

Faculty, Staff, and Student Guide to Research Involving Human Subjects

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I. HISTORY OF THE HUMAN SUBJECTS PROTECTION SYSTEM

The modern story of human subjects protections begins with the *Nuremberg Code*, developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis. The *Code* captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects. The first provision of the *Code* states that "the voluntary consent of the human subject is absolutely essential." Freely given consent to participation in research is thus the cornerstone of ethical experimentation involving human subjects. The *Code* further provides the details implied by such a requirement: capacity to consent, freedom from coercion, and comprehension of the risks and benefits involved. Other provisions require the minimization of risk and harm, a favorable risk/benefit ratio, qualified investigators using appropriate research designs, and freedom for the subject to withdraw at any time. Similar recommendations were made by the World Medical Association in its *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects*, first adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, and subsequently revised by the 29th World Medical Assembly, Tokyo, Japan, 1975, and by the 41st World Medical Assembly, Hong Kong, 1989. The Declaration of Helsinki further distinguishes **therapeutic** from **nontherapeutic** research.

In the United States, regulations protecting human subjects first became effective on May 30, 1974. Promulgated by the Department of Health, Education and Welfare (DHEW),

those regulations raised to regulatory status NIH's Policies for the Protection of Human Subjects, which were first issued in 1966. These regulations established the Institutional Review Board as one mechanism through which human subjects would be protected.

In July of 1974, the passage of the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The Commission met from 1974 to 1978. In keeping with its charge, the Commission issued reports and recommendations identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and recommending guidelines to ensure that research is conducted in accordance with those principles. The Commission also recommended DHEW administrative action to require that the guidelines apply to research conducted or supported by DHEW. The Commission's report that sets forth the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects is titled *The [Belmont Report](#)*, and is discussed in depth below.

In 1981, in response to the Commission's reports and recommendations, both the Department of Health and Human Services (DHHS, formerly DHEW) and the Federal Drug Agency (FDA) promulgated significant revisions of their human subjects regulations. As Levine (1986) points out, these revisions "do not alter the general principles of IRB review as they had evolved over the preceding three decades. Rather, they are concerned with some of the details of what the IRB is expected to accomplish and some of the procedures it must follow" [p. 324].

The DHHS regulations are codified at Title 45 Part 46 of the Code of Federal Regulations. Those "basic" regulations became final on January 16, 1981, and were revised effective March 4, 1983, and June 18, 1991. The June 18, 1991, revision involved the adoption of the Federal Policy for the Protection of Human Subjects. The Federal Policy (or "Common Rule," as it is sometimes called) was promulgated by the 16 federal agencies that conduct, support, or otherwise regulate human subjects research; the FDA also adopted certain of its provisions. As is implied by its title, the Federal Policy is designed to make uniform the human subjects protection system in all relevant federal agencies and departments.

Additional protections for various vulnerable populations have been adopted by DHHS, as follows:

Subpart B, "Additional Protections Pertaining to Research, Development, and Related Activities Involving Fetuses, Pregnant Women and Human in Vitro Fertilization" became final on August 8, 1975, and was revised effective January 11, 1978, and November 3, 1978.

Subpart C, "Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects" became final on November 16, 1978.

Subpart D, "Additional Protections for Children Involved as Subjects in Research" became final on March 8, 1983, and was revised for a technical amendment on June 18, 1991.

FDA regulations on the protection of human subjects are codified at Title 21 Parts 50 and 56 of the Code of Federal Regulations. Part 50, which sets forth the requirements for

informed consent, became final on May 30, 1980, and was revised effective January 27, 1981, March 3, 1989, and June 18, 1991. Subpart C, which provides special protections for prisoners, was adopted on July 7, 1981; the effective date of Subpart C has been stayed until further notice. Part 56, which sets forth the provisions for institutional review boards, was adopted on January 27, 1981, with revisions to some sections effective February 27, 1981, March 3, 1989, and June 18, 1991.

Additional FDA regulations that are relevant to IRB review of research are Parts 312 (Investigational New Drug Application), 812 (Investigational Device Exemptions), and 860 (Medical Device Classification Procedures).

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, which met from 1980 to 1983, produced numerous reports on various aspects of medical ethics and biomedical and behavioral research. Its mandate with respect to the protection of human subjects was, first, to review the federal rules and policies governing human subjects research, and second, to determine how well those rules were being implemented or enforced.

Several excellent sources trace the history of human subjects research and the development of the IRB system as a mechanism for the protection of human subjects. An account of the history of human subjects research and the human subjects protection system in the United States can be found in David J. Rothman's *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making* and in Dennis Maloney's *Protection of Human Research Subjects*. Rothman details the abuses to which human subjects were exposed, culminating in Henry Beecher's 1966 article, "Ethics and Clinical Research," published in the *New England Journal of Medicine*, and ultimately contributing to the impetus for the first NIH and FDA regulations. Other equally useful sources include Robert J. Levine's *Ethics and Regulation of Clinical Research*, Joan E. Sieber's *Planning Ethically Responsible Research*, Robert M. Veatch's "Human Experimentation Committees: Professional or Representative?," and William J. Curran's "Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies."

A. The Belmont Report

On September 30, 1978, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research submitted its report entitled "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research." The Report, named after the Belmont Conference Center at the Smithsonian Institution where the discussions that resulted in its formulation were begun, sets forth the basic ethical principles underlying the acceptable conduct of research involving human subjects. Those principles, **respect for persons**, **beneficence**, and **justice**, are now accepted as the three quintessential requirements for the ethical conduct of research involving human subjects.

Respect for persons involves recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy.

Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm.

Justice requires that the benefits and burdens of research be distributed fairly.

The Report also describes how these principles apply to the conduct of research. Specifically, the principle of *respect for persons* underlies the need to obtain informed consent; the principle of *beneficence* underlies the need to engage in a risk/benefit analysis and to minimize risks; and the principle of *justice* requires that subjects be fairly selected. As was mandated by the congressional charge to the Commission, the Report also provides a distinction between "practice" and "research." The text of the *Belmont Report* (<http://www.med.umich.edu/irbmed/ethics/belmont/belmontr.htm>) is thus divided into two sections: (1) boundaries between practice and research and (2) basic ethical principles.

B. Boundaries Between Practice and Research

While recognizing that the distinction between research and therapy is often blurred, *practice* is described as "interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy to particular individuals." Research is defined as systematic observation and data collection which is (1) intended for release to the scientific community as a contribution to knowledge or (2) portrayed (explicitly or implicitly) by university students, faculty, or staff as "research" or "experimental" investigation or (3) intended to fulfill requirements for a masters thesis, doctoral dissertation, or other research requirements of the university. If a proposed activity can be defined as "research" by one or more of these criteria, the protocol must receive the appropriate review by the DRC and be assigned a docket number by UT Martin's ORGC. If a protocol activity cannot be defined as "research" by one or these criteria, then the protocol does not have to be reviewed by the DRC or UT Martin IRB. Examples of observation or data collection activities involving human participants that do not require departmental review committee or IRB review include:

- Data collection for internal departmental or other university administrative purposes (e. g., teaching evaluations, student evaluations, staff evaluations)
- Program evaluation carried out under independent contract for an external organization that is for their internal purposes only (i. e., no external reporting to any funding or public agency). Examples of program evaluation include: personnel studies, staff effectiveness studies, human cost benefit analysis, treatment effectiveness studies, or human engineering studies.

Course activities that involve the use of human participants, but have no connection of research beyond the instructional function preclude the need for certification or IRB review; **however, efforts that lead to presentation outside of the classroom, and/or the publicizing of the student-prepared documents in any manner are considered research.** If the investigator intends to use the data from such activities as the basis for a scientific contribution, or portrays the activities as "research" or "experiment," then the activity will be considered research involving human participants

and will be subject to DRC review and possibly IRB review and must receive a docket number from UT Martin's ORGC. If the investigator intends to use the data for purposes of a masters thesis or required research project, then the activity will be considered research involving human participants and will be subject to DRC and possibly IRB review and must receive a docket number from UT Martin's ORGC.

C. Classroom-Related Activities

The collection of information from respondents for the purpose of class discussion or for the purpose of training in research or research methods does not require IRB review. In this situation, instructors are responsible for the protection of human subjects. The ORGC recommends that instructors who plan to have their students conduct research complete the IRB 101 training. Instructors will need to contact the ORGC, 881.7015, for instructions to access training. **Class-related projects that must be approved are:**

- All master's theses and research projects that involve human subjects
- All projects for which findings may be published or otherwise disseminated. **Since publication will require consent of the participants, it would be prudent to seek IRB review of the informed consent form and other project materials in advance if there is any chance of publication later.**
- Class-related projects for which the data collected are archived for any purpose other than administrative evaluations. For instance, if a student developed an exemplary plan and collects data that could be impressive enough that the instructor wants to use it as an example for subsequent projects, this would be archived and subject to IRB approval before it can be used. Without IRB approval, these data must be destroyed and cannot serve as an example.

D. Applying the Ethical Principles

1. Respect for Persons. Required by the moral principle of respect for persons (*see* definition, above), **informed consent** contains three elements: information, comprehension, and voluntariness.

b. Information: First, subjects must be given sufficient information on which to decide whether or not to participate, including the research procedure(s), their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Responding to the question of what constitutes adequate information, the *Report* suggests that a "reasonable volunteer" standard be used: "the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation." Incomplete disclosure is justified only if it is clear that: (1) the goals of the research cannot be accomplished if full disclosure is made; (2) the undisclosed risks are minimal; and (3) when appropriate, subjects will be debriefed and provided the research results.

b. Comprehension: Second, subjects must be able to comprehend the information that is given to them. The presentation of information must be adapted to the subject's capacity to understand it; testing to ensure that subjects have understood may be warranted. Where persons with limited ability to comprehend are involved, they should be given the opportunity to choose whether to participate (to the extent they are able to do so), and their objections should not be overridden, unless the research entails providing them a therapy unavailable outside of the context of research. [See discussions on this issue in other sections of the Guidebook]. Each such class of persons should be considered on its own terms (e.g., minors, persons with impaired mental capacities, the terminally ill, and the comatose). Respect for persons requires that the permission of third persons also be given to protect them from harm.

c. Voluntariness: Finally, consent to participate must be voluntarily given. The conditions under which an agreement to participate is made must be free from coercion and undue influence. IRBs should be especially sensitive to these factors when particularly vulnerable subjects are involved.

2. Beneficence. Closely related to the principle of beneficence (see definition, above), **risk/benefit assessments** "are concerned with the probabilities and magnitudes of possible harms and anticipated benefits." The *Report* breaks consideration of these issues down into defining the nature and scope of the risks and benefits, and systematically assessing the risks and benefits. All possible harms, not just physical or psychological pain or injury, should be considered. The **principle of beneficence** requires both protecting individual subjects against risk of harm and consideration of not only the benefits for the individual, but also the societal benefits that might be gained from the research.

In determining whether the balance of risks and benefits results in a favorable ratio, the decision should be based on thorough assessment of information with respect to all aspects of the research and systematic consideration of alternatives. The *Report* recommends close communication between the IRB and the investigator and IRB insistence upon precise answers to direct questions. The IRB should: (1) determine the "validity of the presuppositions of the research;" (2) distinguish the "nature, probability and magnitude of risk...with as much clarity as possible;" and (3) "determine whether the investigator's estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies."

Five basic principles or rules apply when making the risk/benefit assessment: (1) "brutal or inhumane treatment of human subjects is never morally justified;" (2) risks should be minimized, including the avoidance of using human subjects if at all possible; (3) IRBs must be scrupulous in insisting upon sufficient justification for research involving "significant risk of serious impairment" (e.g., direct benefit to the subject or "manifest voluntariness of the participation"); (4) the appropriateness of involving vulnerable populations must be demonstrated; and (5) the proposed informed consent process must thoroughly and completely disclose relevant risks and benefits.

3. Justice. The principle of justice mandates that the **selection of research subjects** must be the result of fair selection procedures and must also result in fair selection outcomes. The "justness" of subject selection relates both to the subject as an individual and to the subject as a member of social, racial, sexual, and to ethnic groups.

With respect to their status as individuals, subjects should not be selected either because the researcher favors them or because they are held in disdain (*e.g.*, involving "undesirable" persons in risky research). Further, "social justice" indicates an "order of preference in the selection of classes of subjects (*e.g.*, adults before children) and that some classes of potential subjects (*e.g.*, the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions."

Investigators, institutions, or IRBs may consider principles of distributive justice relevant to determining the appropriateness of proposed methods of selecting research subjects that may result in unjust distributions of the burdens and benefits of research. Such considerations may be appropriate to avoid the injustice that "arises from social, racial, sexual, and cultural biases institutionalized in society."

Subjects should not be selected simply because they are readily available in settings where research is conducted, or because they are "easy to manipulate as a result of their illness or socioeconomic condition." Care should be taken to avoid overburdening institutionalized persons who "are already burdened in many ways by their infirmities and environments." Nontherapeutic research that involves risk should use other, less burdened populations, unless the research "directly relate[s] to the specific conditions of the class involved."

