms) Even those Events that are not related to the project must be reported.

UNANTICIPATED EVENT REQUIRING REPORTING

Is the adverse event an unanticipated problem and therefore must be reported?

1. Is the adverse event unexpected?
2. Is the adverse event related or possibly related to participation in the research?
3. Does the adverse event suggest that the research places subjects or others at a greater risk of harm than was previously known or recognized?

If the answer to all three questions is yes, then the adverse event is an unanticipated problem and must be reported to appropriate entities under the HHS regulations. 45 CFR 46.103 (a) and 46.1203(b)(5)

SERIOUS ADVERSE EVENT

Any event resulting in death, a life threatening situation, inpatient hospitalization, significant disability or birth defect must be reported to the IRB within **24 hours** of the PI's knowledge of the event. A physician's comment is required and must be included with the report.

UNEXPECTED ADVERSE EVENT

Any adverse event not listed in the current consent form must be reported within **24 hours**.

NEITHER SERIOUS NOR UNEXPECTED ADVERSE EVENT

Any adverse event which is neither *serious* nor *unexpected* must be reported to the IRB within **7 days**.

EXAMPLES

A subject is identified as being in a high risk category that was not anticipated or planned in the selection of human subjects.

A different use of data than originally planned causes a risk of loss of privacy or confidentiality for the human subjects.

Participant consent was waived by IRB due to minimal risk but, as project evolves is now determined to be needed.

Although not occurring within the research activity, any automobile accident involving a subject as driver still needs to be reported. If numerous accidents by subjects in the same study were reported to the IRB, they could be a result of extreme stress caused by the study.

TERMS AND DEFINITIONS

DEFINITIONS

ANONYMOUS DATA Data collected in a manner so the subjects cannot be identified, directly or through identifiers linked to the subject.

ASSENT Agreement by an individual not competent to give legally valid informed consent (*e.g.*, a child or cognitively impaired person) to participate in research. [OHRP]

ASSURANCE A formal, written, binding commitment that is submitted to a federal agency in which an institution promises to comply with applicable regulations governing research with human subjects and stipulates the procedures through which compliance will be achieved [Federal Policy §46.103].

AUTHORIZED INSTITUTIONAL OFFICIAL An officer of an institution with the authority to speak for and legally commit the institution to adherence to the requirements of the federal regulations regarding the involvement of human subjects in biomedical and behavioral research. [OHRP]

BENEFICENCE An ethical principle discussed in the Belmont Report that entails an obligation to protect persons from harm. The principle of beneficence can be expressed in two general rules: (1) do not harm and (2) protect from harm by maximizing possible benefits and minimizing possible risks of harm. [OHRP]

BENEFIT A valued or desired outcome; an advantage. [OHRP]

CERTIFICATION The official notification by the institution to the supporting department or agency, in accordance with the requirements of this policy, that a research project or activity involving human subjects has been reviewed and approved by an IRB in accordance with an approved assurance. [§46.102]

COGNITIVELY IMPAIRED An individual who has either a psychiatric disorder (e.g., psychosis, neurosis, personality or behavior disorders, or dementia) or a developmental disorder (e.g., mental retardation) that affects cognitive or emotional functions to the extent that capacity for judgment and reasoning is significantly diminished is considered cognitively impaired for IRB purposes. Others, including persons under the influence of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain,

terminally ill patients, and persons with severely disabling physical handicaps, may also be compromised in their ability to make decisions in their best interests. [OHRP]

COHORT A group of subjects initially identified as having one or more characteristics in common who are followed over time. In social science research, this term may refer to any group of persons who are born at about the same time and share common historical or cultural experiences. [OHRP]

COMPETENCE Technically, a legal term used to denote capacity to act on one's own behalf; the ability to understand information presented, to appreciate the consequences of acting (or not acting) on that information, and to make a choice. [OHRP]

CONTRACT As used here, an agreement that a specific research activity will be performed at the request, and under the direction, of the agency providing the funds. Research performed under contract is more closely controlled by the agency than research performed under a grant. (*Compare: Grant*.) [OHRP]

DEPARTMENT OR AGENCY HEAD the head of any federal department or agency and any other officer or employee of any federal department or agency to whom authority has been delegated. [§46.102]

DHHS A federal agency: U.S. Department of Health and Human Services; formerly the Department of Health, Education and Welfare (DHEW).

EQUITABLE Fair or just; used in the context of selection of subjects to indicate that the benefits and burdens of research are fairly distributed [Federal Policy §46.111(a)(3)].

GRANT Financial support provided for a research study designed and proposed by the principal investigator(s). The granting agency exercises no direct control over the conduct of approved research supported by a grant. (*Compare: Contract*.) [OHRP]

GUARDIAN An individual who is authorized under applicable state or local law to give permission on behalf of a child for general medical care [45 CFR 46.402(3)].

HUMAN SUBJECT A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable private information. *Intervention* includes both physical procedures by which data are gathered (for example, *venipuncture*) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject. *Private information* includes information about

behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. This can include information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Data is considered *identifiable* if the identity of the subject is associated with the information or may readily be ascertained by the investigator. [§46.102]

INFORMED CONSENT A person's voluntary agreement, based upon adequate knowledge and understanding of relevant information, to participate in research or to undergo a diagnostic, therapeutic, or preventive procedure. In giving informed consent, subjects may not waive or appear to waive any of their legal rights, or release or appear to release the investigator, the sponsor, the institution or agents thereof from liability for negligence [Federal Policy §116; 21 CFR 50.20 and 50.25].

I**NSTITUTION** This is a public or private entity or agency (including federal, state, and other agencies).
[§46.102]

INTERACTION Communication or interpersonal contact between investigator and subject.

INTERVENTION Includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

INVESTIGATOR Title/position of an individual who actually conducts an investigation [21 CFR 312.3]. Any interventions (*e.g.*, drugs) involved in the study are administered to subjects under the immediate direction of the investigator. (*See also: Principal Investigator*.) [OHRP]

IRB An institutional review board established in accord with and for the purposes expressed in this policy. [§46.102]

IRB APPROVAL The determination of the IRB that the research has been reviewed and may be conducted at an institution within the constraints set forth by the IRB and by other institutional and federal requirements. [§46.102]

JUSTICE An ethical principle discussed in the Belmont Report requiring fairness in distribution of burdens and benefits; often expressed in terms of treating persons of similar circumstances or characteristics similarly. [OHRP]

LEGALLY AUTHORIZED REPRESENTATIVE A person authorized either by statute or by court appointment to make decisions on behalf of another person. In human subjects research, an individual or judicial or other body authorized under applicable law to

consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research [Federal Policy §46.102(c)].

MINIMAL RISK A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [Federal Policy §46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of routine physical examination.

MONITORING The collection and analysis of data as the project progresses to assure the appropriateness of the research, its design, and its subject protections. [OHRP]

NONAFFILIATED MEMBER A member of an Institutional Review Board who has no ties to the parent institution, its staff, or its faculty. This individual is usually from the local community (*e.g.*, minister, business person, attorney, teacher, homemaker). [OHRP]

OHRP Office of Human Research Protections, a division of the U.S. Department of Health and Human Services.

PERMISSION The agreement of parent(s) or guardian(s) to the participation of their child or ward in research [45 CFR 46.402(c)].

PRINCIPAL INVESTIGATOR This refers to the scientist or scholar who has primary responsibility for the design and conduct of a research project. (See also: Investigator.) [OHRP]

PRIVATE INFORMATION Information is considered private if it includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. This can include information that has been provided for specific purposes by an individual, which that individual can reasonably expect will not be made public. It also includes information revealed by a primary research subject about another individual without the consent of that individual.

PROTOCOL The formal design or plan of an experiment or research activity; specifically, the plan submitted to an IRB for review and to an agency for research support. The protocol includes a description of the research design or methodology to be employed, the eligibility requirements for prospective subjects and controls, the process for informed consent, and the proposed methods of analysis that will be performed on the collected data. OHRP

RESEARCH A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purposes of this policy, whether or

not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. [§46.102]

RESEARCH SUBJECT TO REGULATION This and similar terms are intended to encompass those research activities for which a federal department or agency has specific responsibility for regulating as a research activity, (for example, Investigational New Drug requirements administered by the Food and Drug Administration). It does not include research activities which are incidentally regulated by a federal department or agency solely as part of the department's or agency's broader responsibility to regulate certain types of activities whether research or nonresearch in nature (for example, Wage and Hour requirements administered by the Department of Labor). [§46.102]

RISK The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." (*See also: Minimal Risk*.) OHRP

SITE VISIT A visit by agency officials, representatives, or consultants to the location of a research activity to assess the adequacy of IRB protection of human subjects or the capability of personnel to conduct the research. [OHRP]

STATISTICAL SIGNIFICANCE A determination of the probability of obtaining the particular distribution of the data on the assumption that the null hypothesis is true. Or, more simply put, the probability of coming to a false positive conclusion. If the probability is less than or equal to a predetermined value (*e.g.*, 0.05 or 0.01), then the null hypothesis is rejected at that significance level (0.05 or 0.01). [OHRP]

SURVEYS Studies designed to obtain information from a large number of respondents through questionnaires, interviews, door-to-door canvassing, or similar procedures. [OHRP]

VOLUNTARY Free of coercion, duress, or undue inducement. Used in the research context to refer to a subject's decision to participate (or to continue to participate) in a research activity. [OHRP]

HUMAN SUBJECT REGULATIONS DECISION CHARTS

The Office for Human Research Protections (OHRP) provides the following graphic aids as a guide for institutional review boards (IRBs), investigators, and others who decide if an activity is research involving human subjects that must be reviewed by an IRB under the requirements of the U.S. Department of Health and Human Services (HHS) regulations at 45 CFR part 46. OHRP welcomes comment on these decision charts. The charts address decisions on the following:

- whether an activity **is research** that must be reviewed by an IRB
- whether the review may be performed by **expedited procedures**, and
- whether **informed consent** or its documentation may be waived.

Considerations

The charts are intended to assist IRBs, institutions, and investigators in their decision-making process and should not be used as substitutes for consulting the regulations. OHRP cautions that the full text of applicable regulatory provisions should be considered in making final decisions.

These charts are necessarily generalizations and may not be specific enough for particular situations. Other guidance documents are available related to specific topics, at OHRP Policy Guidance by Topic: https://www.hhs.gov/ohrp/regulations-and-policy/guidance/.
OHRP invites inquiries for additional information.

The charts do not address requirements that may be imposed by other organizations, such as the Food and Drug Administration, National Institutes of Health, other sponsors, or state or local governments.

Chart 1: Is an Activity Research Involving Human Subjects?

Chart 2: Is the Human Subjects Research Eligible for Exemption?

Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?

Chart 4: Does exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data, Documents, Records and Specimens) Apply?

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?

Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

Chart 8: May the IRB Review Be Done by Expedited Procedures?

Chart 9: May the IRB Continuing Review Be Done by Expedited Procedures?

Chart 10: May Informed Consent Be Waived or Consent Elements Be Altered under 45 CFR 46.116(d)?

Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?

Chart 1: Is an Activity Research Involving Human Subjects Covered by 45 CFR part 46?