E. Suggestions for Further Reading

- **Beauchamp**, Tom L., and Childress, James F. *Principles of Biomedical Ethics*, 3d ed. New York: Oxford University Press, 1989.
- **Beecher**, Henry K. "Ethics and Clinical Research." *New England Journal of Medicine* 274 (1966): 1354-1360.
- **Curran**, William J. "Government Regulation of the Use of Human Subjects in Medical Research: The Approaches of Two Federal Agencies." In *Experimentation with Human Subjects*, edited by Paul A. Freund, pp. 402-454. New York: George Braziller, 1970.
- **Fried**, Charles. *Medical Experimentation: Personal Integrity and Social Policy*. New York: American Elsevier Company, 1974.
- **Levine**, Robert J. *Ethics and Regulation of Clinical Research*. 2d ed. Baltimore: Urban and Schwarzenberg, 1986. See especially Chapter 14, "The Institutional Review Board."
- **Maloney**, Dennis M. *Protection of Human Research Subjects: A Practical Guide to Federal Laws and Regulations*. New York: Plenum Press, 1984.
- **McCarthy**, Charles R. "Experience with Boards and Commissions Concerned with Research Ethics in the United States." In *Research Ethics*, edited by Kare Berg and Knut Erik Tranoy, pp. 111-122. New York: Alan R. Liss, 1983.
- **McCarthy**, Charles R. "Current Regulations for the Protection of Human Subjects." In *Alzheimer's Dementia: Dilemmas in Clinical Research*, edited by Vijaya L. Melnick and Nancy N. Dubler, pp. 13-18. Clifton, NJ: Humana Press, 1985.

- **Marshall**, Ernest. "Does the Moral Philosophy of the Belmont Report Rest on a Mistake?" *IRB* 8 (No. 6, November/December 1986): 5-6.
- **Rothman**, David J. *Strangers at the Bedside: A History of How Law and Bioethics Transformed Medical Decision Making*. New York: Basic Books, 1991.
- **Rothman**, David J. "Ethics and Human Experimentation: Henry Beecher Revisited." *New England Journal of Medicine* 317 (No. 19, November 5, 1987): 1195-1199.
- **Sieber**, Joan E. *Planning Ethically Responsible Research: A Guide for Students and Internal Review Boards*. Applied Social Research Methods Series, vol. 31. Newbury Park, CA: Sage Publications, 1992.
- **Twenty Years After: The Legacy of the Tuskegee Syphilis Study**. *The Hastings Center Report* 22 (No. 6, November/December 1992): 29-40. Includes articles by Arthur L. Caplan, Harold Edgar, Patricia A. King, and James H. Jones.
- **U.S. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research**. A complete list of the National Commission's reports and recommendations is provided in Appendix 1.
- **U.S. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research**. A complete list of the President's Commission's reports is provided in Appendix 1.
- **Veatch**, Robert M. "Human Experimentation Committees: Professional or Representative?" *Hastings Center Report* 5 (No. 5, October 1975): 31-40.

II. INTRODUCTION

The University of Tennessee at Martin (UT Martin) is committed to the furthering of human understanding. Research is regarded as a major avenue leading to the advancement of such knowledge, especially when freedom of inquiry is available to investigators. Such freedom, however, must be earned through the conduct of research in a competent, moral, and responsible manner by investigators who not only hold to scientific values but also have the highest regard for the implications and consequences of their research on society and the individuals therein. At times, it is possible that the scientist's quest for knowledge may endanger the right and welfare of individuals; guaranteeing these rights must be a focus of constant concern and scrutiny. It is the investigator's responsibility to assess research procedures regularly to insure the protection of the individual and, when appropriate, to review them with associates and other responsible members of society.

With due regard for the freedom of inquiry, but with the highest regard for the safeguarding of individual rights and welfare, the following code and procedures are offered to serve as guidelines to be followed at UT Martin for all research. This research includes that conducted by University faculty, staff, or students, on or off campus, whether funded or not. Non-UT Martin personnel conducting research on the UT Martin campus must also follow these guidelines. To be effective, such guidelines will have to be flexible enough to allow for changes in our value systems and for those modifications that necessarily will be required with experience.

III. JURISDICTION OF THE INSTITUTIONAL REVIEW BOARD (IRB)

The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. Research that has been reviewed and approved by an IRB may be subject to review and disapproval by officials of the institution. However, those officials may not approve research if it has been disapproved by the IRB [Federal Policy §____.112].

The IRB also functions independently of, but in coordination with, other committees. For example, an institution may have a research committee that reviews protocols to determine whether the institution should support the proposed research. The IRB, however, makes its independent determination whether to approve or disapprove the protocol based upon whether or not human subjects are adequately protected.

Whenever the IRB reviews a protocol, an initial question is whether the IRB has jurisdiction over approval of the research. That is, the IRB must ask, "Is the research subject to IRB review?" The federal regulations apply "to all research involving human subjects conducted, supported, or otherwise subject to regulation by any federal department or agency" that has adopted the human subjects regulations [Federal Policy §____.101(a)].

The first two questions the IRB faces are whether the activity involves *research*, and second, whether it involves *human subjects*. These terms are defined under Section IX of this [Guide](#). In addition, some research that involves human subjects may be **exempt** from the regulations requiring IRB review [Federal Policy §____.101(b)]. See Section XI of this [Guide](#) for discussion of [exempt review](#).

Jurisdictional questions arise, however, in that the regulations also require that, as part of their Assurances, institutions agree to protect the welfare of all human subjects involved in research, whether or not the research is conducted or supported by a federal department or agency [Federal Policy §____.103(b)(1)]. While the regulations further specify that this requirement "need not be applicable to any research exempt . . . under §____.101(b)," many institutions' human subjects policies provide that all research, even research that is exempt from review under the federal regulations, is to be reviewed by the IRB. In such cases, the IRB has jurisdiction over all human subjects research, thereby providing broader protection for subjects than that required by the regulations. It is crucial that IRBs keep in mind that their authority to approve, require modifications in, or disapprove research derives from both federal law and institutional policy.

Research that has been reviewed and approved by an IRB may be subject to further review and disapproval by officials of the institution. Those officials, however, may not approve research if it has been disapproved by the IRB [Federal Policy §____.112]. Furthermore, approved research is subject to continuing IRB review and must be reevaluated at least annually (and more frequently, as specified by the IRB) [Federal Policy §____.109(e)].

Research versus Therapy. The fact that much biomedical research is conducted for evaluating new therapies or treatments leads to two problems for IRBs. The first is, to some degree, a problem of IRB jurisdiction; the second is a problem of risk/benefit assessment.

The distinction between **research and treatment** can become blurred in patient care settings as well as in some educational and training settings. This distinction raises questions of IRB jurisdiction over the research: *Is the proposed activity one that requires IRB review (pursuant either to federal regulations or institutional policy)?* Research itself is not therapeutic; for ill patients, research interventions may or may not be beneficial. Indeed, the purpose of evaluative research is to determine whether the test intervention is in fact therapeutic. The support of an activity by a research grant may sometimes provide a practical, if somewhat artificial, operational answer to the question of whether or not that activity is research. IRBs that review only activities whose review is mandated because of the source of funding (*e.g.*, by DHHS regulations 45 CFR 46), can be confident that the intent of the activity is research rather than therapeutic (although subjects may obtain some therapeutic benefit from the research). But an IRB that reviews all research, regardless of the source of support, may sometimes face questions about whether or not a particular activity performed with therapeutic intent is, therefore, research and should be reviewed. Or it may face the difficult question of whether a formal research **protocol** should be developed (and reviewed by the IRB) for a new or non-validated procedure that is being used for therapeutic purposes within the institution. IRBs should be prepared to play such a role; some prominent commentators have pointed out the dangers of allowing new procedures to come into widespread use without having been systematically validated in well-controlled trials.

The second distinction between **research and therapies** that may pose a problem for IRBs concerns risk/benefit assessments in research on therapies. Often, the risks of a study may seem justified by a therapy provided as part of the study. IRBs should determine, however, whether the anticipated therapeutic benefits would be available to persons who are not participating in a study that presents additional risks. Such benefits should not be used to justify risks presented by the research.

IV. STRUCTURE OF THE INSTITUTIONAL REVIEW BOARD (IRB) – CFR 45 §46.107

An Institutional Review Board (IRB) can have as many members as necessary for it to perform its duties effectively. Care should be taken, however, to ensure that it does not become so large that its management becomes cumbersome. 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 such issues as community attitudes, 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 (*i. e.*, children, prisoners, pregnant women, or handicapped 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 [34 CFR 350.3(d)2); 34 CFR 356.3(c)(2)].

V. STRUCTURE OF UT MARTIN IRB

The **UT Martin IRB** shall be composed of seven (7) members with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the University. Six (6) of the members shall be on the faculty or staff of UT Martin, including the Director of Research, Grants, and Contracts acting as the Authorized Institutional Official (see [Section VI.B.2](#) below). The remaining member shall be a non-university employee. The Vice Chancellor for Academic Affairs at UT Martin is the appointing authority for the UT Martin IRB. The IRB will elect its own Chair and Secretary. Five (5) faculty members will represent those departments that would more naturally conduct research utilizing human subjects in the normal course of doing business. No one (1) department may have more than one (1) member on the Board. Board members serve three-year overlapping terms and may be reappointed to the Board upon recommendation of the representative department/college. Members of the IRB may serve on the Faculty Research Committee, but may not serve congruently on the Institutional Animal Care and Use Committee, except only in extenuating circumstances. Further, to lessen the possibilities of conflict of interest, the Departmental Review Committee Chair shall not serve on the Institutional IRB at the same time he/she serves in the capacity of DRC Chair.

The UT Martin IRB shall consist of females and males. Further, the IRB shall not consist entirely of members of one department or one college. 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.

The IRB will include at least one member who is not otherwise affiliated with UT Martin and who is not part of the immediate family of a person who is affiliated with UT Martin. Ministers, teachers, attorneys, businesspersons, medical personnel, and homemakers are possible candidates. The person selected shall be knowledgeable about the local community and be willing to discuss issues and research from that perspective. Consideration will be given to the type of community from which the institution will draw its research subjects. The nonaffiliated member(s) should not be vulnerable to intimidation by the professionals on the IRB, and their services should be fully utilized by the IRB. This member shall be appointed as follows: the members of the university IRB shall compile a list of nominees and submit same to the Director of the RGC and chair of the IRB, who, after consultation with the Vice Chancellor for Academic Affairs, shall select the community representative from the prepared list.

No member of the UT Martin IRB will participate in the IRB's initial or continuing review of any project in which that member has a conflicting interest, except to provide information requested by the IRB. **An investigator can be a member of the IRB; however, there is a stipulation that must be adhered to without exception: The investigator-as-member cannot participate in the review and approval process for any project in which he or she has a present or potential conflict of interest.** Where the investigator-member has a conflicting interest, he or she should be present only to provide information requested by the IRB. He or she should be absent from the meeting room during the discussion and voting phases of the review and approval process; IRB

minutes should reflect whether these requirements have been met. Additionally, the IRB, in its discretion, may invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB.

The UT Martin IRB shall meet at a **regularly scheduled time** and place. This time and place will be published in the *Addenda* and on the RGC Web page by July 1 of each year, and Board members will be notified in writing and through email of the schedule. In the event that no IRB application is submitted for full review within 10 working days of the regularly scheduled meeting, the Authorized Institutional Official shall cancel the meeting and notify the IRB accordingly.

The **Expedited Review Board, composed of the IRB Chair and IRB Secretary**, shall review all protocols it can as expeditiously as possible, sending only protocols necessary for full Board review to the entire Board. It is proposed that an Expedited Review will take 10 – 12 days of receipt of the Application to review. Applications during the summer will take longer to review since many faculty do not teach on a regularly scheduled basis and are, therefore, not on campus.

The Board members shall be identified to the U.S. Department of Health and Human Services by name, earned degrees, if any, position or occupation, representative capacity, and by other pertinent indications of experience, sufficient to describe each member's chief anticipated contribution to Board deliberations [Federal Policy §§____.103(b)(3) and _____.115(a)(5)]. Any employment or other relationship between each member and UT Martin shall be identified (i. e., full-time employee, part-time employee, member of governing panel or board, paid consultant, unpaid consultant). Also, changes in Board membership shall be reported to the Department of Health and Human Services in such form and at such times as the Secretary may require [Federal Policy § _____.103(a); 103(b)(3) and 115(a)(5)]

The UT Martin IRB is empowered to call in outside consultants and/or UT Martin faculty consultants and may utilize review subcommittees where it deems appropriate.

VI. RESPONSIBILITIES

A. Responsibilities of UT Martin

In accordance with federal guidelines for the protection of human subjects in research, UT Martin has established a university institutional review board (IRB) and departmental review committees (DRC) in those departments that would be more likely to conduct research utilizing human subjects. This review board and these departmental review committees review and approve research involving human subjects performed at UT Martin. Before any human subjects research can be conducted, UT Martin shall provide the department or agency a written **Assurance** that it will comply with the requirements of the Policy; the Assurance must be approved by the department or agency; and UT Martin shall certify to the department or agency head that the research has been reviewed and approved by an IRB established in accordance with the requirements of the Policy [Federal Policy §____.103]. Note, however, that the FDA does not require the submission and approval of an Assurance.