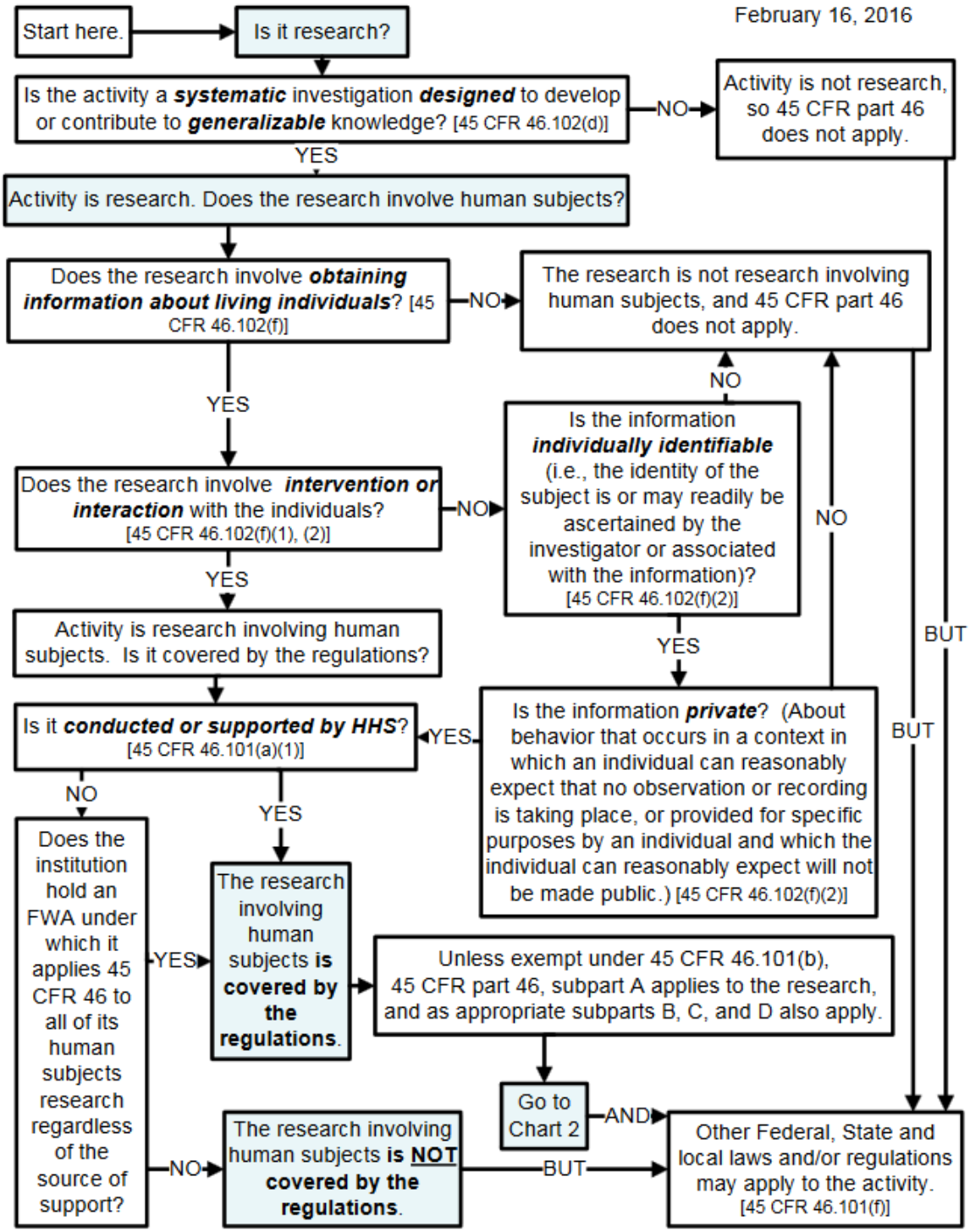


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

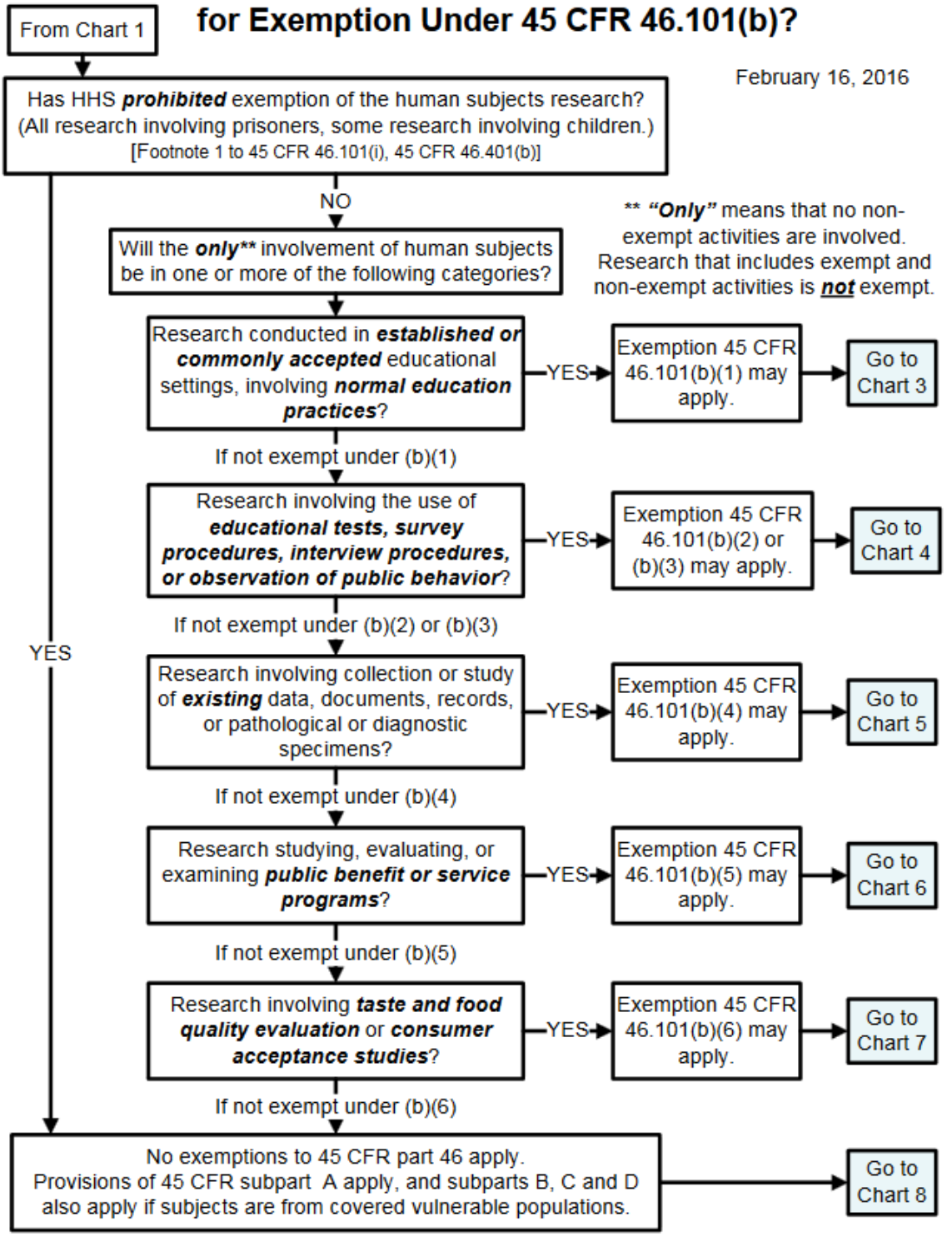
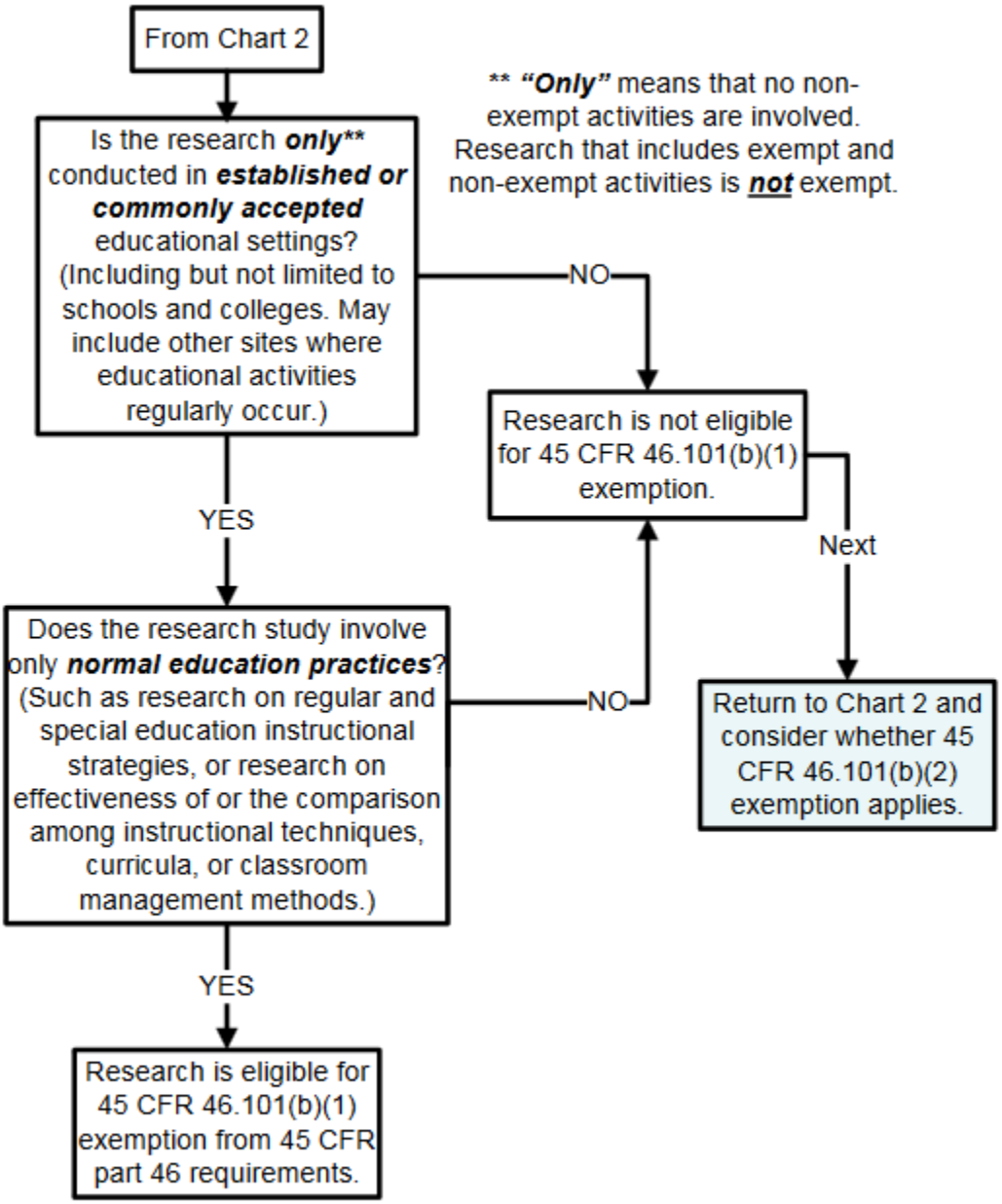


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



February 16, 20126

Chart 4: Does Exemption 45 CFR 46.101(b)(2) or (b)(3) (for Tests, Surveys, Interviews, Public Behavior Observation) Apply?

February 16, 2016

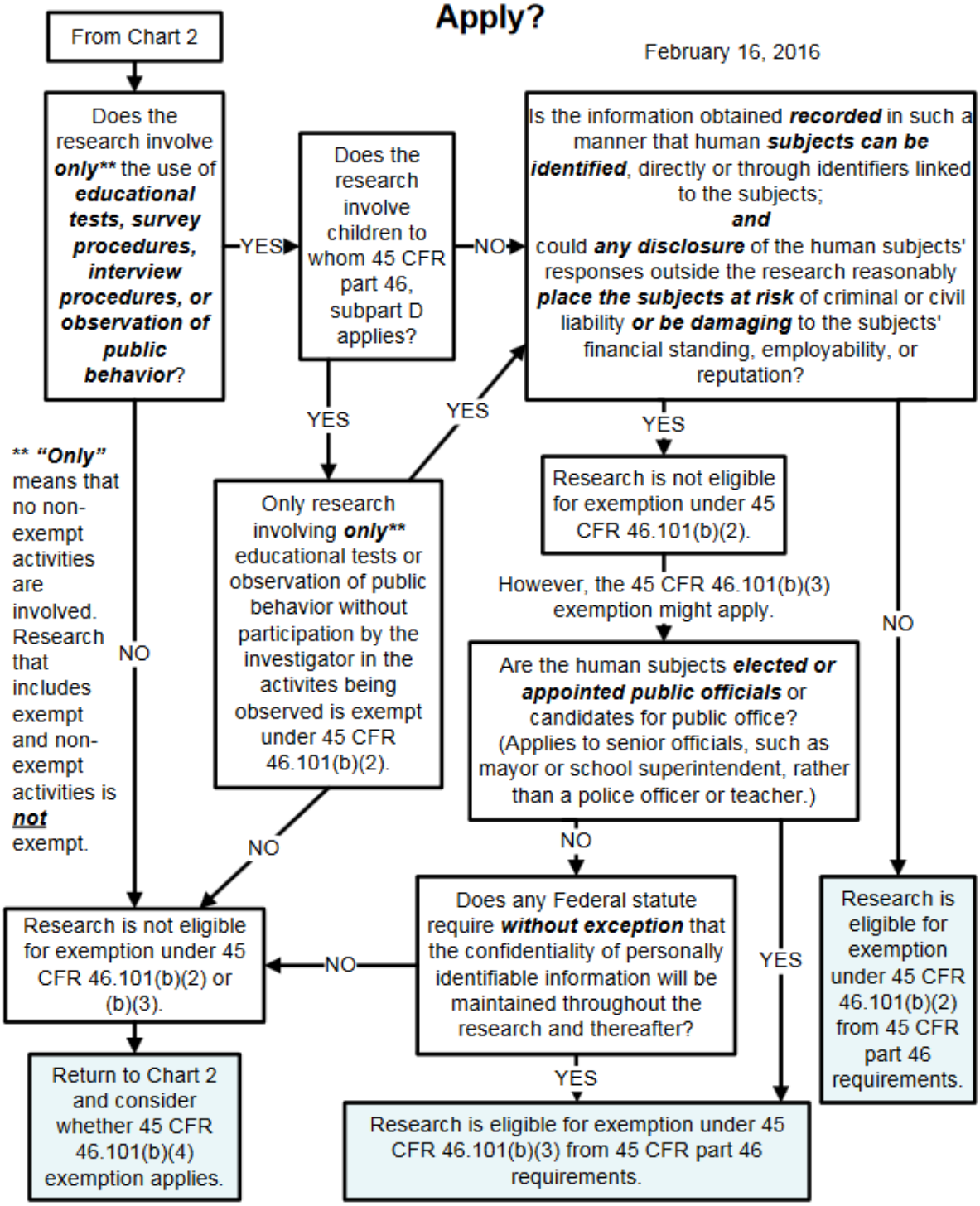
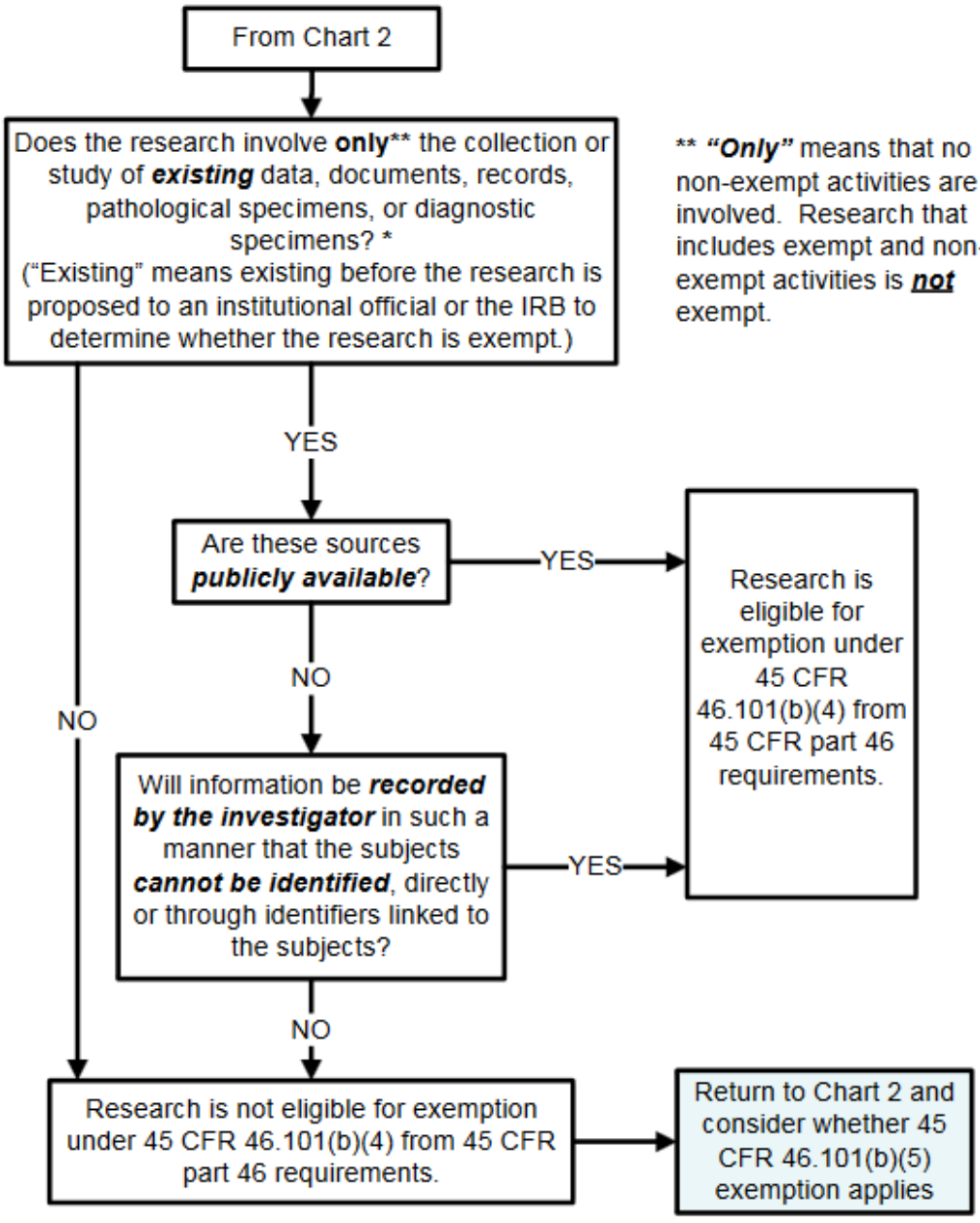


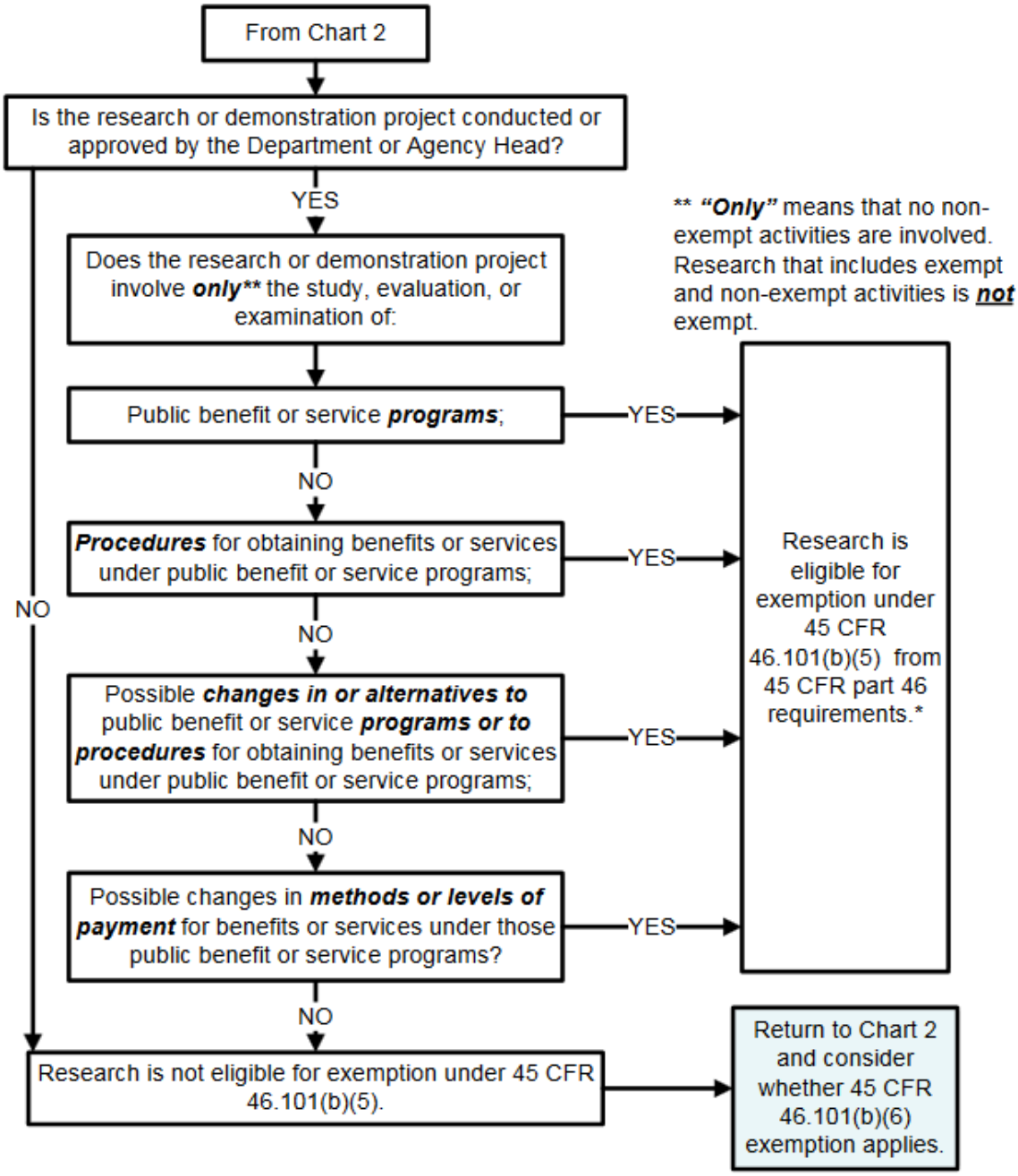
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



* Note: See **OHRP** guidance on research use of stored data or tissues and on stem cells at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/guidance-on-research-involving-stem-cells/index.html, and on coded data or specimens at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html for further information on those topics.