Specification of quality standards in the conduct of research is an important function of UT Martin's leadership. Insistence upon well-conceived and -conducted research is evident both in written policies and in actions of UT Martin officials. Research that is conducted so poorly as to be invalid exposes subjects and the institution to unnecessary risk. Approval procedures have been devised such that UT Martin supports only well-designed and properly executed research.

1. The Assurance. UT Martin as primarily an undergraduate institution would be more likely to be involved in behavioral research, but could be, at times, involved in biomedical research. The university has in place a set of principles and guidelines that govern the institution, its faculty, and staff, in the discharge of its responsibilities for protecting the rights and welfare of human subjects taking part in research conducted at, or sponsored by, UT Martin, regardless of the source of funding [Federal Policy §____.103(b)(1)]. Assurances applicable to federally supported or conducted research must, at a minimum, contain such a statement of principles, which may include an appropriate existing code, declaration, and/or statement of ethical principles as formulated by the institution. In the United States, most institutions cite *The Belmont Report*. Foreign institutions sometimes cite other codes, such as the *Declaration of Helsinki* (<http://www.od.nih.gov/helsinki.php3>).

This set of principles is in the form of a document that is readily available to all faculty, students, and/or staff who have need of it and can be a part of the staff or faculty manual. It is written in clear, concise, unambiguous language, understandable to its intended audience. This document can be accessed in hard copy from UT Martin's Office of Research, Grants, and Contracts, from the department chairs of each academic department, from the deans of each academic college, from each operating department/office on campus, and through the RGC web site (www.utm.edu/rgc).

2. Staff, Space, and Supplies. UT Martin will provide the IRB with sufficient meeting space and staff to support the IRB's review and record keeping duties [Federal Policy §____.103 (b) (2)]. Records will be kept in the Office of Research, Grants, and Contracts.

3. Communication. UT Martin's leadership assures that open channels of communication are maintained at all levels. It is important that staff, subjects, and other interested parties have a means of communicating information about the conduct of a research project directly to the appropriate institutional officials. It is vital that IRB members, department chairs, and other officials with responsibility for oversight of research have open and ready access to the highest levels of authority within the institution.

4. Record Keeping. UT Martin, or when appropriate the IRB, must prepare and maintain adequate documentation of IRB activities [Federal Policy §____.115]. In addition to the written IRB procedures and membership lists required by the Assurance process [Federal Policy §____.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 §____.116(b)(5)).

Minutes of UT Martin IRB meetings will 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 controverted issues and their resolution [Federal Policy §____.115 (a)(2)].

IRB records will be retained for at least three (3) years; records pertaining to research that is conducted will be retained for three (3) years after completion of the research. All records will 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 §____.115(b)].

The Office of Research, Grants, and Contracts at UT Martin shall maintain a file for each IRB application that contains the following: the original completed application with all required attachments, copies of any and all correspondence with the applicant including the authorization to conduct research and the IRB docket number, and originals of required forms (i. e., completion of research, changes in protocol/methods, continuation, etc.). The applicant shall maintain a file on his/her research with sensitive information kept under lock and key in his/her office. Correspondence authorizing the applicant to conduct the proposed research shall outline the responsibilities of the applicant for the data and any items pertaining to his/her research.

B. Institutional Procedures and Guidelines

1. Federal Policy Requirements. According to federal guidelines, as provided for in its **Assurance**, UT Martin has prepared written procedures and guidelines to be followed by the IRB when conducting its initial and continuing review of research, and for reporting its findings and actions to the investigator and the administration of UT Martin. The procedures provide guidance for determining which projects will require review more often than annually and which projects require verification from sources other than the investigator that no material changes have occurred since the last IRB review. The guidelines also delineate procedures for ensuring prompt reporting to the IRB, by the investigator, of proposed changes in a research activity. They must also provide procedures for ensuring that such changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except when necessary to eliminate apparent immediate hazards to the subject [Federal Policy §____.103(b)(4)].

UT Martin also has written procedures for ensuring prompt reporting to the IRB, appropriate institutional officials, and the department or agency head of: (1) any unanticipated problems involving risks to subjects or others, or any serious or continuing noncompliance with the Federal Policy or the requirements or determinations of the IRB; and (2) any suspension or termination of IRB approval [Federal Policy §____.103 (b)(5)].

2. The Authorized Institutional Official. Within the institution there must be a point of responsibility for the oversight of research and IRB functions. This point should be an official of the institution who has the legal authority to act and speak for the institution, and should be someone who can ensure that the institution will effectively fulfill its research oversight function. UT Martin’s Vice Chancellor for Academic Affairs has appointed the

Director of Research, Grants, and Contracts (in the role of Compliance Officer) as the institution's **Authorized Institutional Official**. The Director of RGC shall also vote in the selection of the chair of the IRB. Selection of appropriate personnel assures the protection of the rights and welfare not only of research subjects but also of UT Martin itself.

3. Other Institutional Personnel. Training new personnel is a basic responsibility of any institution. In facilities that conduct research, all personnel should be aware of the applicable institutional policies and mechanisms for the approval of research and for reporting problems with research projects in progress. Personnel involved in the conduct of research should receive additional training in institutional expectations and specific regulations pertaining to research. Training designed to enhance the development of high quality proposals should be encouraged. **IRB members and others charged with responsibility for reviewing and approving research should receive detailed training in the regulations, guidelines, and policies applicable to human subjects research.** Attending workshops and other educational opportunities focused on IRB functions are encouraged and supported to the extent possible. Training in good research practices and in methods for minimizing risk shall be provided to all faculty, students, and staff involved with research utilizing human subjects. Since research conducted by others may have a bearing on research projects conducted by or at the institution, journals and other research-related materials should be available to staff. The UT Martin Office of RGC will provide continual training and updated materials for the utilization of human subjects in research on an annual basis.

4. Internal Audits. Internal audit procedures assure UT Martin's administration that its policies and procedures are being adhered to and that they are proper in scope and content. Evaluation of activities and functions is an accepted management tool, and the monitoring of institutional high- risk areas such as research is good policy. Audits allow the early identification and correction of problems. UT Martin ensures that reporting of noncompliance is accomplished and that appropriate follow-up measures are taken [Federal Policy §____.103].

5. Points to Consider

- a. Do institutional policies comply with applicable regulations and promote appropriate review and approval?
- b. Are the relevant institutional channels of communication sufficiently open?
- c. Do adequate procedures for monitoring research and conducting audits of the research process exist?
- d. Does the institution adequately provide for the training of personnel in policies and procedures related to research with human subjects?
- e. Does the institution support educational activities related to the design, conduct, and approval of research?

6. Applicable Laws and Regulations

- Federal Policy § ____.101 [To what does this policy apply?]
- Federal Policy § ____.102 [Definitions]
- Federal Policy § ____.103 [Assuring compliance with this policy C research conducted or supported by any federal department or agency]
- Federal Policy § ____.107 [IRB membership]
- Federal Policy § ____.108 [IRB functions and operations]
- Federal Policy § ____.109 [IRB review of research]
- Federal Policy § ____.110 [Expedited review procedures]
- Federal Policy § ____.111 [Criteria for IRB approval of research]
- Federal Policy § ____.112 [Review by institution]
- Federal Policy § ____.115 [IRB records]
- 21 CFR 50 [FDA: Protection of human subjects (informed consent)]
- 21 CFR 56 [FDA: Institutional review boards]
- 34 CFR 97 [ED: Protection of human subjects]
- 34 CFR 350.3 [ED: What regulations apply to these programs (IRB membership)]
- 34 CFR 356.3 [ED: What regulations apply to these programs (IRB membership)]

C. Responsibilities of the Investigator/Researcher

The qualifications of the principal investigator should be considered when reviewing proposals. The investigator's professional development should be taken into account and related to the degree of protocol complexity and risk to human subjects. IRBs may require less experienced research investigators to be sponsored by seasoned researchers. Proposals that require skills beyond those held by the principal investigator should be modified to meet the investigator's skills, have additional qualified personnel added, or be disapproved. While the Institutional Review Board (IRB) acts as the official review board, the investigator is not relieved of personal and ethical responsibility for the design and conduct of the research as it may affect the welfare of subjects involved. In addition to complying with the formal procedures for obtaining approval of a project by IRB, each investigator must:

1. be thoroughly familiar with ethical guidelines for conduct or research utilizing human subjects and comply with these guidelines both in fact and spirit;
2. be sensitive to ethical considerations related to his/her research which may not be specifically covered by the guidelines;
3. follow the established University procedures, along with those recommendations for alterations in procedure by the IRB which were given as part of the conditions of acceptance of the proposed project;
4. bring to the attention of the IRB any alterations in procedure which might conceivably have some relation to the rights or welfare of human subjects;
5. bring to the attention of the IRB during any phase of any project problems (e. g., adverse reactions to drugs or medical devices) for further disposition by the IRB and for reporting to the Department of Health and Human Services; and
6. submit a **Change and/or Termination Form** (see Appendix F), as required by the IRB.

Research investigators shall prepare protocols giving **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 those pertinent laws and regulations are observed. Samples of informed consent documents must be included with protocols. Research investigators are responsible for obtaining informed consent and

ensuring that no human subject will be involved in the research **before** obtaining the consent.

The research plan **must address** quality assurance standards set by the institution. In addition, applicable external standards for quality assurance must be met. External standards are of particular concern for research conducted in clinical facilities. Appropriate reviews for scientific merit must be conducted before the research is approved. Mechanisms for monitoring the progress of the research must be in place.

Research investigators, through their research design, determine whether the proposed research will involve human subjects. When it is not clear whether the research will involve human subjects, investigators should seek assistance from the IRB in making this determination [Federal Policy §____.101 (b)(1)-(6), _____.118, and _____.119]. Some IRBs, for example, require that all research protocols involving human subjects be submitted to the IRB for review. The IRB then determines whether the research is **exempted** from IRB review under the applicable regulations and institutional policies, and whether **full** or **expedited** IRB review is appropriate.

Researchers are responsible for complying with all IRB decisions, conditions, and requirements. Research investigators are responsible for reporting the progress of the research to the IRB and/or appropriate institutional officials as often as and in the manner prescribed by the IRB **but no less than once per year** [Federal Policy §____.109 (e)].

1. **Points to Consider**

- a. Does the principal investigator have the appropriate qualifications, experience, and facilities to ensure that all aspects of the project and follow-up will be conducted rigorously and with due regard for the safety and well-being of the subjects?
- b. Are adequate procedures in place through which the researcher will monitor the project and report problems to the IRB?
- c. What is the investigator's past record with regard to approved research?

When a student is conducting research utilizing human subjects under the auspices of the University, it is the responsibility of the graduate coordinators in each college, or the faculty supervisor in case of independent, class, or other study, to review the proposal and insure compliance with the IRB guidelines. **Further, students conducting research at UT Martin that utilizes human subjects to fulfill a graduation requirement should complete the required forms of their department, where applicable, and send them to the Dean of Graduate Studies, 327 Administration Building, before conducting the research.**

2. **Applicable Laws and Regulations**

Federal Policy §____.101 [To what does this policy apply?]

Federal Policy §____.102 [Definitions]

Federal Policy §____.109 [IRB review of research]

Federal Policy §____.111 [Criteria for IRB approval of research]

Federal Policy §____.116 [General requirements for informed consent]

Federal Policy §____.119 [Research undertaken without the intention of involving human subjects]

D. Responsibilities of the Office of Research, Grants, and Contracts (RGC)

1. UT Martin's Office of Research, Grants, and Contracts (ORGC) is responsible for determining if the research protocols qualify for **Exemption** from continuing review under the *Common Rule* regulations. If **Exempt**, the researcher will be notified in writing and no further reports are required except where changes in procedure arise. All nonexempt research protocols will be forwarded to the Expedited Review Committee of the IRB if they qualify for **Expedited** review under the regulations, or to the full IRB if they do not so qualify.
2. All appeals of IRB decisions shall be submitted to the ORGC for forwarding to the IRB for reconsideration.
3. The ORGC will report information, as appropriate, to the IRB; the Office of Protection from Research Risks (OPRR); and the Department of Health and Human Services (DHHS); research investigators; and department chairs.

E. Responsibilities of the UT Martin Institutional Review Board (IRB)

The **UT Martin IRB** (see [Section V](#) of this [Guide](#) for structure of IRB) is an administrative body established to protect the rights and welfare of human subjects recruited to participate in research activities conducted under the auspices of the institution with which it is affiliated. The IRB has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy. The IRB is not concerned with a researcher's choice of topic, research design, methodology, and controls except as they have a bearing on (1) the rights or welfare of the subjects involved or (2) on an assessment of the potential benefits to society in studies posing a definite risk to the subjects. The review responsibilities of the IRB are to:

1. meet as a Board with at least a quorum present and approve or disapprove with or without specified modifications the applications brought to it. A quorum of the Board shall be defined as a majority of the total membership duly convened to carry out the Board's responsibilities under the terms of the Assurance. As necessary, the Board will arrange to have qualified consultants with special competencies relevant to the proposal participate in the review. Approval shall be contingent upon assurance that the risks are kept to an absolute minimum and that any risks are clearly outweighed by the potential benefits. The Board, at its discretion, may invite the principal investigator (and the supervisor in the case of supervised research activities) to be present at the meeting so that any modifications in procedure to protect subjects can be worked out directly between the Board and the investigator.
2. offer consultation and advice on safeguarding the rights and welfare of human subjects;
3. review requests for exceptions or modifications to any University policy and procedures on research with human subjects;

4. periodically review certain projects, when the Board deems review appropriate, with the principal investigator and collect annually a Review Statement for all projects involving human subjects to assure procedural compliance. With respect to the latter, each investigator must submit a **Change and/or Termination Form (Appendix F)** on an annual basis and at the completion or termination of the project. This form can be obtained from the Office of Research, Grants, and Contracts or may be accessed online at the RGC web site. If in the judgment of the IRB Chair some problem may exist, the responsible investigator will be asked to appear before the Board for a comprehensive review; and
5. keep records and maintain a file of all projects reviewed for a period of at least three (3) years following completion of the project. All records shall be accessible for inspection and copying by authorized representatives of the federal government, or the IRB or ORGC, at reasonable times and in a reasonable manner.

VII. APPEALS

Researchers or investigators may appeal a decision of the IRB by presenting additional material to or requesting an appearance before the Board. All appeals should be submitted in writing to the IRB in care of UT Martin's Office of Research, Grants, and Contracts.

VIII. NONCOMPLIANCE BY INVESTIGATORS, INSTITUTIONAL REVIEW BOARDS, AND INSTITUTIONS

A. Investigators

Research investigators are the most frequent source of noncompliance with human subjects regulations. The most common lapses in investigator compliance include:

1. unreported changes in protocols,
2. misuse or nonuse of the informed consent document, and
3. failure to submit protocols to the IRB in a timely fashion. Problems such as these are often caused by communication difficulties. With investigator goodwill, these cases can be resolved by the IRB without jeopardizing the welfare of research subjects.

Occasionally, an investigator will either avoid or ignore an IRB. Such cases present a more serious challenge to the IRB and to the institution. Regardless of investigator intent, unapproved research involving human subjects places those subjects at an unacceptable risk. When unapproved research is discovered, the IRB and the institution should act promptly to halt the research, assure remedial action regarding any breach of regulatory or institutional human subject protection requirements, and address the question of the investigator's fitness to conduct human subject research. Beyond the obvious need to protect the rights and welfare of research subjects, the credibility of the IRB is clearly at stake. In addition, any serious or continuing noncompliance with DHHS human subjects regulations or the determinations of the IRB **must be promptly** reported to the Office of Human

Research Protections (OHRP) or the department or agency head [Federal Policy §____.103(b)(5)].

B. Institutional Review Boards

IRB noncompliance occurs whenever the IRB deviates from the duties imposed upon it by the federal regulations. Such deviations include:

1. the inadequate review of research protocols by failing to ensure that the consent document and process provide sufficient information to allow prospective subjects to make an informed decision whether to participate in the research;
2. failing to ensure that the research design includes adequate monitoring of the data and any additional safeguards necessary to protect the welfare of particularly vulnerable subjects; and
3. failing to conduct continuing review of research at intervals appropriate to the degree of risk.
4. failing to maintain adequate records of IRB business, and
5. failing to hold their meetings with a majority of members present, including a nonscientific member.

A demonstrated inability to carry out IRB responsibilities in accordance with DHHS regulations can be cause for the suspension or withdrawal of approval of an institution's Assurance.

C. Institutions

Although institutions are accountable for the actions of individual investigators and the IRB, institutional noncompliance is more broadly described as a systemic failure of the institution to implement practices and procedures contained in the institution's Assurance. Prime examples are (1) the failure of the institution to ensure that the IRB is appropriately constituted and functions in accordance with the regulations, (2) that the IRB receives appropriate institutional support and staffing, and (3) that investigators meet their obligations to the IRB. Systemic failure to abide by the terms and conditions of an institution's Assurance will result in withdrawal of approval of the Assurance.

D. Applicable Laws and Regulations

Federal Policy for the Protection of Human Subjects

21 CFR 56.108(b) [FDA: IRB functions and operations]

21 CFR 56.120-124 [FDA: Administrative actions for noncompliance]

Federal Register 56 (June 18, 1991): 28026 [FDA]

45 CFR 46.103 [DHHS: Assuring compliance with this policy]

45 CFR 46.123 [DHHS: Early termination of research support]

IX. DEFINITION OF TERMS

A. Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge [Federal Policy §____.102 (d)]. Activities that meet this definition constitute "research" for purposes of these regulations, 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. Classroom activities may also include research activities. Contact UT Martin's Office of Research, Grants, and Contracts if you are not certain if your activity fits the *research* definition.

1. Educational Considerations

a. Research Methods Instruction: Course activities that involve the use of human participants, but have no connection with research beyond the instructional function preclude the need for certification or IRB review. **However, efforts that lead to presentation outside the classroom and/or publicizing of the student-prepared documents in any manner are considered research.**

If the investigator intends to use the data from such activities as the basis for a scientific contribution, or portrays the activity as "research" or "experimentation," then the activity will be considered research involving human participants and will be subject to **Departmental Review Committee** (DRC) and possibly UT Martin IRB review. If the investigator intends to use the data for purposes of a master's thesis or doctoral dissertation, then the activity will be considered research involving human participants and will be subject to DRC and possibly IRB review.

b. Classroom-Related Activities: The collection of information from respondents for the purpose of class discussion or for the purpose of training in research or research methods does not require IRB review. In this situation, instructors are responsible for the protection of human subjects.

Class-related projects that must be approved:

- ✓ All master's theses that involve human subjects.
- ✓ All projects for which findings may be published or otherwise disseminated. Since publication will require consent of the participants, it is prudent to seek IRB review of the informed consent form and other project materials in advance if there is any chance of publication later.
- ✓ Class-related projects for which data collected are archived for any purpose other than administrative evaluations.

B. 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.

C. A Human Subject means 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 (e. g., 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, and information which 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). 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. [Federal Policy §____.102(f)].

D. Informed Consent means that except as provided elsewhere in this policy, **no investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative.** An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. A minor under age 18 may refuse to participate in the research even if the minor's legally-authorized representative (parent or guardian) has given permission for the minor to participate. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative; in addition, minors must be informed about the research in language they can comprehend and asked if they want to participate in the research. No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence (see [Section X.C.3.](#) in this [Guide](#) – The Basic Elements of Consent - for indepth discussion of Informed Consent.). [Appendix C](#) provides an example of Informed Consent.

E. Assent is a child's affirmative agreement to participate in research. Assent is an ethical concept. However, failure to object cannot be construed as assent [45 CFR, 46.402(b)]. Researchers who include children in their research should be especially mindful of the rights of children participating in their research. Even when assent is not required, researchers are asked to demonstrate a good- faith effort to enlist the cooperation of children who participate in their research (**see [Appendices D and E](#) for examples of a Minor Assent Document**).

It is the responsibility of the IRB to decide if researchers should seek a child's assent as apart of a project's consent procedure. The determination of a child's capacity to provide assent is based on the nature of the research, and the child's age (**typically the IRB requires assent from children age 7 and older**), maturity, and psychological state of the population of children from whom participants will be drawn. The decision to require assent depends on the capacity of the children to appreciate the nature, extent, and probably consequences of their participation in a research project.

Assent is especially important in cases where there is no direct benefit to the child – participants. When assent is required, the procedure must include an explanation of the

proposed research in language that is appropriate to the child's age and maturity. The investigator must indicate on his/her Application to the University of Tennessee, Martin Institutional Review Board for the Protection of Human Subjects in Research what the children will be told about the research and how the information will be conveyed. The investigator must discuss how the information provided might vary with the age, maturity, and level of experience of the children involved in the study. The assent process should be free from coercion and unfair inducements. All children who are capable of providing assent must be informed that they are free to withdraw from participation at any time.

F. Permission is the explicit agreement of parent(s) or guardian to the participation of their child or ward in research. Failure to object or other forms of passive permission cannot be constituted as permission [45 CFR, 46.402(c)]. Both parents must give their permission in any research that places the child-participant at greater than minimal risk [45 CFR, 46.406 and 46.607], unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the case and custody of the child [45 CFR, 46.408(b)]. Further, permission of one parent is sufficient for any research that places that child-participant at no more than minimal risk [45 CFR, 46.404]. When permission is required, the information contained in the permission procedure should include all the elements normally required in an informed consent (see Section X.C. in this Guide for discussion of Informed Consent).

G. Guardian is an individual who is authorized under applicable state or local law to give permission for a child [45 CFR, 46.402(3)].

H. A person **cognitively impaired** is one who has either a psychiatric disorder (*e.g.*, psychosis, neurosis, personality or behavior disorders), an organic impairment (*e.g.*, 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. 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.

I. Competence is 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. Competence may fluctuate as a function of the natural course of a mental illness, response to treatment, effects of medication, general physical health, and other factors. Therefore, mental status should be re-evaluated periodically. As a designation of legal status, competence or incompetence pertains to adjudication in court proceedings that a person's abilities are so diminished that his or her decisions or actions (*e.g.*, writing a will) should have no legal effect. Such adjudications are often determined by inability to manage business or monetary affairs and do not necessarily reflect a person's ability to function in other situations.

J. An **institution** is defined as a residential facility that provides food, shelter, and professional services (including treatment, skilled nursing, intermediate or long-term care, and custodial or residential care). Examples include general, mental, or chronic disease hospitals; inpatient community mental health centers; halfway houses and nursing homes; alcohol and drug addiction treatment centers; homes for the aged or dependent, residential

schools for the mentally or physically handicapped; and homes for dependent and neglected children.

K. Secretary means the Secretary of Health and Human Services and any other officer or employee of the Department of Health and Human Services to whom authority has been delegated.

L. DHHS means the Department of Health and Human Services.

M. Prisoner means any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing.

N. Minimal risk is the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons.

X. ETHICAL CONSIDERATIONS

A. Protection of Individual Rights

1. Only qualified investigators should conduct research or by others only where a close supervisory relationship exists and is maintained with qualified individuals. Should an investigator become involved in areas that extend beyond his/her level of competence, appropriate consultation must be obtained.
2. Each research project must be evaluated in terms of its potential benefit to the subject and to society as well as in terms of its potential risk to the emotional and physical welfare of the subjects. Where risk is involved, or where information obtained is of a private nature, extra protection must be afforded the subject. Every effort should be made to minimize the risks or discomfort entailed in the subject's participation.
3. The investigator assumes responsibility for the procedures used throughout the course of the investigation. **It is the investigator's responsibility to report to the IRB for project review any planned changes in format or procedures from those originally approved. A Change and/or Termination Form must be filed** (see [Appendix F](#) in this *Guide*). Should problems or harmful effects arise out of the experimental procedures, such responsibility would continue until the problem or effect is removed or until the subject is referred to an appropriate professional who has assumed responsibility for the subject.
4. The investigator must not only take any immediate steps required to undo harmful effects but must also initiate appropriate follow-up procedures to detect unpredicted harm if the study presents a potential to produce harm that may only manifest itself later.

5. The investigator must be sensitive to individual factors that may predispose certain individuals to experience enduring harmful psychological or physical consequences from participation in the study and to exclude such individuals from the research sample.
6. The investigator is **obligated** to keep the subject's data in confidence. This includes keeping the data in confidence from relatives, friends, employers, school officials, and from other professional associates of the investigator unless: (a) the subject or an authorized representative consents to disclosure, or (b) regulations of the Secretary of the Department of Health and Human Services so provide, or (c) as otherwise required by law. It is the investigator's responsibility to report to the IRB how the data will be used and any subsequent changes in use.
7. Where information about private or personal matters is obtained from the subject for scientific purposes, the subject must be properly informed of how such information will be used, who will or might have occasion to examine such information, and how it might affect his/her future, including his/her civil rights. The subject must be advised that at any point he/she may withdraw from the experiment without penalty.
8. Where feasible, any private information obtained from a subject should be obtained anonymously or, if this is not possible, it should be immediately coded with care taken to keep the code separate from the data and in a secure place.
9. At the completion of the experiment, the investigator has the **obligation** to remove any misconceptions acquired by the subject, whether deliberately created or developed as an accidental byproduct of the procedure.
10. Whenever possible, subjects should receive something of value for their participation. This benefit may be material (e. g., money, gifts, etc.) or educational (e. g., information, self-knowledge, etc.).
11. When the methodological requirements of research lead some subjects to experience failure or require the withholding of a potentially beneficial program or treatment from control subjects, the investigator must, insofar as possible, provide these subjects with a beneficial experience when the experiment is concluded.
12. It is unacceptable to intentionally cause a research subject to suffer embarrassment, fear, anxiety, or loss of self-esteem. Such research may be justified only when (a) the research objectives can be realized in no other way, and (b) the suffering of the research subject is limited in degree and duration to that minimum required to accomplish the research objectives.
13. An individual has the right to control any use of his/her person. Where a condition or circumstance exists which interferes with the right to freely control the use of his/her person, special precautions must be instituted to safeguard his/her rights and welfare.
14. It is incumbent upon the investigator to make sure that all subjects are treated with respect and dignity, and that the subjects are not imposed upon for the convenience of the researcher.

15. Rather than adopting an ethical code, the University encourages researchers to follow the ethical codes established by their disciplines. Ethical codes or statements of principles established by the American Psychological Association, American Dental Association, American Sociological Association, and the World Medical Association will be referred to when appropriate to the conduct of the research.