February 16, 2016

Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See **OHRP** guidance on exemptions at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/exemptions-for-public-benefit-and-service-programs/index.html for further description of requirements for this exemption.

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Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?

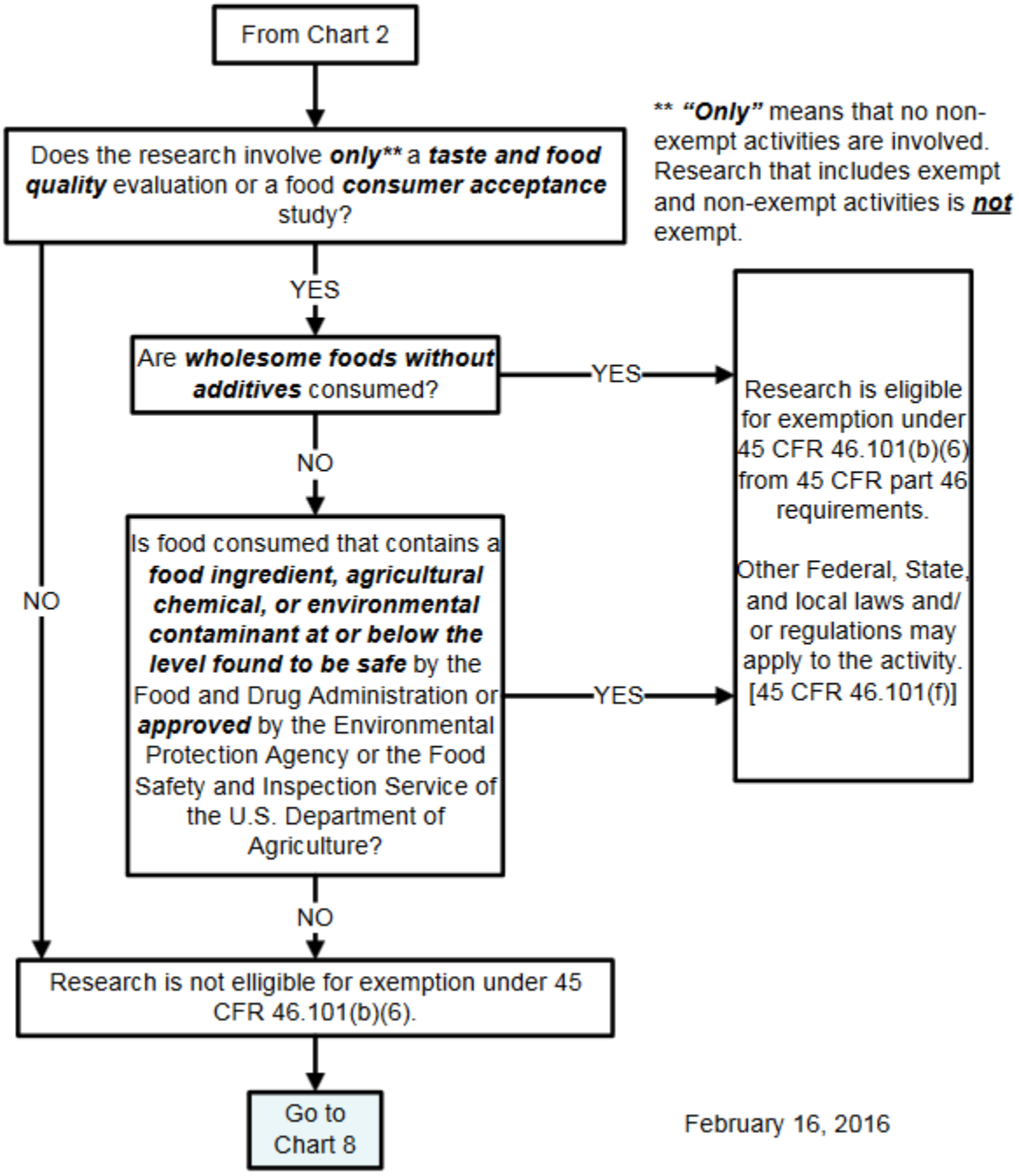

Chart 8: May the IRB Review Be Done by Expedited Procedures Under 45 CFR 46.110?*

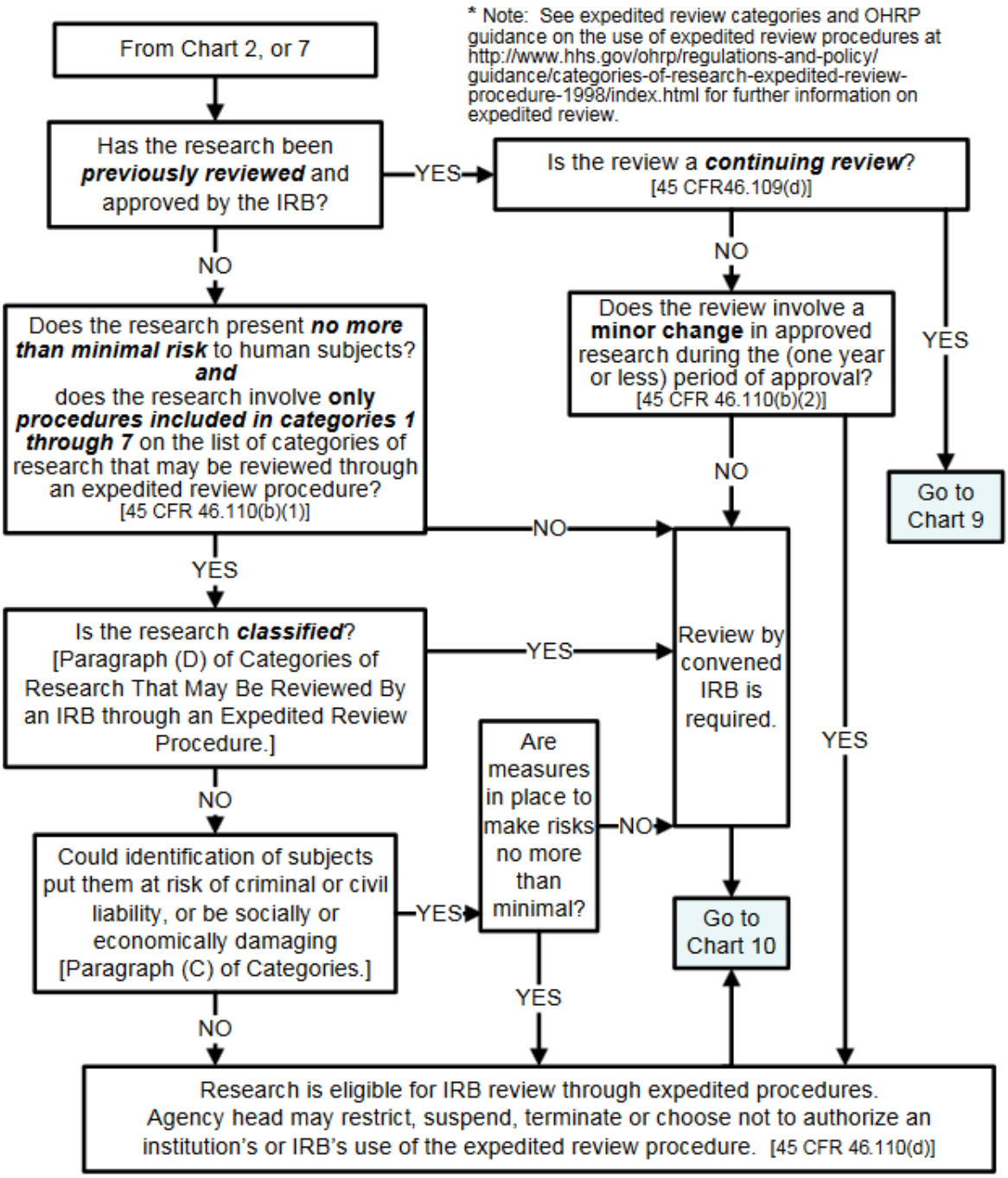

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Chart 9: Can Continuing Review be Done by Expedited Procedures Under 45 CFR 46.110?

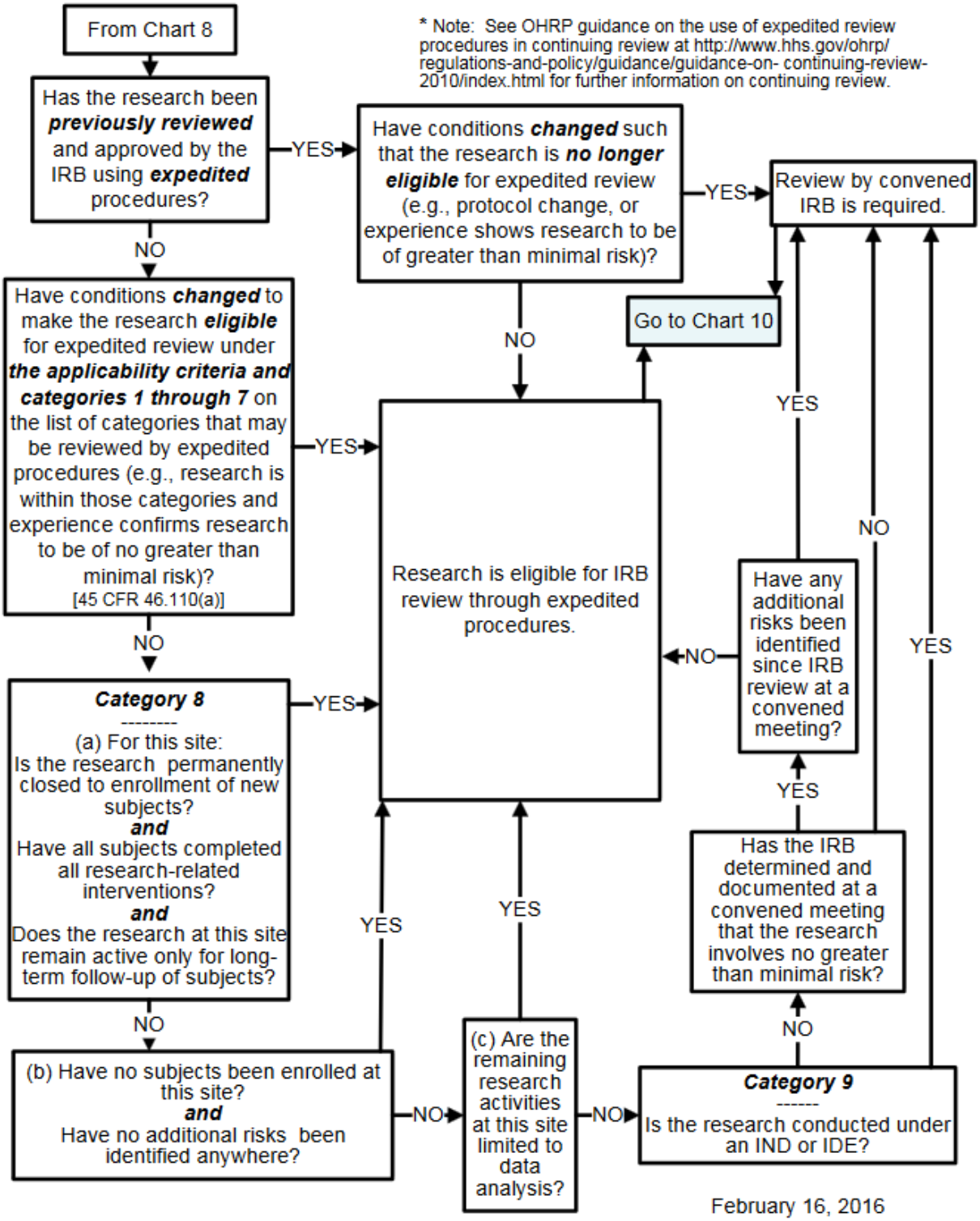

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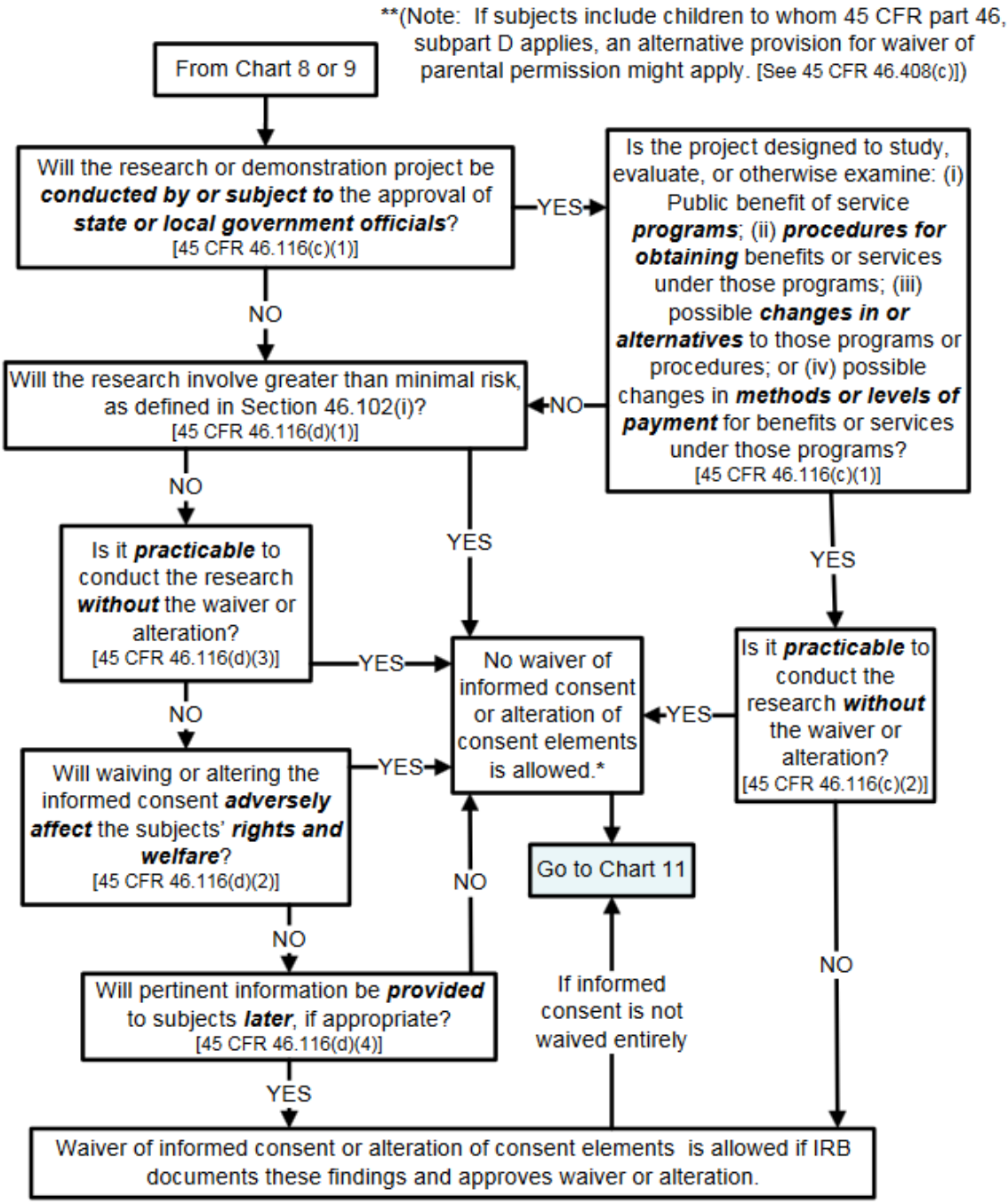
Chart 10: Can Informed Consent Be Waived or Consent Elements Be Altered Under 45 CFR 46.116(c) or (d)?**



* Note: See OHRP guidance on informed consent requirements in emergency research at http://www.hhs.gov/ohrp/regulations-and-policy/guidance/emergency-research-informed-consent-requirements/index.html for further information on emergency research informed consent waiver.

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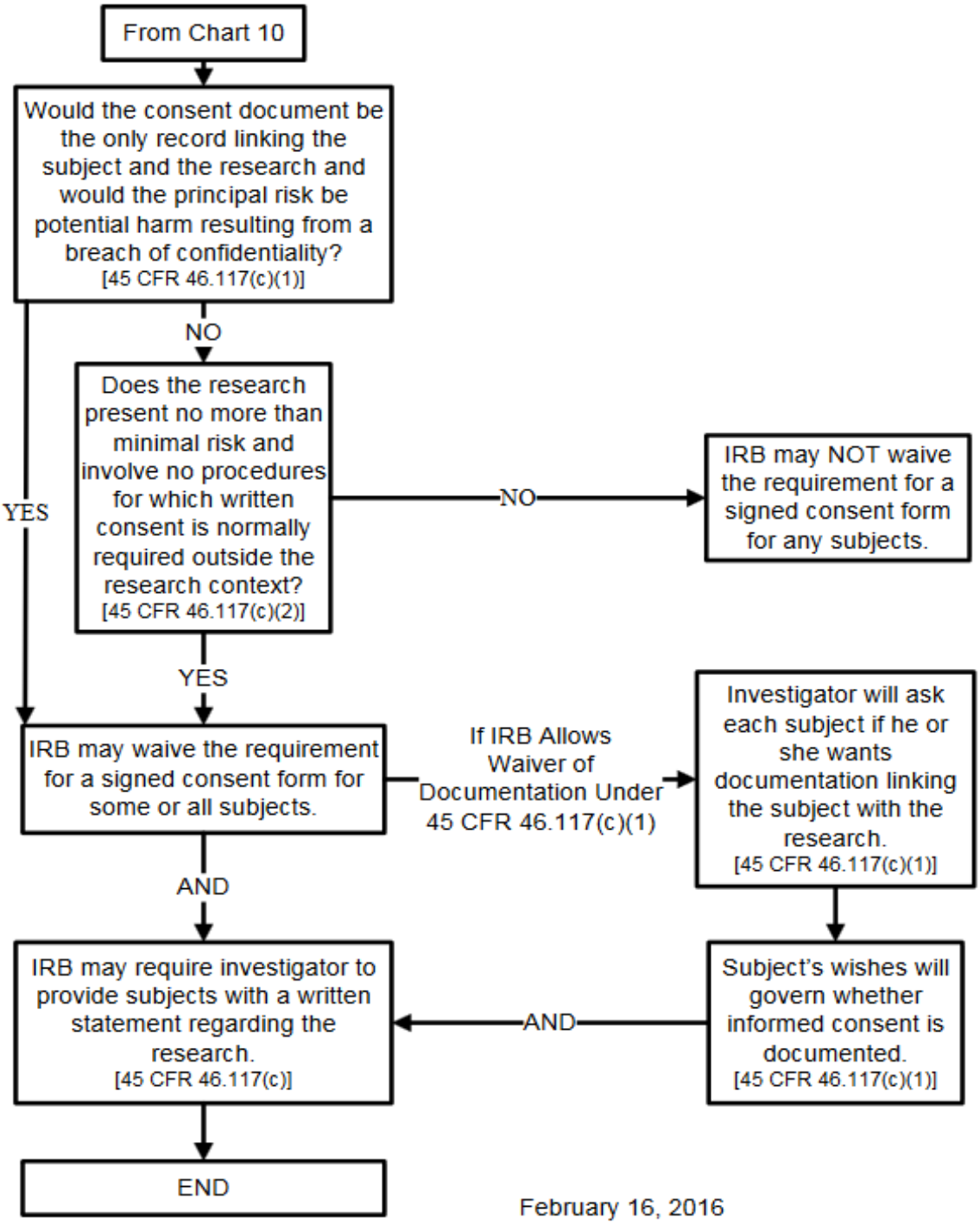
Chart 11: May Documentation of Informed Consent Be Waived Under 45 CFR 46.117(c)?



IRB Forms & Guidelines @ MCC

(Available on the MCC Website)

- Human Subjects Research Checklist
- Checklist for IRB Application
- Guidelines for Submitting an Application
- Application for Review of Human Subjects Research
- Informed Consent Guidelines
- Informed Consent Form
- Request for Amendment Form
- Request for Renewal Form
- Request for Closure of Study Form

Human Subjects Research Checklist

The following checklist is designed to help determine if the proposed research will need review by the MCC Institutional Review Board (IRB). Fill out the checklist completely and submit by email to Bradley Christian, bchristian@mclennan.edu.

Name: _____

MCC email: _____

Phone number: _____

Faculty Mentor's Name and department: _____

Faculty Mentor's email: _____

Title of proposed project: _____

1. Briefly describe the proposed study.

2. Who and/or what do you plan to study (individuals, tissue samples, or existing data)?

3. How do you plan to obtain the information?

4. Will any information about participants or about the data obtained be used for any purpose other than for a class project, even if it will be used for a class project?

5. What do you plan to do with the data (Scholars Day presentation, poster, submit for conference, submit for publication, etc.)?

The U.S. Department of Health and Human Services defines research as:

…a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes.

45 CFR 46.102(d)

Basically, this refers to a study that is specifically designed to generate data for the purpose of adding to the general body of knowledge in its particular discipline.

6. Does your study, as currently envisioned, meet this definition?

Yes ◯ No ◯

7. Does your study involve using nonhuman vertebrate mammals as study subjects?

Yes ◯ No ◯

If so, your study may require review by the MCC Animal Care and Use Committee (IACUC). If so, please contact Dr. Sue Allen, Director of the Veterinary Technician Program, suallen@mclennan.edu.

The U.S. Department of Health and Human Services defines a human participant as:

…a living individual about whom an investigator (whether professional or student) conducting research obtains

> *(1) Data through intervention or interaction with the individual, or*
> *(2) Identifiable private information.*

Intervention includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between the investigator and subject. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information which has been provided for specific purposes by an individual where the individual can reasonably expect it will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.
45 CFR 46.102(f).

8. Does your study involve obtaining information about living persons?

   Yes ◯ No ◯

9. Does the study involve intervention or interaction with living persons?

   Yes ◯ No ◯

10. Does any of the information obtained have the potential to personally identify the study participant (see below)?

    Yes ◯ No ◯

11. Is any of the information private (see below)?

    Yes ◯ No ◯

Examples of individually identifiable private information include: name, address phone number, cell number, email address, social media contact information, certificate or license numbers, Social Security number, employer, specific location and type of

employment, health plan number, full-face photographic images, digital images, handwriting sample, voice recording, fingerprints, vehicle identification and plate number, any significant date more specific than year of birth, distinctive visual identifiers such as tattoos, piercings, scars, unusual physical characteristics such as missing limbs, burn scars, visible skin discolorations, or handicapping conditions (unless all or a significant number of study participants share the same condition and were chosen for the study primarily due to this condition).

If your answers to any of the questions **(4, 6, 8, 9, 10,** and **11)** are *Yes*, your study will likely require review by the MCC Institutional Review Board.

Checklist for IRB Application Submission

Please Check the box(es) that correspond with the documents you have attached to your IRB Application:

- ☐ Application for Review of Human Subjects Research (IRB form 4b)
- ☐ Recruitment Script/Documents
- ☐ Informed Consent Form (IRB form 5b)
- ☐ Measurement Instrument(s) (questionnaires, surveys, etc.)
- ☐ Authorization (Professors, organizations, etc.)
- ☐ Medical Clearance (if required)
- ☐ Protecting Human Research Participants (PHRP) Training Certificate - or- Collaborative Institutional Training Initiative (CITI)

Protecting Human Research Participants (PHRP) is a National Institutes of Health on-line training course required by the Department of Health and Human Services regulations. Visit http://phrp.nihtraining.com/users/login.php PHRP certification is required of all study personnel. Copies of Certificates of Completion must be submitted with the application. Recertification is required every two years, and CITI certification can be substituted.

Contact information for the IRB:

Bradley Christian
Chair, Institutional Review Board
bchristian@mclennan.edu
Submit one hard copy of your application with all required signatures to the MCC's Institutional Review Board, Science Building 110

Submit one electronic copy of all documents to bchristian@mclennan.edu

Guidelines for Submitting an Application for Review of Human Subjects Research

Please note that your application will not be processed until the original application with all required signatures is received.

Each numbered item below corresponds to a numbered item on the IRB Application for Human Subjects Research and is intended to explain what is required for each item when completing the application. Please follow these guidelines closely. If you have any questions, feel free to contact the IRB Chair, Bradley Christian, at bchristian@mclennan.edu

1. **Description of study:** Describe the purpose of the study in enough detail that we can ascertain what the study is about. Describe why it is being done and the importance of the projected results. Explain how the study is intended to contribute to general knowledge.
2. **Description of participants:** Describe the subjects you intend to recruit for this project, the method(s) of recruitment, and where recruitment of subjects will occur. If you will be recruiting from MCC classes, please attach an email from the instructor granting permission. If the recruiting will occur in the classroom, describe how you intend to minimize undue influence or coercion during recruitment. If you plan to recruit from outside institutions or organizations, please attach an email granting permission to recruit from a person authorized to do so, including his/her title and contact information. If you intend to use an oral or written script or any materials such as a flyer or email to recruit research subjects, attach a copy of these scripts/documents.
3. **Number of participants:** How many subjects do you expect to participate in your study? Provide an explanation for that number.
4. **Vulnerable populations:** Vulnerable populations may include minors (<18 years old), pregnant women and neonates, prisoners, cognitively/developmentally impaired persons, or seniors (>65 years old). If you will be specifically including or targeting any members of a vulnerable population for your study, please explain why you are doing so, and provide details about the additional safeguards you intend to use to

protect their rights and interests.

5. **Methods:** Describe the methods you will use for the study, such as interviews, measurements or observations of the participants, what will happen to them during the study, and how long you estimate their actual participation is expected to take. If you will use a questionnaire, a survey, or other written instruments, please attach a copy.
6. **Location of study:** Where will your study actually be conducted? If on campus at MCC, include the building and room number (or other campus location); if off-site, provide the name of the site and an address.
7. **Medical clearance:** If the study involves tissue or blood sampling, the administration of food or drugs, physical exercise or conditioning, medical clearance will need to be secured prior to participation. Explain how this is to be done and include copies of medical clearance for each participant.
8. **Risk(s) to participants:** There are many different types of risks associated with human subjects research including physical stress, psychological stress, economic and/or legal risks, exposure to infectious disease or radiation, personal information about the participant and/or their family, confidential information or records regarding employment, educational background, medical conditions, criminal history, or exposure to materials participants may consider offensive or inappropriate. For each type of risk, describe the amount of risk or harm anticipated, justify why the risk is necessary, and explain how the risk will be minimized.
9. **Retrospective data review:** Will you be using existing data? If so, identify the source(s) of the data and, if relevant, how the data will be de-identified.
10. **Biologic sample disposal:** If your study involves collecting tissue or blood samples, please specify the procedures for disposal.
11. **Deception:** Will the subjects be deceived or misled in any way? If so, describe the type of deception or omission, justify the necessity, and explain how and when subjects will be debriefed. If a specific script is used to debrief, please attach.
12. **Consent:** How will you obtain the consent of the participants? If you are using a written consent form, submit a copy with the study application. If minors or those unable to sign a consent form will be study participants, explain how you will obtain consent from them. Explain where consenting will occur and procedures for securing the signed forms. This includes a master code sheet, if one is used.
13. **Audio or visual imaging:** If you will be making any audio and/or video recordings,

taking photographs or any other digital images of the study participants, explain why this is necessary, how the privacy and identity of the participants will be guaranteed, and detail specific methods to dispose of these materials after they have been analyzed. An explanation of the necessity of using audio and/or visual images must be included on the Informed Consent form, and the participants must specifically consent to the obtaining of these images/recordings.

14. **Data storage and security:** Describe how you plan to ensure the security of the data once it has been obtained. Explain where and how it will be stored, how long you plan to keep it, and who will have access. Once the study is completed, identify who will be responsible for destroying the data and how it is to be done, (e.g., shredding surveys, destructive electronic deletion of files, etc.).
15. **Signed Informed Consent Forms:** Federal regulations require that signed consent forms be kept for a minimum of three (3) years. Explain when, how, and by whom the Informed Consent forms will be destroyed.
16. **Benefits of participation for subjects:** While it is not necessary that study participants directly benefit from their participation, if there is some direct benefit, describe what it may be.
17. **Benefits of your study to society:** Even if the participants in your study do not directly benefit, explain how this study may be of general value to society as a whole.

Application for Review of Human Subjects Research

Title of Project: _____

IRB Project # (Assigned by IRB): _____

Name of Principal Investigator(s): _____

Email (MCC email address required): _____

Phone: _____

Name of Faculty Mentor: _____

Department: _____

Campus Address: _____

Campus Phone: _____

Email (MCC email address required): _____

1. Description of study:

2. Description of participants:

3. Number of participants: _____

4. Vulnerable populations:

5. Methods:

6. Location of study:

7. Medical clearance:

8. Risk(s) to participants:

9. Retrospective data review:

10. Biologic sample disposal:

11. Deception:

12. Consent:

13. Audio or visual imaging:

14. Data storage and security:

15. Signed Informed Consent Forms:

16. Benefits of participation for subjects:

17. Benefits of your study to society:

Required Signatures

Date _____Signature of Primary Investigator (PI) _____

Affirmation of Faculty Mentor:

If the Primary Investigator is a student I certify that I am the PI faculty mentor.I have reviewed this Application for Review of Human Subjects Research and, subject to the approval of the MCC Institutional Review Board, I authorize the Student Investigator to conduct this study. I agree to provide to the best of my ability continuous and responsible oversight of the student conducting the research and ensure that the study will be conducted in full compliance with the policies of MCC, the MCC Institutional Review Board, and general standards of ethical research.

Date _____Signature of Faculty Mentor _____

Date _____Signature of Division Chair _____

Affirmation of Reviewer:

I have reviewed this application for Human Subjects Research and find it to be in compliance with MCC policies, IRB policies, and ethical standards for Human Subjects Research.

Date _____Signature of Reviewer _____

Affirmation of IRB Chair:

I have reviewed this application and have taken the following action:

☐ Approved for Expedited Review

☐ Approved following Full Board Review

☐ Exempt

☐ Disapprove

Date _____Signature of IRB Chair _____

Informed Consent Form Guidelines

Informed consent is an essential part of the design for every research project involving human subjects. Researchers who involve human subjects in their research have both an ethical and legal obligation to secure the informed consent of the potential research subjects before starting their research. These guidelines are intended to assist researchers in complying with the requirements of informed consent for research involving human subjects.

For research involving legal minors, separate age-appropriate Assent forms for minors and Consent forms for parents/guardians are required and a template is available on our webpage. (See page 88-89 of this document.)

General Elements of Informed Consent

The basic elements of effective informed consent are:

A. The full disclosure of the nature of the research, with any risks and benefits, and a description of what the subjects will experience;
B. adequate information for the potential subjects to make an informed choice about participating in the research;
C. disclosure of efforts to ensure privacy and confidentiality; and
D. a guarantee of the subject's voluntary choice to participate.

Specific Elements of an Informed Consent Document

In order to assure that all of these general elements are included, an appropriate informed consent document should include the following written in a language easy for potential subjects to understand:

A. A general description of the study and its purpose or goal.
B. A description of the procedures and measures or observations involved in the study (tell them what they will experience).
C. A statement indicating how much time their participation in the study is expected to take.