B. Participant Data and Identity Confidentiality Considerations

Whenever researchers promise participants that their responses and data will be maintained in confidence, all research project members (investigators, directors, transcribers, students, and staff) are **required** to prevent accidental and intentional breaches of confidentiality. In most cases, confidentiality can be assured by following simple practices (e. g., substituting codes for identifiers, removing survey cover sheets that contain names and addresses, limiting access to identified data, and/or storing research records in a locked cabinet). However, all measures used to assure confidentiality of data need to be understood by all research staff before research is initiated, and followed once research is initiated. Confidentiality procedures **must be described** in research applications that come before the UT Martin IRB.

Researchers should recognize that the assurance of confidentiality includes keeping the identity of participants confidential. Researchers proposing projects that will address sensitive, stigmatizing, or illegal subjects must explicitly outline the steps they will take to assure any information linking participants to the study is maintained in confidence. The requirement of signed consent forms is often waived in sensitive studies, if the consent document is the only written record linking participants to the project **and** a breach of confidentiality presents the principal risk of harm anticipated in that research.

If there is any chance that data or participants' identities might be sought by law enforcement agencies or subpoenaed by a court, a **grant of confidentiality** should be obtained. Under federal law (Public Health Act § 301(d)), researchers, prior to the initiation of the research project, may request grants of confidentiality to protect against forced data and participant identity disclosures. These grants provide protection for specific research projects where protection is judged necessary to achieve the research objectives.

To take advantage of § 301(d), the investigator must request a grant of confidentiality from the appropriate official. Protection for research on mental disorder or the use and effect of alcohol and other psychoactive drugs can be obtained from the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute on Drug Abuse (MIDA), or the National Institute of Mental Health (NIMH). Certificates for confidentiality for biomedical, behavioral, clinical, or other research that does not fall into these categories are issued by the Assistant Secretary of Health. A more complete discussion of § 301(d) can be found at the OHRP website (www.hhs.gov/ohrp/humansubjects/guidance).

C. Informed Consent

A subject's participation in research should at all times be voluntary on the basis of informed consent. It is incumbent upon the investigator to provide the subject with all information about the study that is likely to bear upon the subject's willingness to participate.

No informed consent, whether oral or written, may include any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. --- 45 CFR 46.116

Examples of Exculpatory Language:

- By agreeing to this use, you should understand that you will give up all claims to personal benefit from commercial or other use of these substances.
- I voluntarily and freely donate any and all blood, urine, and tissue samples to the U.S. Government and hereby relinquish all right, title, and interest to said items.
- By consent to participate in this research, I give up any property rights I may have in bodily fluids or tissue samples obtained in the course of the research.
- I waive any possibility of compensation for injuries that I may receive as a result of participation in this research.

Examples of Acceptable Language

- Tissue obtained from you in this research may be used to establish a cell line that could be patented and licensed. There are no plans to provide financial compensation to you should this occur.
- By consenting to participate, you authorize the use of your bodily fluids and tissue samples for the research described above.
- This hospital is not able to offer financial compensation nor to absorb the costs of medical treatment should you be injured as a result of participating in this research.
- This hospital makes no commitment to provide free medical care or payment for any unfavorable outcomes resulting from participation in this research. Medical services will be offered at the usual charge.

1. Recommendations for Researchers. Researchers are accountable for the quality of the informed consent protocol and for assessing comprehension of information for an informed consent. Accountability should take two forms: (a) researchers should incorporate empirically-based strategies that have been shown to increase comprehension and (b) researchers should assess research subjects' level of comprehension of information for an informed consent prior to admitting them into a study. If comprehension is inadequate, the researcher should make an effort to enhance the research subject's comprehension based on empirically effective strategies or, if impossible to attain adequate comprehension, the researcher should exclude the subject from the study (or obtain a proxy).

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided that the IRB finds and documents that various conditions under the federal common rule regulations are met.

2. Researchers should consider the following:

1. present an amount of information for an informed consent that research subjects perceive to be the right amount for them;
2. present information clearly;
3. present any necessary anxiety-producing information (e.g., risks, complications, side effects) in as non-threatening a manner as possible;
4. present information simply -- ensure that level of difficulty of information in consent forms does not exceed research subjects' preferences or capabilities;
5. have the investigator, a nurse, or a health care team present (or follow up) information for an informed consent;
6. if possible, leave the informed consent form with research subjects so that they have adequate time to reflect upon it;
7. possibly use an audiovisual format to present information for an informed consent; and
8. actively involve research subjects in the processing of information for an informed consent.

3. The Basic Elements of Informed Consent:

- a. 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;
- b. a description of any reasonably foreseeable risks or discomforts to the subject;
- c. a description of any benefits to the subject or to others which may reasonably be expected from the research;
- d. a disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
- e. a statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
- f. 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;
- g. 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

h. 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.

4. Additional Elements of Informed Consent. When appropriate, one or more of the following elements of information shall also be provided to each subject:

a. 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;

b. anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;

c. any additional costs to the subject that may result from participation in the research;

d. the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

e. 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

f. the approximate number of subjects involved in the study.

5. Appropriate Methods for Obtaining Consent

a. Conducting the proposed research in violation of this principle of informed consent may be justified only when all of the following conditions are met:

1. the risk to any subject is minimal;

2. the rights and welfare of any subject will not be adversely affected;

3. the research objectives cannot be realized without concealment;

4. any reasonable alternative means for attaining those objectives would be less advantageous to the subjects;

5. there is sufficient reason for concealment so that when the subject is later informed, he/she can be expected to find the concealment reasonable and suffer no serious loss of confidence in the integrity of the investigator or others involved in the situation;

6. the subject is allowed to withdraw his/her data from the study if he/she so wishes when the concealment is revealed to him/her before publication and/or publicity of data; and

7. the investigator takes full responsibility for detecting and removing stressful aftereffects and, insofar as possible, for providing the subject with positive gain from the research experience.

- b. In recruiting subjects for research and obtaining their informed consent, the investigator must give potential subjects an honest description of the study without misrepresenting the purposes, procedures, benefits, or sponsorship of the research. Potential subjects should also be informed of the investment being asked of them (e.g., amount of time involved). Violations of this principle can be justified only under the conditions noted under [C.4.](#) above.
- c. Where private information is sought or where risk may be involved, the subject should be fully informed regarding the nature of the information he/she will be asked to divulge and/or the possible risks, discomforts, or harm that he/she may undergo as a result of participating.
- d. Where minors are used as the subjects for research outside of a school system or institution, **only** the parent or guardian shall give informed consent. In addition to this consent, children must have the research and informed consent information discussed with them so that they can understand these items and must be asked if they will participate in the research, thus providing their assent to participate in the research. Conditions noted under [C.4.1 and C.4.2.](#) above also apply. Contact the UT Martin Office of Research, Grants, and Contracts for information on obtaining implicit consent from the parent or guardian if signing the consent form presents difficulties. (e. g., some researchers send letters home to the parents/guardians asking them to contact the school if they do not want their child[ren] to participate in the described research; if the parents/guardians do not contact the school, they are told that they have given their implicit consent for the child[ren] to participate in the research.)
- e. In the circumstances that the research is conducted in an institutional setting, such as a school or hospital, where minors or committed patients are used as the subjects for research, informed consent should be secured both from the appropriate official and from the parent or guardian if any, as well as assent from the children or patients. Conditions noted under [C.4.1. and C.4.2.](#) above also apply.
- f. In the circumstance of captives and/or dependents as found in institutions, prisons, hospitals, schools, etc., and relationships such as employer/employee, teacher/student, etc., where control is inherent in the circumstance, particular care is necessary to obtain informed consent using procedures that maximize the freedom of the subject to refuse participation. In the case of prisoners, UT Martin will follow the Department of Health and Human Services regulations. Any value offered as a participation reward should not take advantage of any subject's deprived state. Conditions noted under [C.4.1. and C.4.2.](#) above also apply.
- g. Care must be taken that the subject's decision concerning participation is truly free and voluntary. To be avoided are:
1. being required to participate in research as a course requirement where no course-related pedagogical benefit can be justified;
 2. direct or implicit suggestions that needed services (such as counseling, employment, housing) may be withheld or reduced if the subject refuses to

participate in the research it is the responsibility of the investigator to make clear to the subject that such services are not contingent upon participation;

3. pressure to participate because the subject's relationship to the investigator creates a situation where it is difficult to refuse (e.g., teacher/student, superior/subordinate relationships); and

4. pressure to participate put on subjects by arousing anxieties concerning personal shortcomings (e.g., cowardice, defensiveness) or by the use of undue social influence or moral appeals.

h. Once involved in the study, the subject should still have the prerogative, at any time, to refuse to participate or to withdraw from an experiment, regardless of the reasons. Should he/she choose to exercise this prerogative, this right must be respected without obstruction or coercion by the investigator. An opportunity to discuss the reasons for withdrawal may be offered to the subject for the purpose of clarifying misunderstandings or reducing anxiety or other discomfort that may have been aroused by participation as a subject.

C. Risks versus Benefits

1. All guidelines in [PART X.A.](#) apply here.

2. Each research project must be evaluated in terms of the potential benefits to new knowledge, to society, and to the research subject as against the potential risks to the individuals involved. Where a proposed project involves substantial potential risks to subjects, the investigator:

- a. has the responsibility to justify the possible benefits of the project, and
- b. must be cognizant of previous research, both animal and human, done in the subject area.

3. Any project in which there exists a possibility of alteration or impairment of physical or psychological functions; of acute discomfort; or of emotional, social, or other harm constitutes a risk. Such projects require special precautions and must follow approved procedures as set forth in [Section XII](#), below, to obtain approval. Furthermore, any project which solicits private or confidential information as defined by the subject or qualified person (or if this is not possible, by a parent, guardian, or other designated authority) must also be reviewed according to approved procedures under [PART X.A.](#)

XI. TYPES OF RESEARCH REVIEW

A. Exempt refers to various types of research (including some survey and ongoing educational research projects) that do not require continued monitoring by the IRB. Guided by the federal regulations, the Office of Research, Grants, and Contracts determines which projects fall into the Exempt classification.

An exemption may be used for studies in which children are participants only if the research is limited to observation of public behavior. The use of surveys or interviews, review of any records, and direct or indirect interaction by the researcher, or any adjustment

of the setting in which the observations take place does not qualify as an observation of public behavior. Research activities exempt from formal review must present no greater than minimal risk to participants **and** meet the definition of one or more of the six (6) categories listed below.

According to 45 CFR, 46.101(b), research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from IRB review:

1. **Category A** [45 CFR, 46.101(b)1]: Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Limitations to Category A – Confidentiality of identifiable information must be maintained without the express permission of the participants to do otherwise.

2. **Category B** [45 CFR, 46.101(b)2]: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

Limitations to Category B – This exemption does not apply if (a) the information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to the participants; **and** (b) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation. The exemption does not apply to observation of public behavior if the investigator interacts with participants or manipulates the setting in which the observations take place.

3. **Category C** [45 CFR, 46.101(b)3]: Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if: (i) the participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Limitations to Category C – Confidentiality of identifiable information must be maintained without express permission of the participants to do otherwise.

4. **Category D** [45 CFR, 46.101(b)4]: Research involving the collection of study of existing data, documents, records, pathological specimens or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Limitations to Category D – The requirement for consent of the participants is waived if the data, documents, records, or specimens are publicly available. The authorization of the custodian of the data or document can serve in lieu of specific participant consent for access to the data, if the data or records are not publicly available. However, the investigator and the UT Martin IRB must be satisfied that the custodian is authorized to release the data for research purposes.

Note: The researcher must be sure to have legal access to the materials in question, even if the data is recorded without identifiers. Some records are by nature confidential (e. g., school records) and others are property of clients only held in trust by an institution (e. g., patient records). These records **do not** qualify for exemption. However, they may fall under a classification for **expedited review**.

5. **Category E** [45 CFR, 46.101(b) 5]: Research and demonstration projects which are conducted by or subject to the approval of Federal Department or Agency heads, and which are designed to study, evaluate, or otherwise examine: (i) Public benefit or service programs; (ii) procedures of obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Limitations to Category E - The UT Martin requirements for informed consent may be waived if the research cannot be carried out practicably without the waiver.

6. **Category F** [45 CFR, 46.101(b) 6]: Taste and food quality evaluation and consumer acceptance studies, if wholesome foods **without** additives are consumed or if a food is consumed that contains a food ingredient **at or below the level and for a use found to be safe**, or agricultural chemical or environmental contaminants **at or below the level found to be safe**, by the Food and Drug Administration (FDA) or approved by the Environmental Protection Agency (EPA) or the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA).

B. Expedited review procedure consists of a review of research involving human subjects by the UT Martin IRB Expedited board consisting of the chair and the secretary of the university board in accordance with the requirements set forth in 45 CFR, 46.110. Research activities may be eligible for **expedited review** if they present no more than minimal risk to human subjects **and** involve only procedures listed in one or more of the nine categories listed below. The nine categories activities listed should not be considered to be of minimal risk simply because they are listed. Inclusion on this list means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects

1. **Category G:** Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly

increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

b. Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) the medical device is cleared/approved for marketing

2. **Category H:** Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

a. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amount drawn may not exceed 550 ml in an 8-week period and collection may not occur more frequently than 2 times per week; or

b. From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8-week period and collection may not occur more frequently than 2 times per week.

NOTE: Children are defined in the HHS regulations as “persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402 (a).

3. **Category I:** Prospective collection of biological specimens for research purposes by noninvasive means.

4. **Category J:** Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwave. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.)

Examples:

(a) applying physical sensors either to the surface of the body or at a distance and not involving input of significant amounts of energy into the subject or an invasion of the subject's privacy;

(b) weighing or testing sensory acuity;

(c) magnetic resonance imaging;

(d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography; or

(e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. **Category K:** Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for non-research purposes (such as medical treatment or diagnosis).

Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45CFR 46.101 (b)(4). This listing refers only to research that is not exempt.

6. **Category L:** Collection of data from voice, video, digital, or image recordings made for research purposes.
7. **Category M:** Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identify, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

Note: Some research in this category may be exempt for the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.

8. **Category N:** Continuing review of research previously approved by the convened IRB as follows:

Where

- a. the research is permanently closed to the enrollment of new subjects;
 - b. all subjects have completed all research-related interventions; and
 - c. the research remains active only for long-term follow-up of subjects; or
 - d. no subjects have been enrolled and no additional risks have been identified; or
 - e. the remaining research activities are limited to data analysis.
9. **Category O:** Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
- a. Categories two (2) through eight (8) do not apply; and

- b. The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

10. Applicability of Expedited Review Categories

- a. The categories in this list apply regardless of the age of subjects, except as noted.
- b. The **Expedited** review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- c. The **Expedited** review procedure may not be used for classified research involving human subjects.
- d. IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened – utilized by the IRB.
- e. Categories one (1) through seven (7) pertain both to initial and continuing IRB review.

11. Additional Expedited Review Category Information

- a. The Federal policy concerning expedited review categories is contained in the *Federal Register* (Volume 63, Number 216: pages 60634-60367).
- b. Sources of Categories: Department of Health and Human Services-Office for Protection from Research Risks (OPRR), National Institutes of Health, HHS. OPRR and the Food and Drug Administration (FDA) have identical lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure.
- c. Historical Information: The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the *Federal Register* on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies* and institutions receiving support from those agencies for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research involving human subjects by an IRB with limited exceptions, informed consent of all research subjects; and informal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (DHHS) codification of the Federal Policy can be found at 45 CFR Part 46, Subpart A.
- d. Section 56-110 of the Federal Policy provides for expedited review procedures for certain categories of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the expedited review list as needed after consultation with the departments and agencies that are subject to the Federal

Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 (46FR 8392, 46FR 8980). It listed categories of research that could be reviewed by the IRB through an expedited review procedure. The FDA also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists have differed slightly, in that item nine (9) on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR 56.110.

*The following agencies adopted the Common Rule: Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency-Agency for International Development, Department of Housing and Urban Development; Department of Justice, Department of Defense; Department of Health and Human Services; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; Department of Transportation; Central Intelligence Agency; and the Social Security Administration. (OHRP)

C. Full Review procedure consists of a review of research involving human subjects by the UT Martin IRB in compliance with the requirements set forth in 45 CFR, 46.110. The full UT Martin IRB typically reviews research projects that involve participants selected from groups that are considered especially vulnerable to coercion or undue influence in research settings. These groups include children (including indirectly infants if their nursing mothers are research participants), fetuses, pregnant women, mentally disabled (i. e., cognitively impaired) persons, prisoners, and economically or educationally disadvantaged persons. The primary review concerns are (1) that the use of persons from these groups is justified, (2) that risks are minimized, and (3) that additional safeguards are implemented to minimize risks unique to each group. If the research risks are greater than minimal risks (i. e., those ordinarily encountered in daily life of during routine psychological or physical examinations), then the research must directly benefit participants, and those benefits must exceed the risks.

1. Categories of Full IRB Reviewed Research

- a. Projects requiring the use of deception.
- b. Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.
- c. Collection of information or recording of behavior which, if known outside the research, could reasonably place the subject at risk of civil, or criminal liability or damage the participant's social standing, financial standing, or employability.
- d. Collection of information regarding sensitive aspects of the participant's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.
- e. Studies in which the anticipated risks exceed the minimal risk definition.
- f. Survey and Interview research involving children requires full IRB review [Federal Policy §____.101(b)(2): 45 CFR 401(b)].

D. 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. Charts 10 and 11 also provide guidance for determining whether a waiver or alteration of consent is allowable.

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. 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?

September 24, 2004

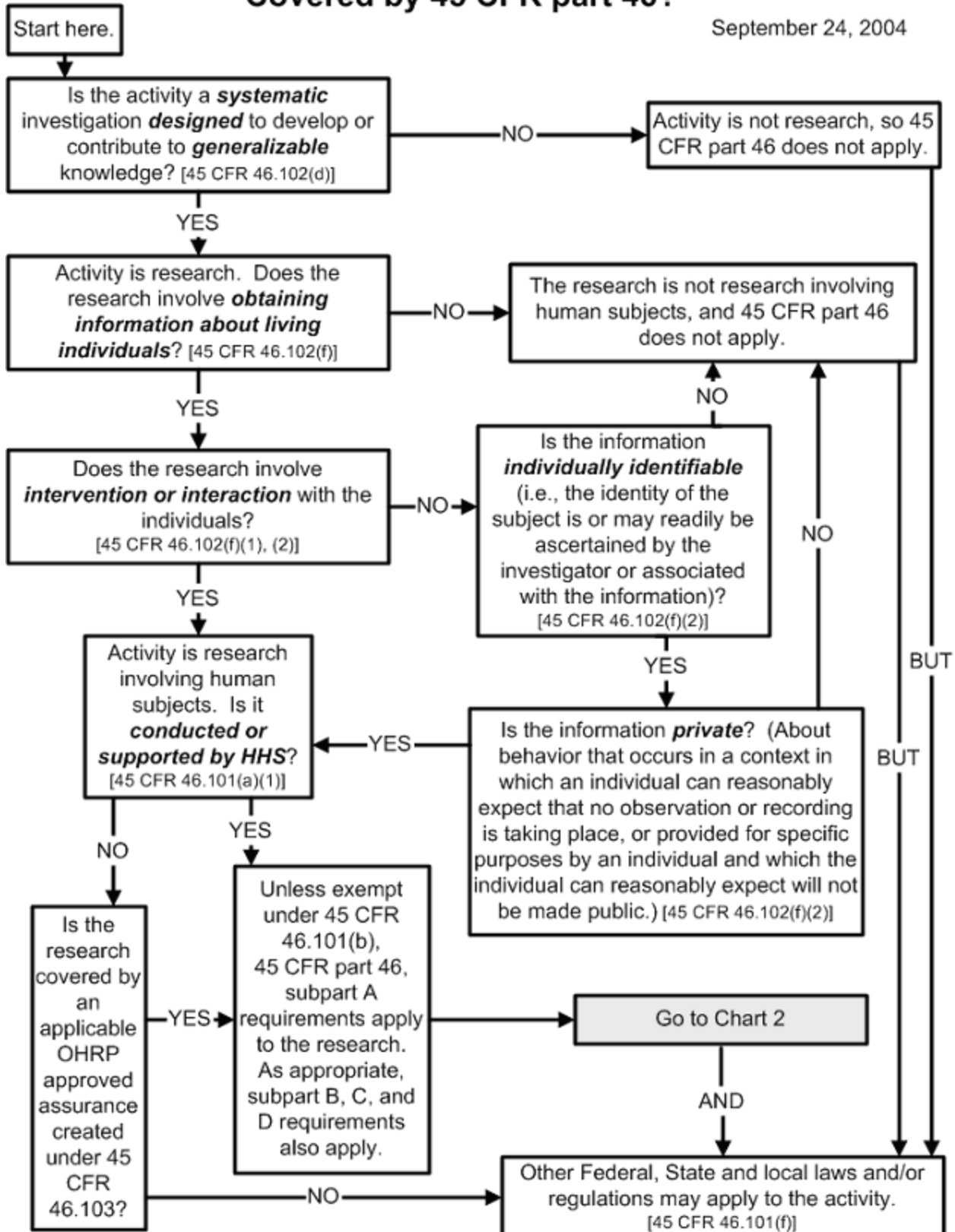


Chart 2: Is the Research Involving Human Subjects Eligible for Exemption Under 45 CFR 46.101(b)?

September 24, 2004

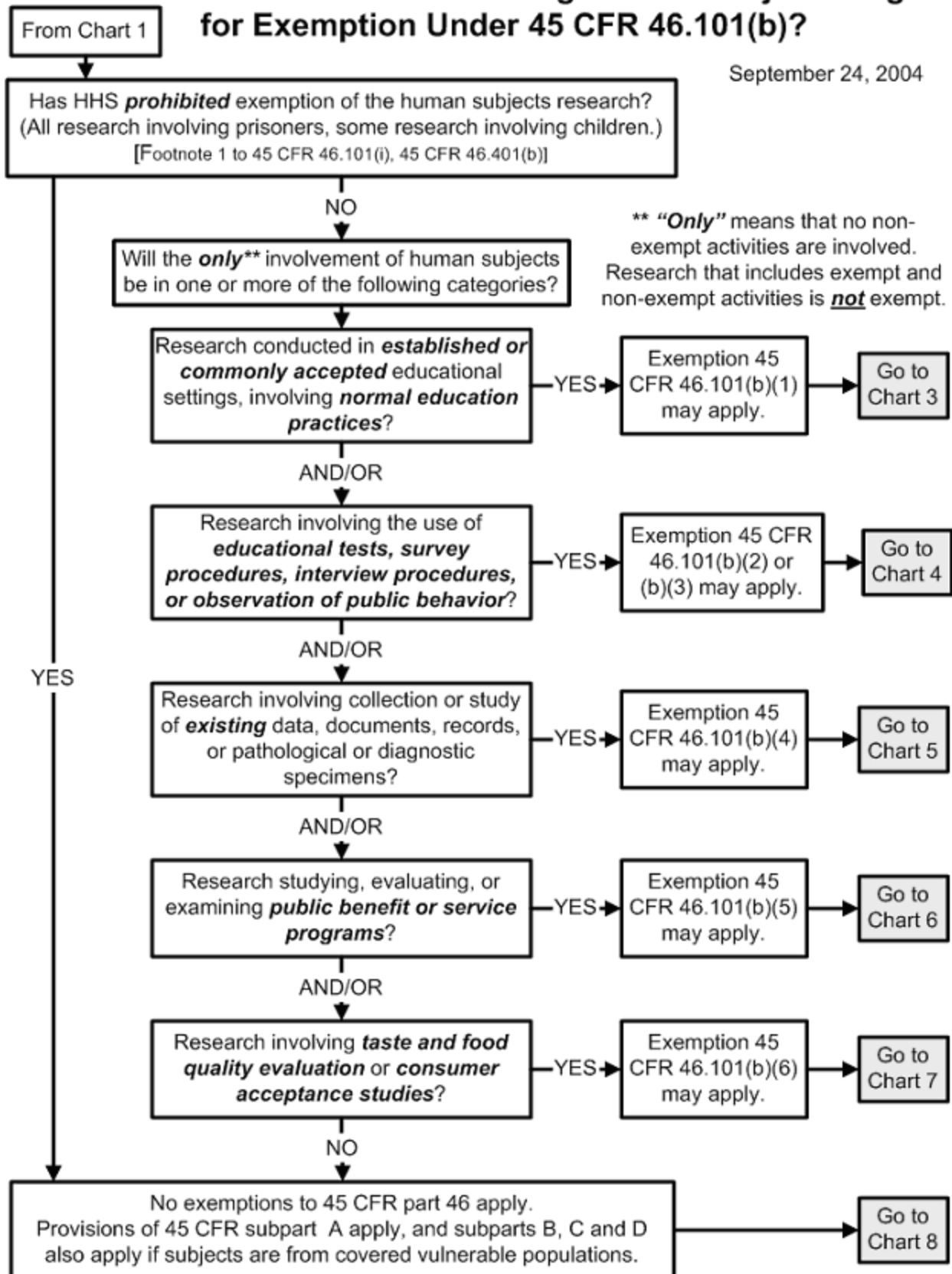
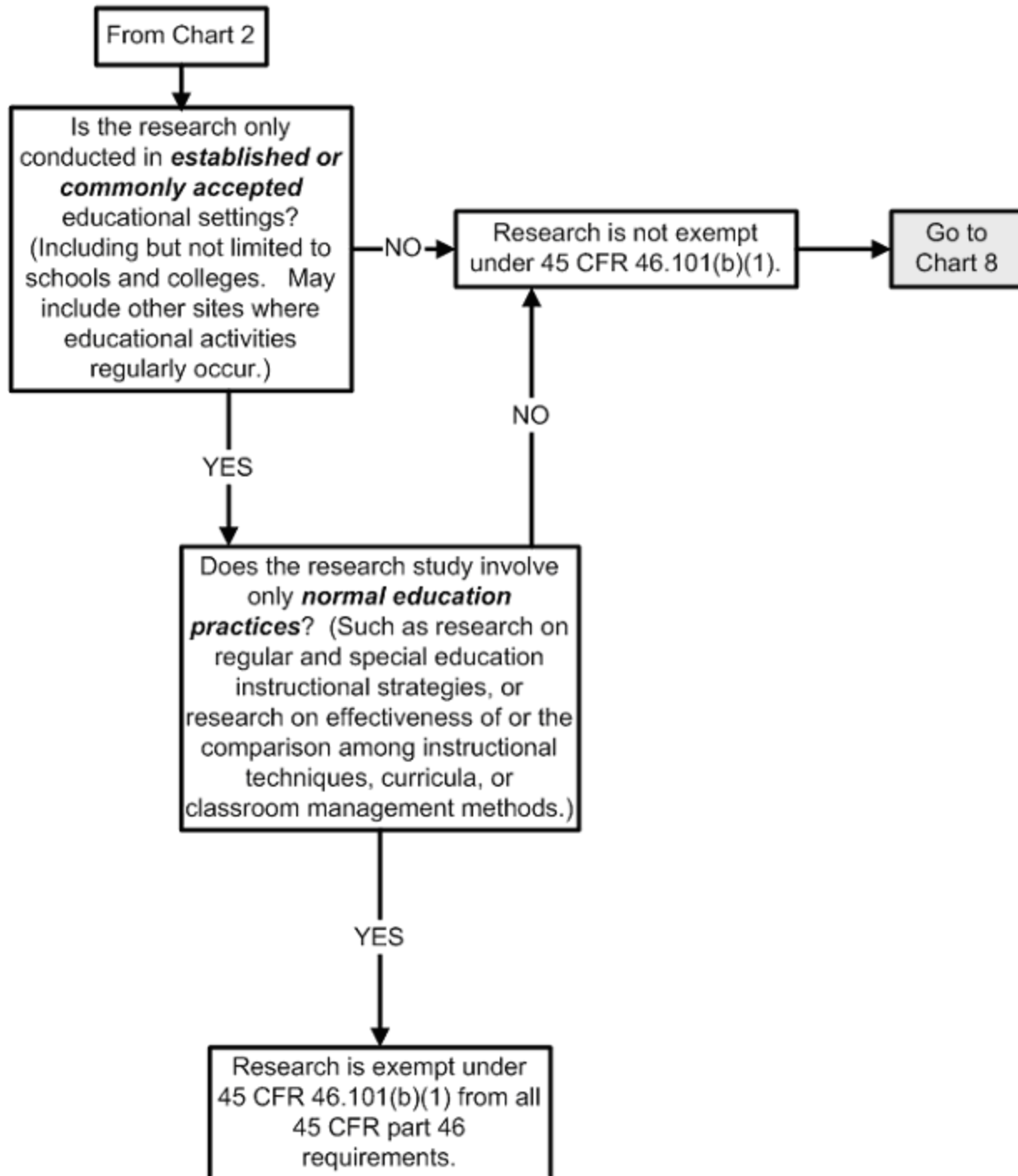
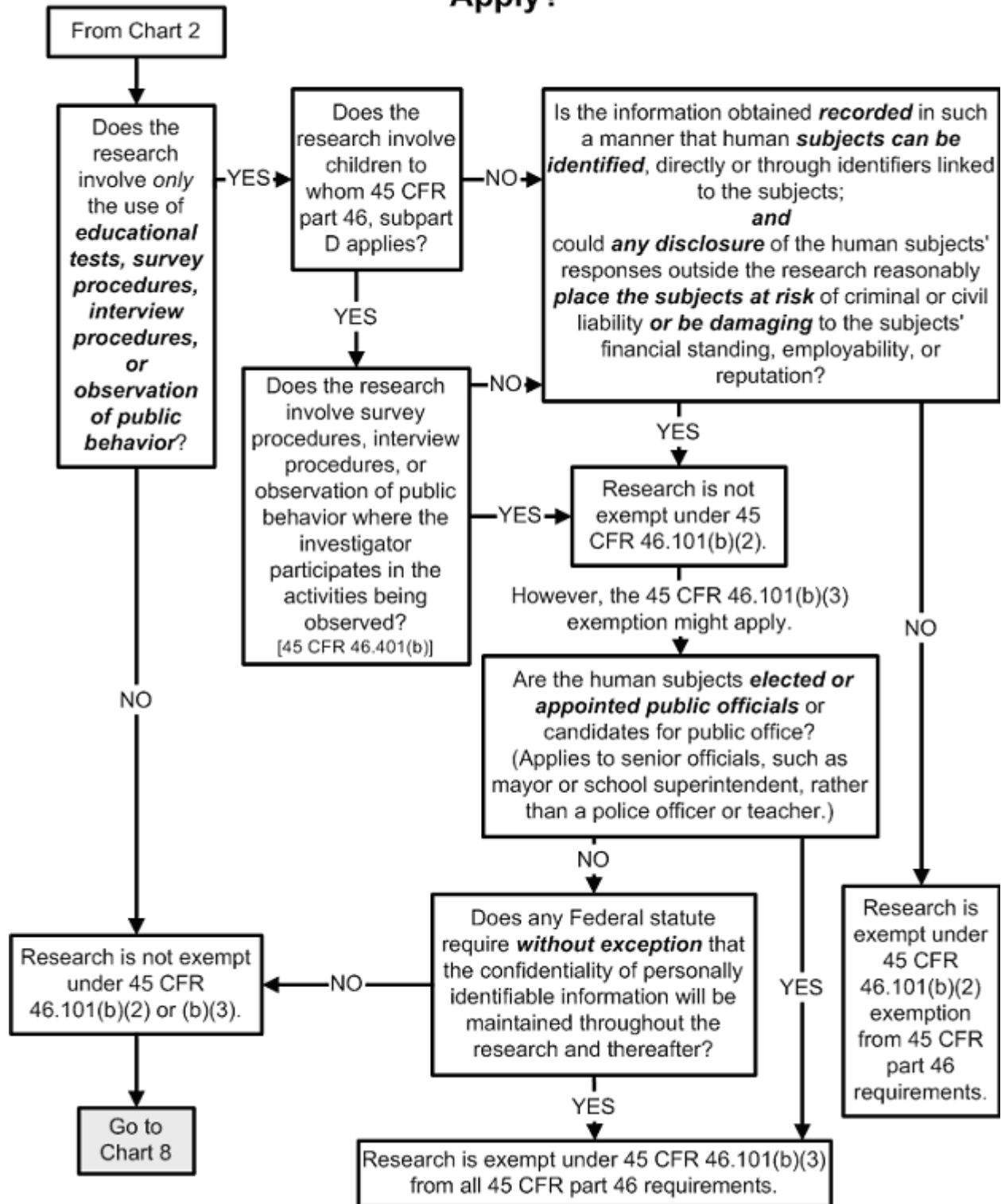


Chart 3: Does Exemption 45 CFR 46.101(b)(1) (for Educational Settings) Apply?



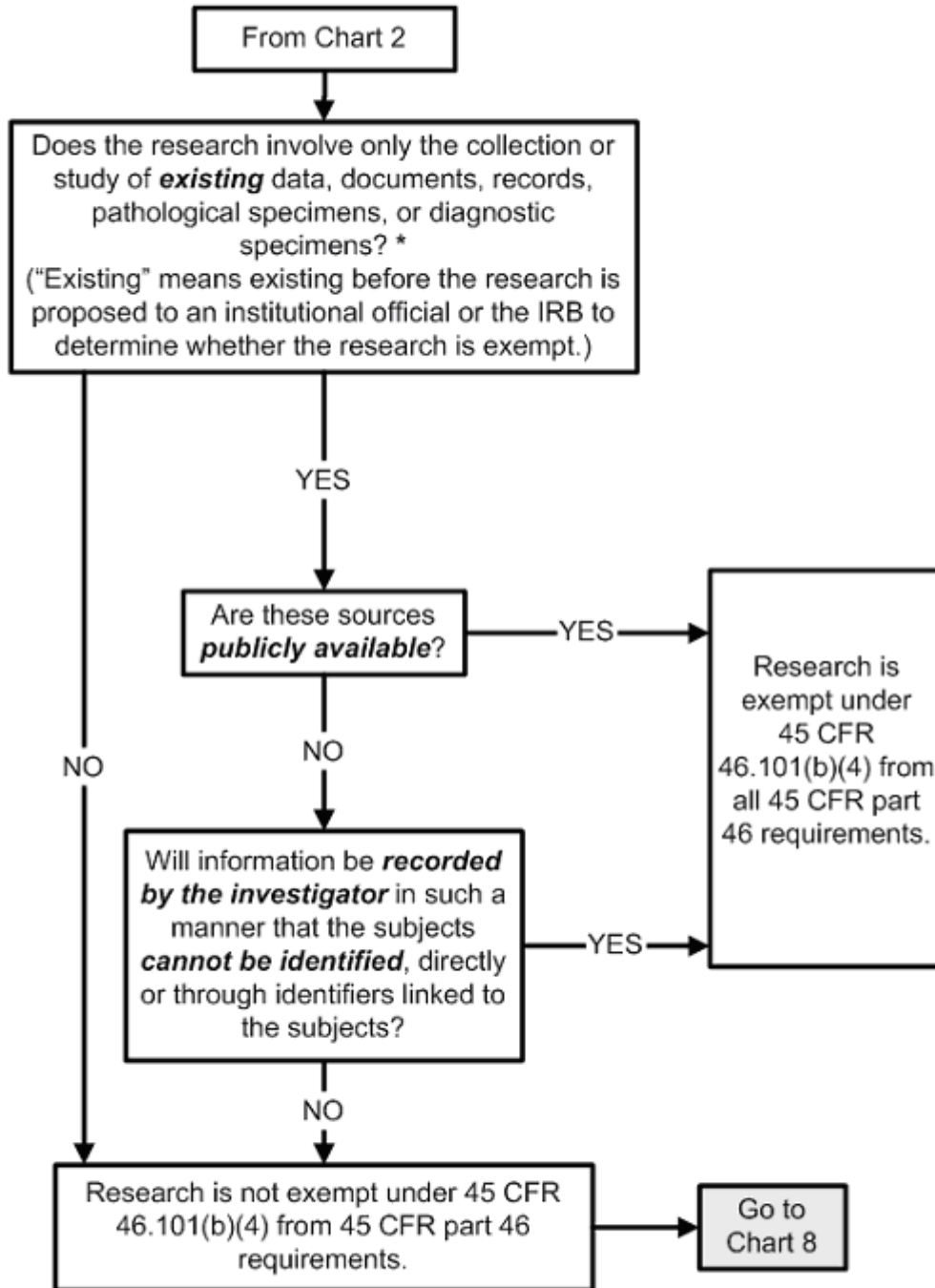
September 24, 2004

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



September 24, 2004

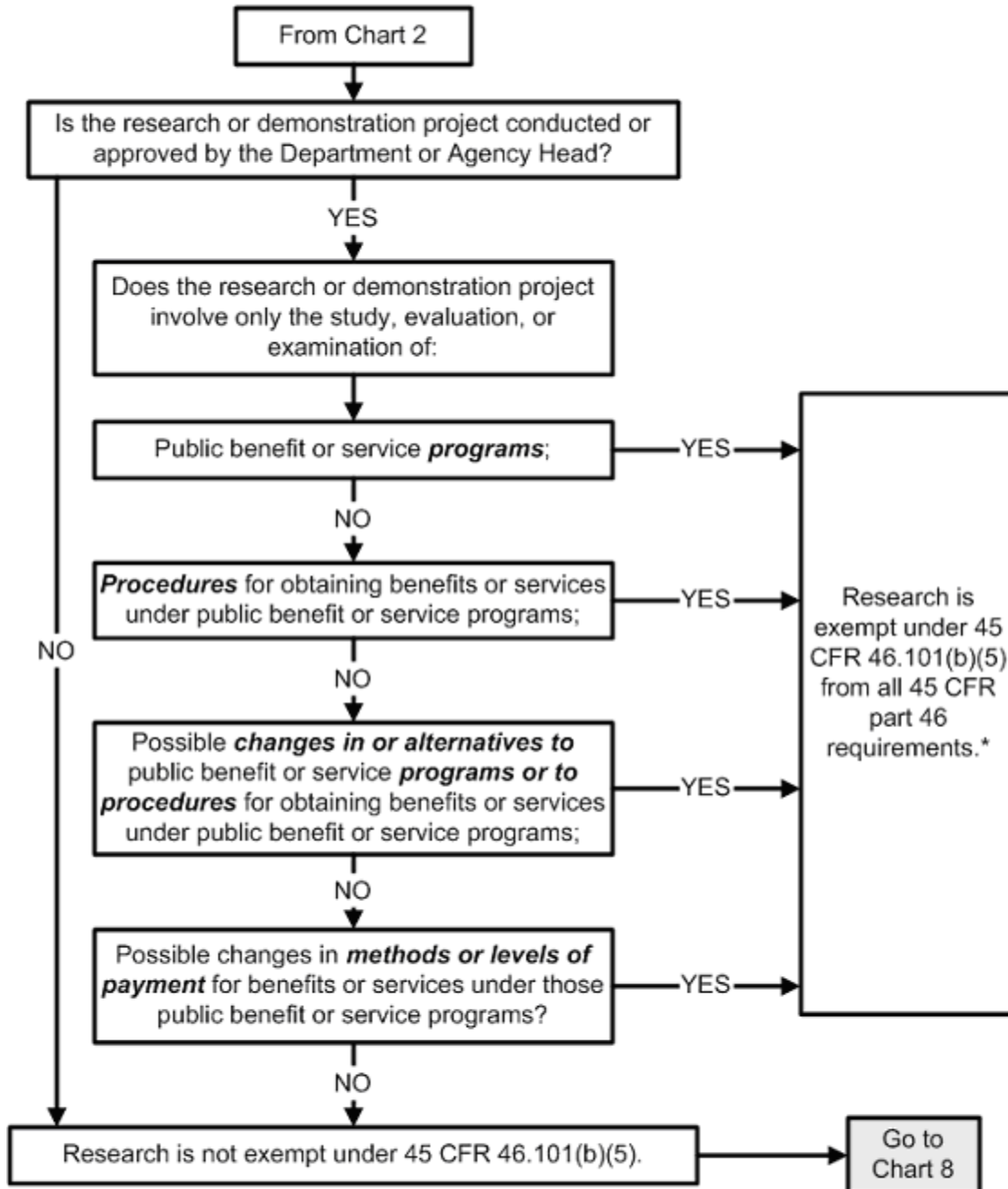
Chart 5: Does Exemption 45 CFR 46.101(b)(4) (for Existing Data Documents and Specimens) Apply?