D. A description of any benefits which may be reasonably expected for both the potential research subject and for society. If there is no direct benefit for subjects, you should say so.

E. A description of any foreseeable risks or discomforts to the potential research subject. This section should include information from your IRB application regarding possible stress or risks for the research subjects, information regarding personal or sensitive questions, and disclosure, if any, (of the materials to be presented might be considered offensive, threatening, or degrading).

F. An explanation as to what medical and/or mental health care services are available and contact information (the location, and phone number of the MCC Counseling Services) in cases where research involves more than minimal risk to participants.

G. Phone and email contact information for questions or concerns about the research (for each Principal Investigator and faculty mentor).

H. MCC IRB contact information for questions about research participation.

I. A description of how the confidentiality of records identifying the subject will be maintained. This section should include information from your IRB application. We strongly urge that, where possible, data be stored on campus in a secure office file. Your faculty mentor should be able to assist you with this.
You must specify the location of all documents related to the study and the person responsible for them in case these records need inspection. (Federal guidelines require that signed consent forms be kept at least 3 years following the end of the study.
You can contact the IRB to discuss storage issues. Completely de-identified data records may be kept as long as needed.

J. A statement that participation in the research is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is entitled, and that the subject has the option to discontinue participation at any time without penalty or loss of benefits.

Informed Consent Modifications & Waivers

In special situations, evaluated on a case-by-case basis, the MCC IRB may approve a consent which modifies or waives the requirement to obtain written informed consent under one or more the following conditions:

A. The research cannot practicably be carried out without the waiver; (e.g., research that must, due to its design, mislead/deceive research subjects).

B. It is research that involves no more than minimal risk to the research

subjects.

C. Subsequent to the research, the research subjects will be provided a statement (information sheet) containing the basic elements of the consent form which describe the research project.

Informed Consent Form

Research Project Title:

Researcher(s):

1. Purpose of this study:

2. Procedures and/or treatments involved:

3. Anticipated time required for participation:

4. Potential benefits:

5. Potential risks or discomforts:

6. Medical/mental health contact information (if required):

7. Contact information for researcher(s):

8. Contact information for MCC IRB:

9. Explanation of confidentiality and privacy:

10. Assurance of voluntary participation:

AFFIRMATION BY RESEARCH SUBJECT

By signing below, I voluntarily agree to participate in the above listed research project, and I understand the above listed explanations and descriptions of the research project. I also understand that there is no penalty for refusal to participate and that I may withdraw my consent and participation in this project at any time without any penalty. I acknowledge that I am at least 18 years old. I have read (or had read to me) and fully understand this Informed Consent Form. I sign it freely and voluntarily. I acknowledge that at my request a copy of this Informed Consent Form will be provided to me to keep.

Research Subject's name: _____

Date _____ Signature: _____

Request for Amendment of Active Human Subjects Research Project

Title of Project:

_____

IRB Project # (Assigned by IRB):

_____

Name of Principal Investigator(s):

_____

Email (MCC email address required): _____

_____ Phone: (____) - _____

Name of Faculty Mentor:

_____

Email (MCC email address required):

_____

Department:

_____

Campus Address:

_____

Campus Phone: (_____) - _____

Briefly describe the nature of requested amendment:

Approval of IRB Chair:

I have reviewed this amendment request and have taken the following action:

- ☐ Approved
- ☐ Approved following Full Board Review
- ☐ Disapprove

Date _____Signature of IRB Chair _____

Request for Renewal of

Active Human Subjects Research Project

Title of Project:

_____

IRB Project # (Assigned by IRB):

_____

Name of Principal Investigator(s):

_____

Email (MCC email address required): _____

_____ Phone: (_____) - _____

Name of Faculty Mentor:

_____

Email (MCC email address required):

_____

Department:

_____

Campus Address:

_____

Campus Phone: (_____) - _____

Briefly describe the nature of requested renewal:

Approval of IRB Chair:

I have reviewed this renewal request and have taken the following action:

- ☐ Approved
- ☐ Approved following Full Board Review
- ☐ Disapprove

Date _____Signature of IRB Chair _____

Request for Closure of Active Human Subjects Research Project

Title of Project:

_____

IRB Project # (Assigned by IRB):

_____

Name of Principal Investigator(s):

_____

Email (MCC email address required): _____

_____ Phone: (_____)- _____

Name of Faculty Mentor:

_____

Email (MCC email address required):

_____

Department:

_____

Campus Address:

_____

Campus Phone: (_____) - _____

Briefly describe the nature of requested amendment for closure:

Approval of IRB Chair:

I have reviewed this closure request and have taken the following action:

Date _____Signature of IRB Chair _____

TEMPLATES & CHECKLISTS

TO BE USED AS GUIDELINES

- Informed Consent/Assent Checklist
- Informed Consent Form (Template)
- Parental Consent Letter (Example)
- Informed Consent (Template) for use of Photo/Video/Media Materials

Informed Consent/Assent Checklist

McLennan Community College

	Required Elements	Comments
☐	Study/Project name	
☐	Purpose of project	
☐	Duration of subject's participation	
☐	Description of procedures	
☐	Possible risks	
☐	Possible benefits	
☐	Confidentiality statement	
☐	Voluntary consent explanation	
☐	Guarantee withdrawal statement	
☐	Contact information	
☐	Investigator's statement, signature, and date	
☐	Participant's signature and date	
	Additional elements for assent of minors or vulnerable subjects	
☐	Child/subject's assent statement if appropriate	
☐	Parent's permission statement (or responsible representative)	

Informed Consent Form (Template)

McLennan Community College

Project Name:

Investigator(s):

Provide name, phone number, and email information.

Purpose and Benefits

You are invited to participate in a research study. The purpose of this study is to investigate (here you explain the purpose of the study or as much information as you want participants to know going in). Here is also where you explain any benefits the subject will receive for participation.

Procedures

Explain what the participant should expect to do for the duration of the study. What will they be required to do? How long will it take the participant? How many participants are anticipated?

Risks and Benefits

Describe any risks, both physical and psychological (e.g. stress) that the participant may experience during or after completion of the study. If there are no risks, say so. Describe benefits to the participant and/or to the investigators or others.

Confidentiality

Describe the nature of data collection and storage in terms of confidentiality/anonymity. If personal information will be obtained, how long will it be kept and will it be linked to other data collected in the study? When will data be destroyed? Will information from the study be made public and what steps will be taken to ensure confidentiality of participant information?
E.G.: Your consent form will be separated from the questionnaire immediately upon collection. To further guarantee anonymity, no link will remain between your name and your data. Data will be stored securely and will be made available only to the persons listed above who are conducting the study. No reference will be made in oral or written reports that could link you to the study. Your confidential data may be used in future research, presentations or teaching opportunities.

Contact

If you have questions at any time about the study or the procedures, (or if you experience adverse effects as a result of participating in this study,) you may contact the faculty sponsor/investigator, Joe Smith, at joesmith@joesmith.com, or (206) 555-5555. If you have questions about your rights as a participant, contact the Institutional Review Board at ….

Participation

Your participation in this study is voluntary, you may decline to participate without penalty. It is okay to say NO. Likewise, the investigator may terminate your participation in the study at any time if they observe potential problems with your continued participation.

Withdrawal Guarantee

If you decide to participate, you may withdraw from the project at any time without penalty and without loss of benefits to which you are otherwise entitled. If you withdraw from the study before data collection is completed, your data will be project at any time. Your decision will not affect your relationship with McLennan Community College or cause a loss of benefits to which you might otherwise be entitled.

Voluntary Consent

Your signature on this form indicates that you are at least 18 years of age and have understood to your satisfaction the information regarding participation in this research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, sponsors, or involved institutions from their legal and professional responsibilities.

I have read the above information and agree to participate in this study. I have received a copy of this form.

Participant's name (print)

Participant's signature

Date

This project was approved by the McLennan Community College Institutional Review Board for Human Subject Protection on (insert date) and expires on (insert date)

Investigator's Statement

I certify that I have explained to this subject the nature and purpose of this project, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to participants and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

Investigator's name (print)

Investigator's signature

Date

(Template may be modified for minor's assent. Language must be age appropriate.)
Copies to: Participant Principal Investigator

Parental Consent Letter (Example)

McLennan Community College

Dear Parents:

I will be conducting a research project designed to study how children think and develop strategies on games. I request permission for your child to participate. The study consists of two twenty-minute sessions where children will play tic-tactoe one day and a guessing game the next day. The goals of the study are to detail the strategies of game-playing used by children of different ages and to see how thinking strategies differ in the two games.

Each child will be invited to leave the classroom to participate in this special activity, and will accompany me only if he or she is willing to do so. Any child who expresses a desire to stop the activity or to return to the classroom will be escorted back immediately. I will conduct the sessions and my assistant will video the activity. Children's responses will be reported as group results only. Taped sessions will be used as examples of scoring procedures; however, the children will not be identified by name. The videos will be reviewed by the child's teacher and may be shown at professional conferences. To preserve confidentiality, only first names will be used to identify children. In addition to the game participation, I will need to look at the school's records to obtain the child's date of birth and scores on the Iowa Tests of Basic Skills.

Your decision whether or not to allow your child to participate in the study will in no way affect your child's standing in his or her class or school. At the conclusion of the study a summary of group results will be available to all interested parents and teachers.

Should you have any questions or desire further information call me at (insert phone number).

Sincerely,

John Doe, Assistant Professor
Biology
McLennan Community College

This project was approved by the McLennan Community College Institutional Review Board for Human Subject Protection on (insert date) and expires on (insert date).

Contact Information

If you have questions at any time about the study or the procedures, (or if you experience adverse effects as a result of participating in this study,) you may contact the faculty sponsor/investigator, Joe Smith, at joesmith@joesmith.com, or (206) 555-5555. If you have questions about your rights as a participant, contact the Institutional Review Board at irb@mclenannan.edu or call ….

Parent's consent

I, _____, do hereby state that I have read the material and understand the above. I give permission for

my son or daughter, _____, to participate in this project.

Signed (parent or guardian)_____date_____

It is ethically essential that your son or daughter understand exactly what will be expected of him or her and willingly agree to participate. Your child must also understand that he or she can "call it quits" at any time. Please help explain the above project and have your son or daughter sign below if appropriate.

Subject's Assent

I, _____, voluntarily agree to play the games in this project and know that I may choose to drop out at any time.

Signed_____ Date_____

Investigator's Statement

I,_____, certify that I have explained to this subject, in age appropriate language, the nature and purpose of this project, including benefits, risks, costs, and any experimental procedures. I have described the rights and protections afforded to participants and have done nothing to pressure, coerce, or falsely entice this subject into participating. I am aware of my obligations under state and federal laws, and promise compliance. I have answered the subject's questions and have encouraged him/her to ask additional questions at any time during the course of this study. I have witnessed the above signature(s) on this consent form.

Investigator's Signature_____ Date_____

Informed Consent (Template)
For use of Photo/Video/Media Materials
McLennan Community College

Date:

Project Title:

Principle Investigator:

Phone: E-Mail Address:

Description:
The researchers would also like to take photographs or videotapes of you performing (insert activity) in order to illustrate the research in teaching, presentations, and/or or publications.

Confidentiality:
You would not be identified by name in any use of the photographs or videotapes. Even if you agree to be in the study, no photographs or videotapes will be taken of you unless you specifically agree to this. (All consent material should always advise subjects how anonymity of confidentiality will be maintained. The confidentiality statement should address how the tapes will be stored to maintain confidentiality. The form should describe how long the tapes will be stored and what will happen to the videotapes at the completion of the study.)

Voluntary Consent:
By signing below, you are granting to the researchers the right to use your likeness, image, appearance and performance - whether recorded on or transferred to videotape, film, slides, photographs - for presenting or publishing this research. No use of photos or video images will be made other than for professional presentations or publications. The researchers are unable to provide any monetary compensation for use of these materials. You can withdraw your voluntary consent at any time.
If you have any questions later on, the researchers should be able to answer them: (include the contact information for the investigators). If at any time you feel pressured to participate, or if you have any questions about your rights or this form, then you should contact the Institution Review Board at bchristian@mclennan.edu or irb@mclennan.edu

Subject's Printed Name & Signature:

Date:

Parent / Legally Authorized Representative's Printed Name & Signature:
(If applicable)

Date:

Investigator's Printed Name & Signature:

Date:

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Institutional Animal Care and Use Committee (IACUC) Procedures and Guidelines

I. Introduction

Policy

The USDA regulations (Title 9, Chapter 1, Subchapter A - Animal Welfare) require that each research facility have an Animal Care and Use Committee. McLennan Community College will be in compliance with the regulatory requirements and standards of the Animal Welfare Act. (See Appendix 1- Mission Statement)

Purpose

The purpose of this policy is to describe the responsibilities of the McLennan Community College Institutional Animal Care and Use Committee (IACUC), its membership, and its procedures for voting, review of animal use protocols, conduct of facility inspections and program reviews, for preparing minutes, for reviewing concerns regarding the care and use of teaching animals, and for providing training and/or instruction for personnel regarding the use of animals in teaching at McLennan Community College.

II. Responsibilities of the McLennan Community College Animal Care and Use Committee (IACUC)

It is the responsibility of the IACUC to ensure that the care and use of animals used in teaching is in accordance with the Animal Welfare Act and other laws, guidelines, and policies that address humane care and use of teaching animals. The IACUC is responsible for evaluating the care, treatment, housing and use of animals and for certifying compliance with the Animal Welfare Act. Specific responsibilities include:

1. Review, at least once every six months, the facility's program for the humane care and use of animals.
2. Inspect, at least once every six months, the animal facilities to include all areas where animals are used.
3. Prepare reports of evaluations and submit the reports to the Institutional Official.
4. Make recommendations to the Institutional Official regarding any aspect of the facilities, animal programs, physical plant, or personnel training.
5. Review and, if warranted, investigate concerns involving the care and use of teaching animals.
6. Review and approve, require modifications (to secure approval), or withhold approval of those components of proposed teaching procedures that relate to the care and use of animals.
7. To suspend, when warranted, teaching procedures involving animals.
8. Perform other duties as required by the Animal Welfare Act or any other regulatory agencies.

III. Membership of the Institutional Animal Care and Use Committee

The membership of the IACUC will be appointed by the Chief Executive Officer of the Institution (or designate) and will consist of the following:

1. The Chief Executive Officer of the Institution (or designate) will appoint a Chairman and at least two other Committee members. The Chairman will perform the duties outlined in *IV. Responsibilities for Committee Activities.*
2. One member will be a graduate veterinarian with training and/or experience in laboratory animal medicine and who serves as the attending veterinarian for the facility or whom the attending veterinarian designates.
3. At least one member who is not affiliated with McLennan Community College other than as a member of the committee and is not a member of the immediate family of a person who is affiliated with the facility. This member is to represent the general community interests in the proper care and treatment of teaching animals.
4. Personnel who routinely use animals in teaching.