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

September 24, 2004

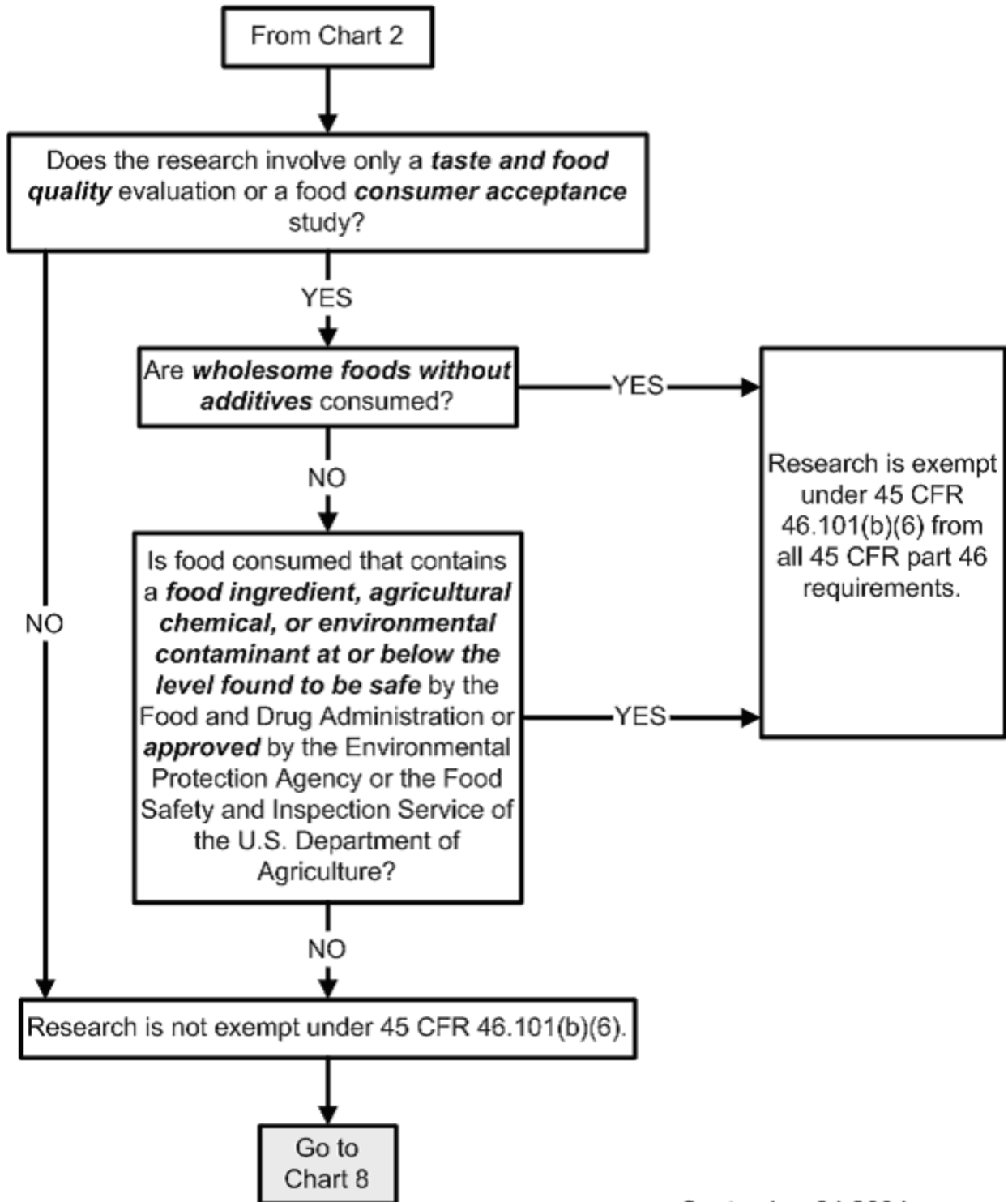
Chart 6: Does Exemption 45 CFR 46.101(b)(5) (for Public Benefit or Service Programs) Apply?



* Note: See OHRP guidance on exemptions at <http://www.hhs.gov/ohrp/policy/index.html#exempt> for further description of requirements for this exemption.

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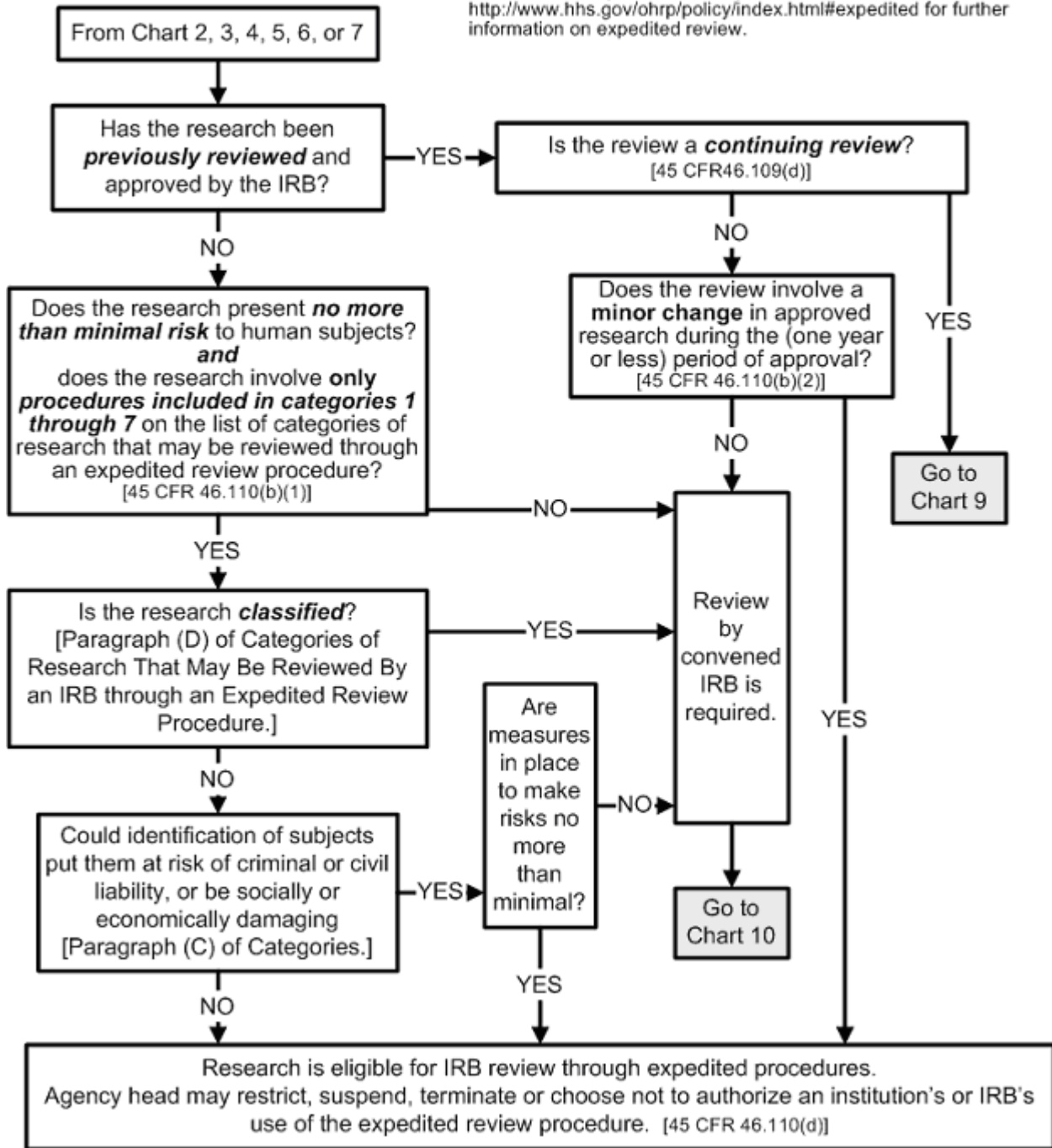
Chart 7: Does Exemption 45 CFR 46.101(b)(6) (for Food Taste and Acceptance Studies) Apply?



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

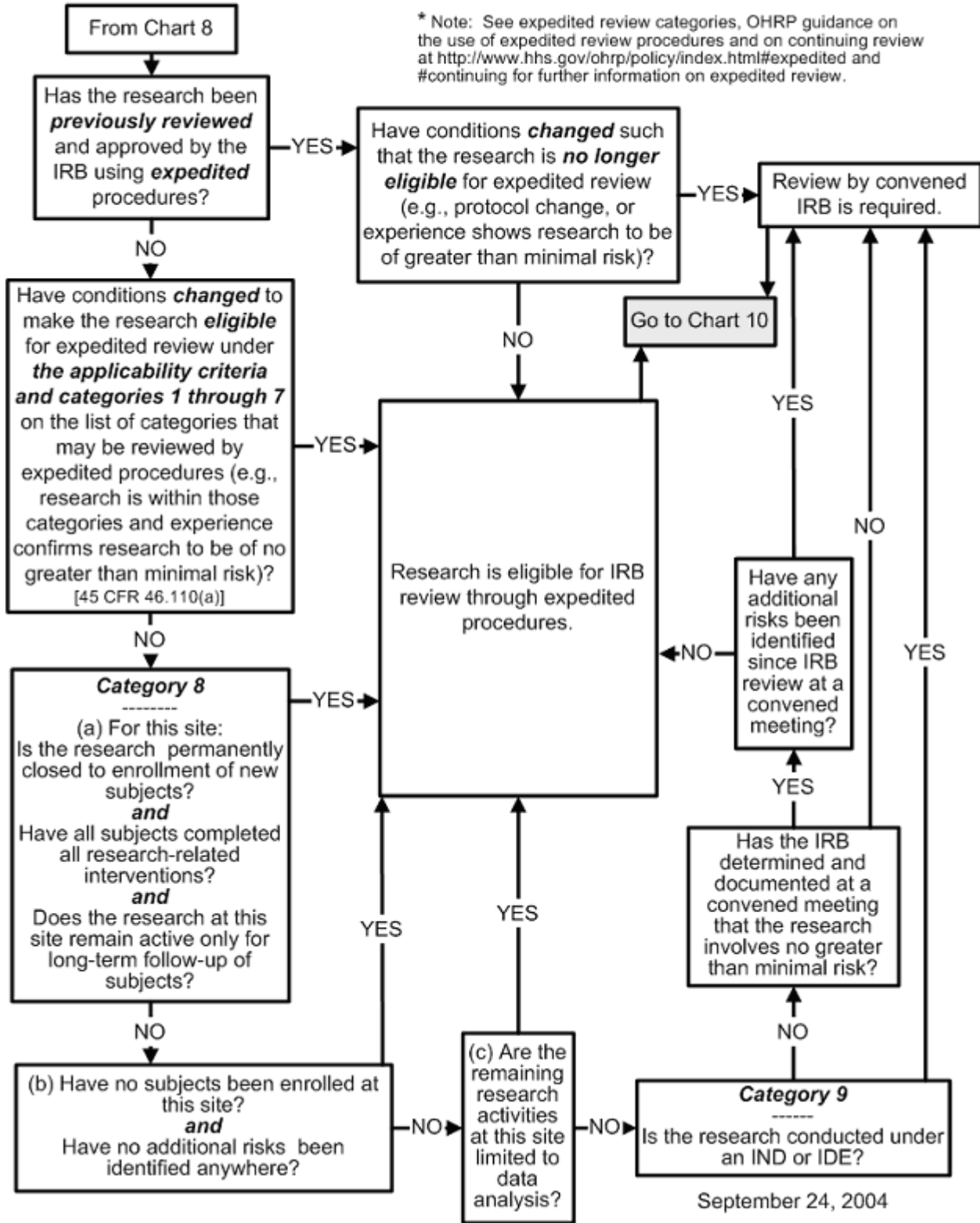
* Note: See expedited review categories and OHRP guidance on the use of expedited review procedures at <http://www.hhs.gov/ohrp/policy/index.html#expedited> for further information on expedited review.



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