5. The committee may include members whose primary concerns are in non-scientific areas (e.g., biostatistician, ethicist).
6. Not more than 3 members shall be from the same administrative unit of the facility.
7. Ex-officio, non-voting members may also serve on the committee.
8. Members will normally serve for a period of three years but members may serve multiple consecutive terms. In addition, members may be appointed on an as needed basis by the Chief Executive Officer of the Institution (or designate). (See Appendix 2 - Committee Membership List)

IV. Responsibilities for Committee Activities

I. Committee Chair - The duties and responsibilities of the Committee Chair are as follows:

a. Chair the meetings
b. Serve as a point of contact between the committee and instructors
c. Coordinate other activities of the committee to include facility inspections, program reviews, etc.
d. Appoint subcommittees to review employee complaints, to perform committee inspections, etc., and perform other duties per the Animal Welfare Act rules and regulations.
e. Maintain hardcopy files of minutes of the meetings, any reports generated by the committee, protocols, and correspondence to instructors.
f. Maintain copies of correspondence and reports to all regulatory agencies.
g. Perform the duties of a voting member
h. Represent the committee in communications with regulatory agencies.
i. Chair the self-assessment subcommittee
    1. Appoint self-assessment subcommittee members and consultants
    2. Oversee the coordination of the self-assessment site visits and meetings
    3. Oversee the preparation of the draft of the self-assessment report
j. Oversee personnel training programs

II. Veterinary Member - The chief responsibility of the veterinarian is to provide for the health care and welfare of the animals. The committee responsibilities of the veterinary member are as follows:

a. Consult with instructors regarding the design and implementation of their animal use proposal.
b. Review all protocol applications to assure the utilization of suitable anesthetic and analgesic agents, appropriate selection of species; proper performance of surgical procedures; and that pre- and post-surgical care is adequate.
c. Participate in providing training and instruction to personnel on humane methods of animal maintenance and use.
d. Perform other duties to fulfill federally mandated IACUC functions. (See appendices 3 through 10)

III. Scientific, Non-scientific, and Non-affiliated voting members - The duties of the voting members of the committee are as follows:

a. Thoroughly review all new, renewal, and major modification applications. The review will include assuring that:

1. The activities will be conducted in accord with USDA regulations
2. The number of animals requested are the minimum necessary for use in classes
3. The animal use avoids/minimizes discomfort/distress/pain. If pain/distress is caused, appropriate sedatives, analgesics, or anesthetics will be used. The attending veterinarian and/or the committee veterinarian has been involved in planning. Paralytics are not used without anesthesia. Animals with chronic/severe un-relievable pain will be euthanatized. The instructor has considered alternatives to procedures that may cause pain and distress to the animals and has provided a written narrative of the methods/sources used.
4. The use of animals is justified
5. The requirements for sterile surgery and pre/post operative care are met. Multiple major survival surgery is not proposed without meeting federal requirements

6. The euthanasia methods meet AVMA recommendations
7. The animal living conditions are consistent with federal standards of housing, feeding, and care
8. The personnel are appropriately qualified
9. If there are deviations from requirements, they are justified in writing

b. Participate in self-assessment visits and any other duties required to meet federally mandated requirements. (See appendix 11 - Application for Use of Animal Subjects)

IV. Ex-officio, Non-voting members - The responsibilities of the ex-officio members are to attend the regularly scheduled IACUC meetings and provide information to the voting members regarding physical plant issues, animal care and housing issues, legal issues, student body issues, etc. Ex-officio members will also participate in self-assessment site visits.

V. Secretary - The IACUC secretary will be responsible for the following:

a. Notify the principal instructors of requirements for annual reviews including third year in-depth review.

b. Prepare and distribute meeting materials to committee members prior to meetings. These meeting materials include a meeting notice, a copy of the minutes of the previous meeting, a meeting agenda, a list of all protocols scheduled for review, and copies of all new protocols.

c. Notify principal instructor of the review status (approved, deferred, etc.) of protocols

d. Draft the IACUC minutes

e. Schedule semi-annual facility inspection and program reviews. Prepare copies of the materials to be maintained by the Chairman, including minutes, reports, protocols, and correspondence to instructors.

V. Voting

1. A quorum, consisting of at least one more than half of the number of appointed, voting members, must be present before a vote can be taken on an animal-related procedure or issue. Ex-officio members and members with a conflict of interest will not be counted for a quorum.

2. Voting on the acceptability of animal use methods or other animal-related procedures will be by simple majority of those voting. Voting on the acceptability of individuals as Animal Use Supervisors will be by simple majority of those voting

3. No member may participate in the IACUC review or approval of a protocol or Animal Use Supervisor in which the member has a conflicting interest. The member, however, may provide information for clarification if requested by the IACUC.

4. Votes on animal use protocols are made according to the following guidelines:

    a. Approved - the investigator may order animals and conduct animal use as described in the application. The Secretary notifies the instructor of the approval date, the approval expiration date, the number of animals approved and the Animal Use Number assigned to the application.

    b. Approved with contingencies - the application has no major problems but the committee requires clarification on specified minor points or administrative issues. Animals may not be ordered and animal use must not be initiated until the instructor has provided the required information. The Secretary will notify the instructor in writing of the committee's requirements and requests that the application pages of the form be revised to address the requirements. This notification also includes the approval date, the approval expiration date, the number of animals approved, and the Animal Use Number assigned to the application.

c. Deferred - The committee has serious concerns with the application as it is presented; however, they feel that appropriate revisions are possible. The secretary will notify the instructor in writing of the committee's concerns and requests a revised protocol to be submitted for committee review.

d. Disapproved - the application is unacceptable and/or there is insufficient information for the IACUC to make a judgment. The Secretary will notify the instructor in writing of the committee's decision. The instructor may appeal a disapproval vote by submitting a revised application following consultation with the veterinary member of the committee and/or the Chair of the committee. The appeal should include the provision of additional evidence by the instructor or the solicitation of experts able to assist the committee in their concerns. Committee records will reflect any lack of committee unanimity.

(See appendices 11 and 15)

5. Votes on approved Animal Use Supervisors (AUS) are made according to the following guidelines:
   a. Approved - the AUS may supervise the use and care of college owned animals within the restrictions of the law and approved protocols in any course in the veterinary technology program curriculum with a current approved protocol. The Secretary notifies the AUS of the approval date and the approval expiration date.

   b. Approved with contingencies - the AUS has no major deficiencies but the committee requires that further training on specified minor points or administrative issues be undertaken by the AUS. The Secretary will notify the instructor in writing of the committee's requirements and the deadline for completing the requirements. Once these requirements have been met to the satisfaction of the IACUC, the AUS may be upgraded to Approved status.

   c. Deferred - The committee has serious concerns with the AUS applicant as presented; however, they feel that, with appropriate training and instruction, the AUS may become capable of supervising animal use in an

appropriate manner. The secretary will notify the individual in writing of the committee's concerns and delineate the training and instruction required to bring the individual to an acceptable level as an AUS.

d. Disapproved - the AUS applicant is unacceptable and/or there is insufficient information for the IACUC to make a judgment. The Secretary will notify the AUS applicant in writing of the committee's decision. The AUS applicant may appeal a disapproval vote by submitting a revised application following consultation with the veterinary member of the committee and/or the Chair of the committee. The appeal should include the provision of additional evidence by the applicant or the solicitation of experts able to assist the committee in their concerns. Committee records will reflect any lack of committee unanimity.

VI. Frequency of Meetings

The committee will meet on an as needed basis at the call of the Chair but will normally meet at semiannual intervals.

VII. Procedure for Review of Proposals for the Use of Laboratory Animals in Research, Testing, and Teaching

The United States Department of Agriculture/Animal and Plant Health Inspection Service consider the McLennan Community College Veterinary Technology Program a Research Program as defined. However, research is not performed on MCC animals. The animals are utilized in classroom and laboratory teaching applications. In these situations, animals are used as subjects for students to learn common veterinary care and nursing techniques, including venipuncture, intravenous catheterization, urinary catheterization, diagnostic sampling techniques, and other commonly performed veterinary procedures. The vast majority of procedures performed on these animals cause only minimal or transient pain or discomfort. Procedures that cause more than transient pain are performed under the direct supervision of a licensed veterinarian utilizing appropriate restraint and use of analgesics or sedatives.

From year to year, very little change occurs in the uses for animals utilized in teaching. As such, routine review of protocols as is performed in true "research" facilities is unwarranted. Once established, protocols rarely vary. When it becomes necessary to make a major modification to an established animal use protocol, it must be completely reviewed by the IACUC. Minor changes in a protocol will be reviewed and approved by the Institutional Veterinarian based on compliance with current IACUC guidelines.

Instructors teaching the course may change depending on the semester in which the course is offered. When instructors in a course change, the same procedures performed in a previous instructor's course are utilized by the current instructor. This process is verifiable because specific competencies are taught in individual courses regardless of instructor. As such, instructors who teach in the program should be examined by the IACUC for suitability to teach any and all courses rather than on a course-by-course basis. By examining the credentials and qualifications of individual instructors, the IACUC can determine whether these individuals possess appropriate knowledge and skills to safely and humanely perform various teaching techniques on MCC owned animals. In addition, the committee can determine whether these individuals are capable of carrying out accepted procedures with the animal's welfare placed foremost.

Policies on Animal Use Protocol Review

The following policies establish the basis for initial animal use protocol review, ongoing oversight of continued protocols, and policies for approval of current protocols when revisions necessitate.

1. The Institutional Veterinarian or designee will be responsible for determining which courses taught in the MCC Veterinary Technology Program incorporate animal use and thereby require review by the IACUC. Within each course, the Institutional Veterinarian or designee will assign a Principal Instructor.

2. For new applications or requests for major modifications, the Principal Instructor will submit an original "Application for the Use of Animal Subjects"

form to the IACUC Secretary at least 60 days prior to the intended start date of the course in which the animal use protocol will be used. Requests for annual renewals will be submitted using the same deadline. The Secretary will notify the instructor of the annual renewal requirements. (See IX. Frequency of Review for Previously Approved Procedures)

3. Prior to the scheduled IACUC meeting, a copy of the full form, new applications, and/or applications for major changes in approved use of animals will be distributed by the IACUC Secretary to members for review. A list of applications for annual renewals with no changes or applications with minor changes will be included with the full forms. Committee members may request a full review of any annual renewal or application for modification if there are questions regarding its approval.

4. The Secretary shall notify the Principal instructor in writing of the committee's decision to approve or withhold approval of proposals related to the care and use of animals in teaching procedures. If the IACUC decides to withhold approval of a proposed activity, the IACUC shall include in its written notification a statement describing the reasons for its decision and will give the Principal instructor an opportunity to respond in writing. (See V. Voting)

5. Reviewed protocols will be assigned an Animal Care and Use Number (ACUN). The ACUN will be included in the notice to the instructor. (See appendices 13 and 14)

6. In the event that a full committee review (new applications or applications that have been previously returned for revisions) is required outside the regularly scheduled meeting dates/deadlines, the committee may elect for a *Designated Member Review* (DMR). Justification for a DMR request must be presented to the Chair of the committee. This review will be conducted only after the Chair has determined there is adequate justification. After the Secretary has received permission from the Chair, copies of the application will be mailed to all voting committee members. All members of the committee will be given the opportunity, by polling, to request full committee review. If no member calls for full committee review, then the IACUC Chair may designate one or more qualified IACUC members to review proposed protocols and give them authority to approve, approve with contingencies,

defer, or disapprove a protocol. The designated reviewers also have the authority to request full committee review of a protocol. By agreeing to a DMR, each member of the IACUC agrees to abide by the reviewer's decision concerning a protocol.

Polling is an acceptable mechanism for providing all IACUC members with the prior opportunity to call for full review. Polling is not an approval vote on the proposed protocol. Records will be kept of each member's response to a poll to document that each member was given the opportunity to call for a full committee review.

7. In the event that a change in a protocol is required after said protocol has been reviewed and approved, the original submitter of the protocol may submit a *Request for Protocol Revision* form to the IACUC Chair. (Appendix 17) The request will be presented at the next regular meeting of the IACUC and the same procedures as for a protocol renewal will be followed. The form will state the revision(s) requested and the justification(s) for the revision. The request will receive the same committee actions as a regular protocol but will be effective only on the specific changes noted on the request. If the revision is required under emergency circumstances or the next meeting is too far in the future, the Chair of the IACUC may poll the members for the purpose of initiating a Designated Member Review. The above policies will be followed in that event.

Policies on Review and Approval of Animal Use Supervisors

The following policies establish the basis for review and approval of college staff as Animal Use Supervisors (AUS). After staff members of MCC complete the approval process, they shall be considered capable of supervising animal use in any and all IACUC approved protocols.

1. On an annual basis, the Institutional Veterinarian shall compile a list of all current faculty and staff that supervise instruction utilizing college-owned animals. These individuals will be designated as Animal Use Supervisor candidates. This list shall contain the following items for each individual:
   a. Name of faculty or staff member
   b. Title of faculty or staff member

c. Academic credentials and preparation
d. Additional information relevant to suitability for supervising animal use and welfare

2. Prior to the scheduled meeting, the list of Animal Use Supervisor candidates will be distributed to each member of the IACUC for review.

3. During the scheduled meeting, committee members will discuss the appropriateness and qualifications of each Animal Use Supervisor candidate and vote to approve or withhold approval as an Animal Use Supervisor (AUS). If accepted by the committee, each AUS will be allowed to instruct students in the program and determine appropriate animal use within the constraints of the law and approved animal use protocols. Approval status means that the Supervisor is cognizant of all relevant USDA/APHIS and IACUC policies and regulations and understands and utilizes the principles of humane animal use. This approval status in no way allows AUS's, which are non-veterinarians to determine appropriate therapy, diagnose, prescribe, or perform surgery. Ultimate responsibility for the actions of AUS's rests with the Institutional Veterinarian.

4. The Secretary shall notify each faculty/staff member, in writing, of the committee's decision regarding approval status as an AUS. If the IACUC decides to withhold approval of an AUS candidate, the IACUC shall include in its written notification a statement describing the reasons for its decision and will give the Principal instructor an opportunity to respond in writing.

5. Animal Use Supervisors will be approved for a period of up to one year, at which time they may be re-approved after review by the IACUC.

VIII. Procedures for Administrative Approvals

To efficiently serve instructors who use animals at McLennan Community College, the veterinary member of the IACUC may administratively approve minor changes in approved, current protocols, or instructor responses to committee requirements and /or contingencies. At any time, however, the veterinarian may consult the Chair or other committee members or request full committee review. Examples of requests for minor protocol changes that may be administratively approved include:

1. Use of replacement animals resulting from problems with transport or housing that makes the animal unsatisfactory for use in the approved protocol.
2. Use of small groups of additional animals to complete an approved protocol. These animals must be of the same species as originally approved. Approval to increase the number of rabbits or larger species or of animals used in a survival surgery or category "C" procedure will require the co-approval of the Chair.
3. Use of an unanticipated, repeated or additional survival surgical procedure that must be conducted quickly to prevent loss of the animal. If the additional surgeries are to become a standard part of the course, the instructor must submit a revision explaining and justifying the modifications for approval by the IACUC.
4. Protocol modification that may include:
    a. Changes in antibiotic, anesthetic, tranquilizing, or analgesic agents or regimens that are equivalent to or are more effective than the approved agents or regimens. (Use of paralyzing agents such as curare must be approved by the IACUC)
    b. Changes in technical or support personnel when the personnel are appropriately trained and qualified.
    c. Changes in teaching locations when the locations are acceptable McLennan sites.
    d. Changes in animal strains when there are no changes in humane issues and the animals are not listed as "endangered species"
    e. Changes in injection, catheterization, or incision sites consistent with previously approved sites or standard veterinary practice.
5. Review of responses to committee requirements or to contingencies if requested by the principal instructor.

A list of all administrative approvals that were given since the last committee meeting is provided to committee members at each regularly scheduled committee meeting.

IX. Frequency of Review for Previously Approved Protocols

1. All previously approved protocols will be reviewed at least once per year. The instructor will submit a completed annual renewal form to be placed on the meeting agenda. In-depth review may be required if it is determined that there are changes that may significantly affect the well being of the laboratory animals.

2. At least once every three years the committee will conduct an in-depth review of each approved protocol. The committee may require more frequent in-depth review of any application as deemed necessary. An in-depth review will require re-submission of the complete "Application for Use of Animal Subjects" form. (**See appendix 11**)

3. Protocols will be reviewed and approved for annual use regardless of the number of times a course will be offered over a year's time. For example, if the animal use protocol for a given course is approved by the committee, animal use within the course will be considered approved regardless of the number of times during a year the course is offered, within the constraints of the law and the animal use protocol for the course. In addition, any approved Animal Use Supervisor will be allowed to oversee animal use within the approved course.

X. Inactivation and Suspension of Ongoing Teaching Procedures Involving Animals

A. Inactivation of Ongoing Teaching Procedures Involving Animals

1. Coursework that involves the use of animals may be immediately interrupted by the attending veterinarian or his designate if the veterinarian has concerns regarding the humane care and use of animals. The veterinarian will promptly notify the Chair of the committee and the principal instructor of the animal use interruption and explain the concerns. In the event the principal instructor cannot be contacted, the veterinarian will use his best judgment to provide

care for the animals, which may include euthanasia. The veterinarian's concerns must be satisfactorily addressed prior to reactivation of the use of animals in the course. The committee will be informed of the inactivation procedure at the next committee meeting.

2. Animal use studies will be inactivated by the Chair if the principal instructor neglects to submit the protocol to the committee for annual renewal. This will occur automatically on the committee approval expiration date. The protocol will be reactivated only after appropriate review procedures have taken place.

B. Suspension of Ongoing Teaching Procedures Involving Animals

1. The IACUC may suspend an activity that it previously approved if it determines that the activity is not being conducted in accordance with the description of the approved activity (including assurance statements provided by the principal instructor).

2. The IACUC may suspend an ongoing activity only after a review of the matter at a convened meeting with a suspension vote of a majority of the quorum present.

3. If the IACUC suspends an activity, the Institutional Official shall review the reasons for suspensions, take appropriate corrective action, and report that action with a full explanation to the USDA. (**See appendix 16**)

XI. Facility Inspection and Program Review

1. The IACUC shall review at least once every six months the program for humane care and use of animals and shall inspect at least once every six months the animal facilities including teaching areas. The McLennan Community College Self Assessment Program will be coordinated through the Chair and Secretary. The Chair will assure that a period of not longer than six months will lapse between site visits. The USDA regulations (Title 9,

Chapter 1, Subchapter A - Animal Welfare) and the *Guide* will be used as the basis for these evaluations.

2. The program review and facility inspection shall be conducted by a subcommittee comprised of at least two IACUC members provided that no IACUC member may be excluded if such member wishes to participate in such evaluations. The self assessment subcommittee will meet immediately following the program review and facility inspection to summarize the findings of the inspection. Based on the summary, the subcommittee will make recommendations for the preparation of the report to be presented in full at the next IACUC meeting for full committee approval.

3. This report must contain a description of the nature and extent of the research facility's adherence to the Animal Welfare Act.

4. This report will include a description of deficiencies and must distinguish significant deficiencies from minor deficiencies. A significant deficiency is one, which in the judgment of the IACUC may be a threat to the health and/or safety of the animals.

5. If program or facility deficiencies are noted, the report must contain a reasonable and specific plan and schedule with dates for correcting such deficiency.
6. The final report shall be signed by a majority of the IACUC members and must include any minority views. The final, signed report will be forwarded to the Institutional Official. A copy will be maintained by the Chair.

7. The IACUC will notify instructors of minor deficiencies noted within areas under the instructor's supervision. The IACUC will request that corrective action be instituted according to schedules and dates determined by the committee to be reasonable. Significant deficiencies will be reported to and handled by the IACUC Chair, who will inform the Institutional Official. Copies of notifications and reports of corrective action will be maintained

by the IACUC. Subcommittee members may revisit areas in which deficiencies were noted to assure the corrective actions are satisfactory.

XII. Committee Minutes

IACUC minutes will be prepared following each meeting. The minutes will include a record of the deliberations of the meeting and all approved protocols (including the assigned ACUN) and Animal Use Supervisors. The minutes will be distributed to all members for review and any requisite changes will be made. A copy of the IACUC minutes will be forwarded to the Institutional Official (or his designate).

XIII. Procedure for Concerns Involving the Care and Use of Animals

1. The IACUC will review, and if warranted, investigate complaints involving the care and use of animals in the animal facility. Such complaints may result from public concerns or from reports of noncompliance received from the facility personnel, employees, or students. If a complaint is received by the IACUC, the committee Chair is promptly notified.

2. The concern may be reviewed by the IACUC or by a subcommittee appointed by the Chair.

3. If warranted, suspension of animal use activity will be carried out following the procedures described in Section X.B of this document.

4. The IACUC recommendations regarding the complaint will be documented and a copy will be maintained on file for review by USDA inspectors. If the IACUC determines that corrective action is required, it will notify the Institutional Official in writing and will maintain a record of any corrective action that is taken. (See appendix 16)

Index of Appendices

Appendix 1

MISSION STATEMENT

INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE

The goal of the Institutional Animal Care and Use Committee (IACUC) is to provide quality care and use in all areas involving warm-blooded mammals used for teaching at McLennan Community College (Institution). In order to achieve these goals, the following statement of responsibilities has been developed.

The Institution is responsible for assuring regulatory, funding and accrediting agencies that the Institutional animal care and use program is consistent with all federal, state, local, and Institutional requirements. The animal care and use program includes all aspects of the care and use of animals for teaching purposes. Responsibility and authority for conducting the Institutional animal care and use program is delegated by the Institutional chief administrative officer to the IACUC and Institutional veterinary medical staff. The IACUC as an agent of the Institution has the following responsibilities:

1. To review, and approve or disapprove, all warm-blooded mammal use in teaching at the Institution including the justification for animal use, and to carry out other responsibilities as outlined in the Animal Welfare Regulations (AWR's).

2. To monitor all the Institutional animal facilities and programs, and to report and correct deficiencies in these areas according to the AWR's.

3. To ensure that all personnel involved in the care and use of warm-blooded mammals at the Institution are qualified to perform their duties. This is fulfilled by providing appropriate training and instruction to these personnel.

4. To assure that adequate veterinary care is provided within the Institution.

5. To review and investigate concerns regarding animal care and use.

6. To maintain records and provide reports as required by regulation.

As an agent of the Institute and the IACUC, the attending (Institutional) veterinarian is charged with providing veterinary care and animal care as required by regulatory, funding, and accrediting agents. The attending veterinarian is responsible for:

1. Establishing and conducting a veterinary care program that includes:
   a. Appropriate facilities, personnel, equipment, and services.
   b. Appropriate methods to prevent, control, diagnose, and treat diseases and injuries; and program of emergency, weekend, and holiday care.
   c. Guidance to personnel regarding animal care and use to include anesthesia, analgesia, and euthanasia: and appropriate pre- and post- procedural care.
2. Establishing and providing an animal care program that includes:
   a. Living conditions appropriate to the species.
   b. Daily observation of all animals.

Principal instructors are responsible for compliance with all federal, state, local, and Institutional laws and /or guidelines concerning:

1. The use of animals in teaching.
2. Efforts to minimize animal pain and distress.
3. Training of any personnel or students handling animals.
4. Consideration of alternatives to animal use in teaching and utilization of procedures to minimize pain and distress in all warm-blooded mammals.

The principal instructor is directly responsible to the IACUC in the above matters, according to the AWR's. The principal instructor is directly responsible to the IACUC for all personnel and students involved in the instructor's course protocols.

Appendix 2

VTHT

Institutional Animal Care and Use Committee Members

2018-2019

Ronald Chmielewski	rchmielewski@mclennan.edu	MCC Co-Program Director, Agricultural Science
Stephanie Randell	srandell@mclennan.edu	MCC Biology Professor
Dennis Clark, DVM	dclark@mclennan.edu	MCC Veterinary Technology Program Veterinarian, Associate Professor
Laurel Schrawder, LVT	lschrawder@mclennan.edu	MCC Veterinary Technology Program Instructor
Julie Brannen, DVM	julie slayden@att.net	Public Veterinarian, Hewitt Veterinary Clinic
Sue Allen, LVT	suallen@mclennan.edu	MCC Veterinary Technology Program Director/Instructor
Alicia Matthews, LVT	amatthews1083@gmail.com	MCC Veterinary Technology, Adjunct Instructor
Wes Allison	wes@hotfair.com 717-0429	Public member, Executive Director, Extraco Events Center
Glynnis Gaines, MSHS	ggaines@mclennan.edu	MCC Dean of Health Professions
Fred Hills, PhD	fhills@mclennan.edu	MCC VP of Instruction
Drew Canham, PhD, JD	dcanham@mclennan.edu	MCC VP of Student Success
G. W. Willis, PhD	GW_Willis@Baylor.edu	Public member, Professor Information Systems Department, Hankamer School of Business, Baylor University

Appendix 3

Institutional Statement of Animal Care and Husbandry

1. Each animal (rabbits and larger) will have an individual record to include animal care, history, and treatments administered. Animals smaller than rabbits will be identified by box number.
2. The Attending Veterinarian will be responsible for oversight of all animal care. Students in the program will provide daily care for all animals under supervision of the staff.
3. Animals will be fed a commercial diet appropriate for the species at a frequency of once or twice daily unless a procedure to be performed dictates otherwise. Food will be provided in receptacles that are accessible to all animals in a cage or pen and placed so as to minimize contamination. Food receptacles will be easily cleaned and sanitized, and those functions will be performed on a schedule that meets USDA Regulation requirements.
4. Animals will have access to clean, fresh water at all times unless a procedure to be performed dictates otherwise.
5. Animals will be housed in cages or other facilities that conform to USDA guidelines.
6. All animals must have fully completed USDA Acquisition and Disposal Forms. All forms and records will be kept for a period of 5 years after the animal has left MCC.

Appendix 4

Emergency, Weekend, and Holiday Care

1. Each faculty and staff member will rotate "on-call" or weekend responsibility. This responsibility includes the direction of student assistants and part-time staff hired by the college for the care of animals.
2. The "on-call" staff member will be available to the part-time (weekend) staff by telephone during a specific time for consultation. The staff member will be available by telephone or pager at other times. If necessary, the "on-call" staff member will perform the duties of the part-time staff if they are unavailable, will come to campus to personally examine a serious animal condition, or can correct animal care situations on an as needed basis.
3. The institutional veterinarian will be available by cell phone for consultation and treatment of animals. If the institutional veterinarian will be unavailable (planned absence), specific instructions will be provided using the emergency procedure developed by the Program Director.
4. Emergency care will be provided by the Veterinary Technology staff. In the event that the institutional veterinarian is not available, private practitioners will be utilized for care of MCC animals.
5. Weekend care will be the responsibility of student workers and will be in the same manner as weekday animal care and husbandry. The MCC staff will supervise student workers.
6. Holiday care will be the responsibility of student workers and will be in the same manner as weekday animal care and husbandry. The MCC staff will supervise student workers.

Emergency Procedure

1. In cases of serious or profound illness to a MCC animal, the institutional veterinarian should be contacted immediately.
2. **In the event that the institutional veterinarian is unavailable**, all small animal emergencies will be transported to an appropriate veterinary facility for medical care.

3 Emergency procedures, names, and telephone numbers will be prominently posted.

Appendix 5

Statement of Veterinary Care

1. All animals (rabbits and larger) must have fully completed USDA Acquisition and Disposal Forms. All forms and records will be filed and kept for a period of 5 years after the animal has left MCC.

2. Each animal (rabbits and larger) will have an individual record to include animal care, history, and treatments administered.

3. The institutional veterinarian will be responsible for oversight of all veterinary care.

4. All animals will be observed on a daily basis for signs of illness, injury, or abnormal behavior by a person trained to recognize such signs.

5. Unexpected deaths and signs of illness, distress, or other deviations from normal should be reported promptly to ensure appropriate and timely delivery of veterinary medical care.

6. Animals showing signs of a contagious disease will be isolated from healthy animals.

7. Methods of disease prevention, diagnosis, and therapy will be those currently accepted in veterinary practice.

8. The institutional veterinarian will have access to all animals for evaluation of their health and well-being.

9. The institutional veterinarian will have the authority to oversee the adequacy of other aspects of animal care and use, including animal husbandry and nutrition, sanitation practices, zoonosis control, and hazard containment.

Appendix 6

Policy on Animals Born at the Facility

1. Animals born at the facility (rabbits and larger) will receive individual identification numbers within 3 days of birth.

2. Animals born at the facility (rabbits and larger) will fall under the same regulations as animals that are procured by the usual methods.

Appendix 7

POLICY ON SPACE REQUIREMENTS FOR HOUSING ANIMALS

1. Primary enclosures (PE) will allow for the normal physiologic and behavioral needs of the animals, including urination and defecation, maintenance of body temperature, normal movement and postural adjustments.
2. PE will allow animals to remain clean and dry as consistent with the requirements of the species.
3. PE will allow adequate ventilation.
4. PE will allow the animals easy access to food and water and permit easy filling, refilling, changing, servicing, and cleaning of food and water utensils.
5. PE will provide a secure environment that does not allow escape of or accidental entrapment of animals or their appendages between opposing surfaces or by structural openings.
6. PE will be free of sharp edges or projections that could cause injury to the animals.
7. PE will allow observation of the animals with minimal disturbance of them.
8. PE will be constructed of materials that balance the needs of the animal with the ability to provide for sanitation.
9. PE will be kept in good repair to prevent escape of or injury to animals, promote physical comfort, and facilitate sanitation and servicing.
10. Outdoor PE will provide protection from extremes in temperature or other harsh weather conditions.
11. Outdoor PE will provide adequate security via perimeter fence or other means and allow grouping of compatible animals.
12. PE will be of a size published in the tables found in the *Guide for the Care and Use of Laboratory Animals,* National Research Council.

Appendix 7 (Cont)

Recommended Space for Rabbits, Cats, and Dogs (from the *Guide for the Care and Use of Laboratory Animals*, Table 2.2, page 28)

Animals	Weight , kg	Floor Area/Animal, ft^2	Height, in
Rabbits	<2	1.5	14
	Up to 4	3.0	14
	Up to 5.4	4.0	14
	>5.4	≥5.0	14
Cats	≤4	3.0	24
	>4	≥4.0	24
Dogs	<15	8.0	---
	Up to 30	12.0	---
	>30	≥24.0	---

Recommended Space for Commonly used Farm Animals (from the *Guide for the Care and Use of Laboratory Animals*, Table 2.3, page 30)

Animals/Enclosure	Weight, kg	Floor Area/Animal, ft^2
Sheep and Goats		
1	<25	10.0
	Up to 50	15.0
	>50	20.0
2-5	<25	8.5
	Up to 50	12.5
	>50	17.0
>5	<25	7.5
	Up to 50	11.3
	>50	15.0
Swine		
1	<15	8.0
	Up to 25	12.0
	Up to 50	15.0
	Up to 100	24.0
	Up to 200	48.0
	>200	60.0
2-5	<25	6.0
	Up to 50	10.0
	Up to 100	20.0
	Up to 200	40.0
	>200	52.0
>5	<25	6.0
	Up to 50	9.0
	Up to 100	18.0
	Up to 200	36.0
	>200	≥48.0
Cattle		
1	<75	24.0
	Up to 200	48.0
	Up to 350	72.0
	Up to 500	96.0
	Up to 650	124.0
	>650	≥144.0
2-5	<75	20.0
	Up to 200	40.0
	Up to 350	60.0
	Up to 500	80.0
	Up to 650	105.0
	>650	≥120.0
>5	<75	18.0
	Up to 200	36.0
	Up to 350	54.0
	Up to 500	72.0
	Up to 650	93.0

	>650	≥108.0
Horses	----	144.0

Appendix 8

McLennan Community Veterinary Technology Program

POLICY ON THE USE OF OUT OF DATE DRUGS, FLUIDS AND CHEMICALS FOR ANIMAL TREATMENT AND EXPERIMENTATION

1. The USDA, Public Health Service, and AAALAC expect that out of date drugs will not be used for animal therapy and experimentation involving survival procedures. This view is upheld by an internal document of the USDA, which states that use of outdated drugs in animals is contrary to sound veterinary medical practice.
2. For survival procedures, drugs, fluids, and chemicals that exceed the expiration date on the container must not be used, unless the manufacturer provides documentation of efficacy and safety in writing.
3. Out of date drugs, fluids, and chemicals that exceed the expiration date by not longer than six months may be used in animals for non-survival procedures. Materials more than six months past the expiration date may be used if the manufacturer provides documentation of efficacy and safety in writing. Out of date materials must be stored separate from other materials and clearly labeled.
4. Periodically, the McLennan Community College IACUC and/or Vet Tech personnel will check the Veterinary Technology Program stocks in animal procedural areas to assure adherence to this Policy. Also, such drugs will be checked during semi-annual IACUC self-assessment reviews.

Appendix 9

Policy on Post-Surgical Care of Animal Subjects

1. Post-procedural care will be monitored by the institutional veterinarian or other qualified personnel.

2. During the anesthetic-recovery period, animals will be kept in a clean, dry area where frequent observation by trained personnel is possible.

3. Attention will be given to thermoregulation, cardiovascular and respiratory function, and post-operative pain or discomfort. Additional care will be at the discretion of the institutional veterinarian.

4. Animals will be monitored at least until they can maintain thermoregulation and are capable of maintaining sternal recumbency.

Appendix 10

Policy on Number of Procedures per Animal Subject

Multiple Survival Surgery: Only one surgery will be performed on an animal unless additional surgeries are deemed medically necessary by the attending veterinarian for the health or well being of an animal.

Multiple Anesthetic Events: An individual animal will undergo a maximum of one anesthetic event per week unless deemed medically necessary by the attending veterinarian for the health or well being of an animal. An individual animal will undergo a maximum of ten anesthetic events per year.

Basic Procedures: The following procedures will be restricted on an individual animal as follows unless deemed medically necessary by the attending veterinarian for the health or well being of an animal:

Venipuncture:	Maximum of 5 times per week
Injections (IM or SQ):	Maximum of 10 times per week
Urinary Catheterization:	Maximum of 2 times per week
Cystocentesis:	Maximum of 2 times per week
Blood Collection:	Maximum of 1% of body weight every 2 weeks

Appendix 11

Application For Use Of Animal Subjects

McLennan Community College

Principal Instructor: _____

Course Title: _____

Course Duration Dates: Begin: _____ End: _____

This application is (mark the description that best fits):

___ New
___ Renewal/Continuation of Protocol No._____ Addendum to Protocol No._____

INSTRUCTOR'S ASSURANCE STATEMENT

I certify that I have truthfully and completely described the use of animals for this course and that I will notify the Institutional Animal Care and Use Committee in Writing of any changes in this information prior to proceeding with the animal use. Furthermore, the activities I plan do not unnecessarily duplicate previous animal use.

As a Principal Instructor, I accept and will conform to all federal, state, and institutional laws or guidelines concerning: the care and use of animals in teaching; efforts to minimize animal pain and distress; training of any assistant personnel or students handling animals as described herein; and consideration of alternative to animal use in teaching.

_____ _____ _____
Signature Date Phone Number

CO-INSTRUCTOR(S) ASSURANCE

I understand that my name is listed on this project as co-instructor. I have read this application and understand that only the described procedures are to be conducted.

Name	Signature	Phone Number
_____	_____	_____
_____	_____	_____
_____	_____	_____

DIVISION DEAN ASSURANCE

I understand that responsibility for assessing the quality of animal use in teaching must be shared by both the department and the IACUC. My signature as Department Director certifies that the proposed course has been reviewed for merit.

_____	_____	_____
Signature	Date	Phone Number

1. What are the goals of the course/ Describe the potential benefits of the course.

2. Provide the following information:

Species #1:	Sex:	Size or Age:
Species #2:	Sex:	Size or Age:
Species #3:	Sex:	Size or Age:

3. List the number of animals of each species to be used per procedure category per year.

PROCEDURE CATEGORY A - Procedures will produce minimal, transient, or no pain/distress (e.g. minor injections or collections).

Species	Year 1	Year 2	Year 3

PROCEDURE CATEGORY B - Procedures that cause pain, distress, or discomfort will be relieved by anesthetics, analgesics, or tranquilizers (surgery, trauma, tissue collections).

Species	Year 1	Year 2	Year 3

PROCEDURE CATEGORY C – Procedures that may produce pain/distress which will not be relieved by anesthetics, analgesics, or tranquilizers.

Species	Year 1	Year 2	Year 3

4. Discuss your basis for determining the number of animals needed for each year of the course.

5. Describe why animals must be used in the proposed course. What alternatives to the use of animals have been considered?

6. Discuss physiologic, anatomic, or other (literature, personal experience, etc.) features that were considered when selecting these species for the course.

COMPLETE ITEMS 7 THROUGH 22 FOR EACH SPECIES TO BE USED

7. Describe all non-surgical procedures to be performed.

8. Describe non-survival and/or survival surgical procedures. Include in your description the anticipated duration of the anesthetic period.

9. Pre-operative health status will be determined by evaluating (circle all that apply):

Activity level	General physical condition	Body temperature
Heart rate	Respiratory rate	Body weight

10. List all pre-operative medication(s), dose (mg/kg body weight), route, and frequency.

a.
b.
c.

11. List anesthetic agents, dose (mg/kg body weight), route, and frequency.

a.
b.
c.

12. List paralyzing drugs, dose (mg/kg body weight), route, and frequency. If paralyzing drugs are to be used, describe measures to ensure adequate levels of anesthesia are maintained while animals are paralyzed.

13. If animals will regain consciousness following surgery, describe observations that will assure the animals are stable. Animals must be monitored until they regain the ability to control head movement and maintain sternal recumbency.

14. During post-surgical recovery, describe observation frequency and management of expected clinically significant, adverse effects.

15. Postoperative pain/distress will be determined by evaluating (circle all that apply):

Body Weight Unprovoked behavior Respiratory/heart rate Other clinical signs

Appearance Body temperature Behavior responses to external stimuli (e.g. palpation)

16. List all postoperative medications, dose (mg/kg body weight), route, and frequency.

a.
b.
c.

17. If individual animals will be subjected to major multiple survival surgical procedures, explain and justify the necessity for this requirement.

18. Describe the methods used to search for alternatives to procedures that might cause more than slight pain or distress (i.e. category "b" or "c" procedures).

19. If un-anesthetized animals will be subjected to prolonged physical restraint, provide the following information:

a. Indicate the duration of restraint.

b. Explain rationale for restraining animal longer than one hour.

c. Describe the restraint device.

d. Indicate the number of observations per restraint period.

e. Describe the method(s) to be used for acclimation to restraint.

20. Will animals be subjected to procedures involving pain/distress without pain/distress medication (i.e. category "c" procedures)? If yes, describe all procedures thoroughly.

21. Describe the method of euthanasia to be used. If indictable drugs are used, list the name, dosage, and route of administration. If un-anesthetized or un-sedated animals will be euthanized by decapitation, cervical dislocation, or stunning, a written justification must be provided.

22. List the facilities to be used for animal use.

a. Non-surgical and non-survival surgical procedures _____
b. Survival surgery _____
c. Post-surgical care _____

Discuss any special animal housing requirements that may be required.

23. Will hazardous materials and/or infectious agents (irradiation, radio nuclides, mutagens, teratogens, toxic materials, infectious organisms) be used? If yes, complete the following:

a. Describe the hazardous agents and precautions that will be used to protect persons and animals.

b. Describe the method to be used for carcass disposal.

c. If carcinogens are used, list name, dose, route, and frequency.

24. In accordance with Federal Regulations, provide for all non-student participants a summary of their training, experience and skills in the care and use of animals and the techniques to be employed in this study.

NAME	TITLE	YEARS EXP. IN PROCEDURE	SPECIFIC ROLE IN COURSE

Appendix 12

NOTIFICATION OF ANNUAL ANIMAL USE PROTOCOL REVIEW

Principle Instructor: Title:

Previously Assigned ACUN:

Previous Approval Date: Approval Expiration Date:

Federal regulations require that the IACUC conduct annual reviews of applications that require the use of animal subjects. IACUC approval for the use of animal subjects as described in the above referenced application will expire soon. Please answer the following questions, sign, and return this form to the Chairman of the IACUC by **(DATE)** so that your response may be considered at the **(DATE)** Committee meeting.

1. Should the request to use animals remain active? Yes_____ No_____
   If No, you need not answer the remaining questions. Sign this form and return it to the IACUC Chairman.
   If Yes, review your Application for Use of Animal Subjects form including any amendments or modifications and answer the following questions.

2. Have there been unexpected complications with the animals (physical, behavioral, etc.) since the last IACUC review? Yes_____ No_____

3. Are there any changes in:
   a. the number of species of animals used? Yes_____ No_____
   b. the location where animal use is conducted? Yes_____ No_____
   c. the experimental or surgical procedures? Yes_____ No_____
   d. the anesthetics, analgesics, or tranquilizers used? Yes_____ No_____
   e. the animal restraint procedures or duration of restraint? Yes_____ No_____
   f. the method of euthanasia? Yes_____ No_____
   g. any methods that could impact on the humane care or use of the animals? Yes_____ No_____

4. Attach a list of all MCC employees directly handling animals in the protocol.

If you answered Yes to question 2 or 3, describe the complications or changes in detail on a separate page and attach it to this form. (Substantial changes or the addition of new species requires completion of a new Application for Use of Animal Subjects form for each species.) If you have any questions, call the IACUC Chairman.

Principle Instructor Signature _____ Date _____

(FOR COMMITTEE USE ONLY)
Date received by the IACUC _____ Assigned ACUN _____

Committee Action	Date	Committee Action	Date
Approved	_____	Deferred	_____
Approved Contingent	_____	Disapproved	_____

Signature of Institutional Representative _____

Appendix 13

Annual Animal Research Protocol Review Form

Application for Review

Appendix 14

MEMORANDUM

TO: Instructors Who Use Animals in Research or Teaching

FROM: McLennan Community College IACUC

SUBJ: **Notification of Scheduled Animal Use Protocol Review**

Principle Instructor:

Title:

Previously Assigned ACUN:

Previous Approval Date

Approval Expiration Date:

Last Full Form Review Date:

Federal regulations require that the IACUC conduct annual reviews of applications that describe the use of animal subjects. IACUC approval for the use of animal subjects as described in the above referenced application will expire soon. The IACUC requires that a full form that describes all animal uses for this application be submitted at least once every three years. Your application for the above referenced study is scheduled for a full review. If you wish to continue this study, please complete the attached "Application Form" by **(DATE)**, so that it may be considered at the **(DATE)** Committee meeting.

Note: All new applications, competitive renewals, or requests for substantial changes to previously approved studies require the submission of a full form regardless of the 3 year review schedule.

** If this request to use animals should **not** be renewed, please sign this form and return it to IACUC.

Principal Instructor Signature _____ Date _____

Appendix 15

GUIDELINES ON SANCTIONS

The Institutional Animal Care and Use Committee (IACUC) is charged with the responsibility to oversee animal research at the Veterinary Technology Program of McLennan Community College. This responsibility includes ensuring that all animal use complies with applicable PHS, USDA, State, Federal, and Institutional regulations, requirements and guidelines. Instructors who conduct animal use not in compliance with these regulations, requirements and guidelines may face sanctions up to and including loss of animal use privileges.

Violations, or deficiencies, as determined by the IACUC Chair, may be termed "significant" or "minor" deficiencies. It is not possible to list significant deficiencies exhaustively, but in general they are defined as: (1) Activities that pose a threat to the safety and health of animals, (2) Conducting animal-related activities without appropriate IACUC review and approval, (3) Failure of animal care and use personnel to adhere to IACUC reviewed and approved institutional policies and procedures. Other less significant deficiencies are termed "minor."

Significant deficiencies result in a probation period as determined by the IACUC during which the instructor will be subject to spot inspections by the Self Assessment Team of the IACUC, and/or other inspections as directed by the IACUC. The Dean of the Division, the Vice-President for Academic and Student Affairs, and the President of the college will be notified of violations resulting in probation.

If the deficiency(s) is not resolved at the end of the probationary period, the violation(s) will be considered as a repetitive and/or willful significant deficiency(s). It is not necessary to fail a probation period to have a violation classified as a willful significant deficiency.

Repetitive and/or willful significant deficiencies will be considered individually by the IACUC. These deficiencies may result in termination of animal use privileges by the instructor or other actions as determined by the IACUC and Institutional Administration.

Appendix 16

POLICY ON REPORTING DEFICIENCIES IN ANIMAL CARE AND TREATMENT

The Institutional Animal Care and Use Committee (IACUC) has the responsibility of reviewing, and when warranted, investigating complaints involving the care and use of research and teaching animals at the Veterinary Technology Program of McLennan Community College, whether such complaints are received from the public or from College personnel or employees. The Director of the Veterinary Technology Program also serves as the Chairman of the IACUC.

Complaints concerning the misuse or abuse of research animals may be made to the Director of the Veterinary Technology Program either verbally or in writing. If the complaint is directed against the Veterinary Technology Program, the complaint should be made to the Dean of Workforce Education.

If warranted, the Chairman of the IACUC will appoint a sub-committee of members of the IACUC to complete an internal review, and pursue an investigation of the complaint. An individual who is the subject of a complaint will be notified in writing of the specific nature of the complaint, and will be given an opportunity to comment, either verbally or in writing, concerning the complaint. Once the investigation is complete, the sub-committee will present the results of its investigation to the IACUC for consideration. The Chairman of the IACUC will notify the individual who is the subject of the complaint of the results of the IACUC's investigation and determinations concerning corrective actions.

The IACUC will maintain a file documenting the complaint, the review, investigation, and corrective action. The complainant will be notified that action has been taken at the conclusion of the investigation.

No College employee, IACUC member, laboratory personnel, or other complainant will be discriminated against or be subject to any reprisal for reporting complaints concerning misuse or abuse of research animals.

Appendix 17

Request for Protocol Revision

To: **MCC Animal Care and Use Committee**

From: _____

ACUN: _____

Previous Approval Date: _____

Approval Expiration Date: _____

In the space below, describe the revisions to the protocol and justify the revisions. Include any pertinent information that the IACUC may need.

_____

_____

_____

_____

_____

_____

_____

IACUC USE ONLY

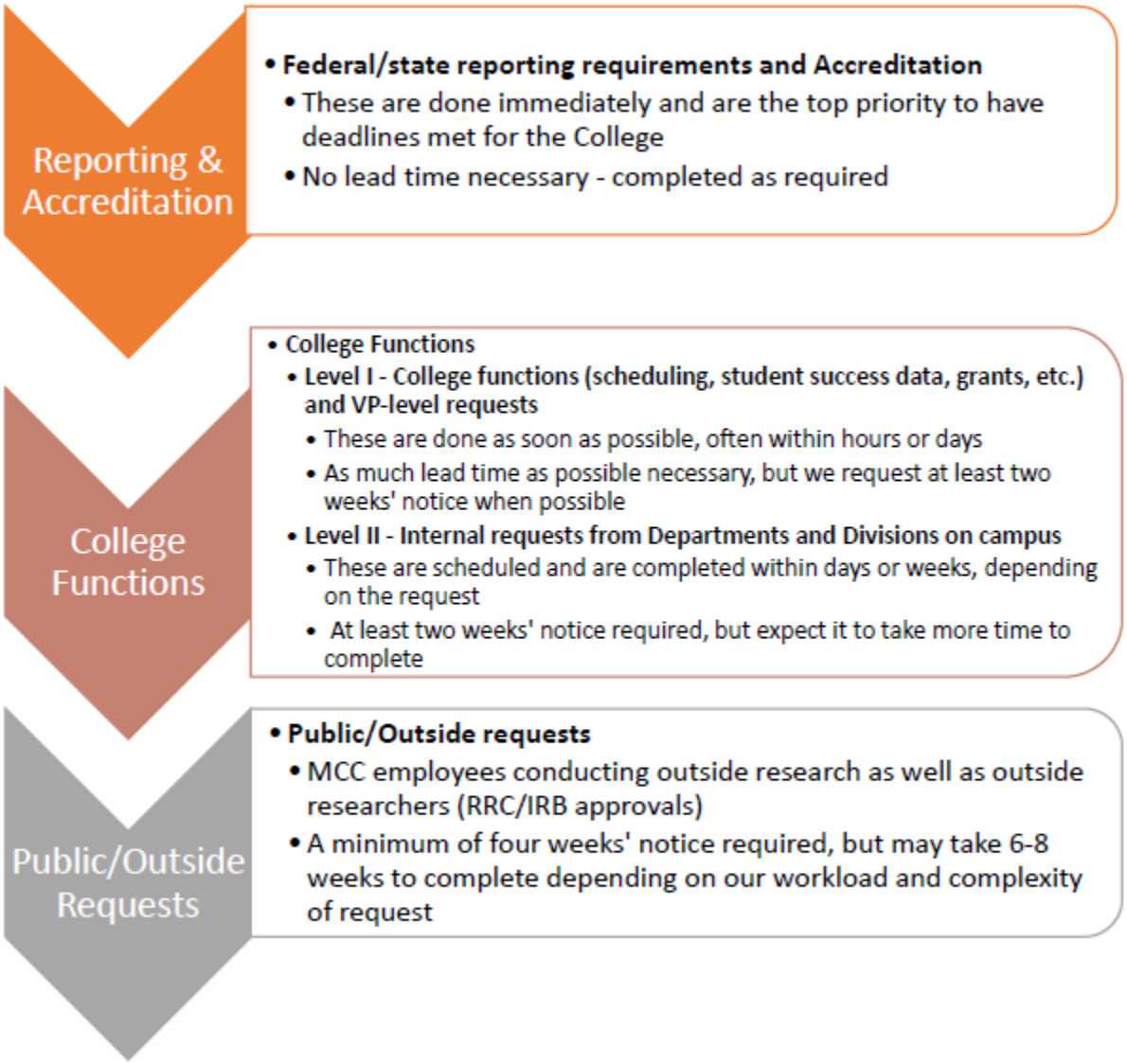
Date received by IACUC _____

Committee Action	**Date**
Approved	_____
Approved Contingent	_____
Deferred	_____
Disapproved	_____

Signature of Committee Chair _____

** Minority opinions will be listed on a separate page if they are present

MCC IR Office Priority List for Requests



Notes: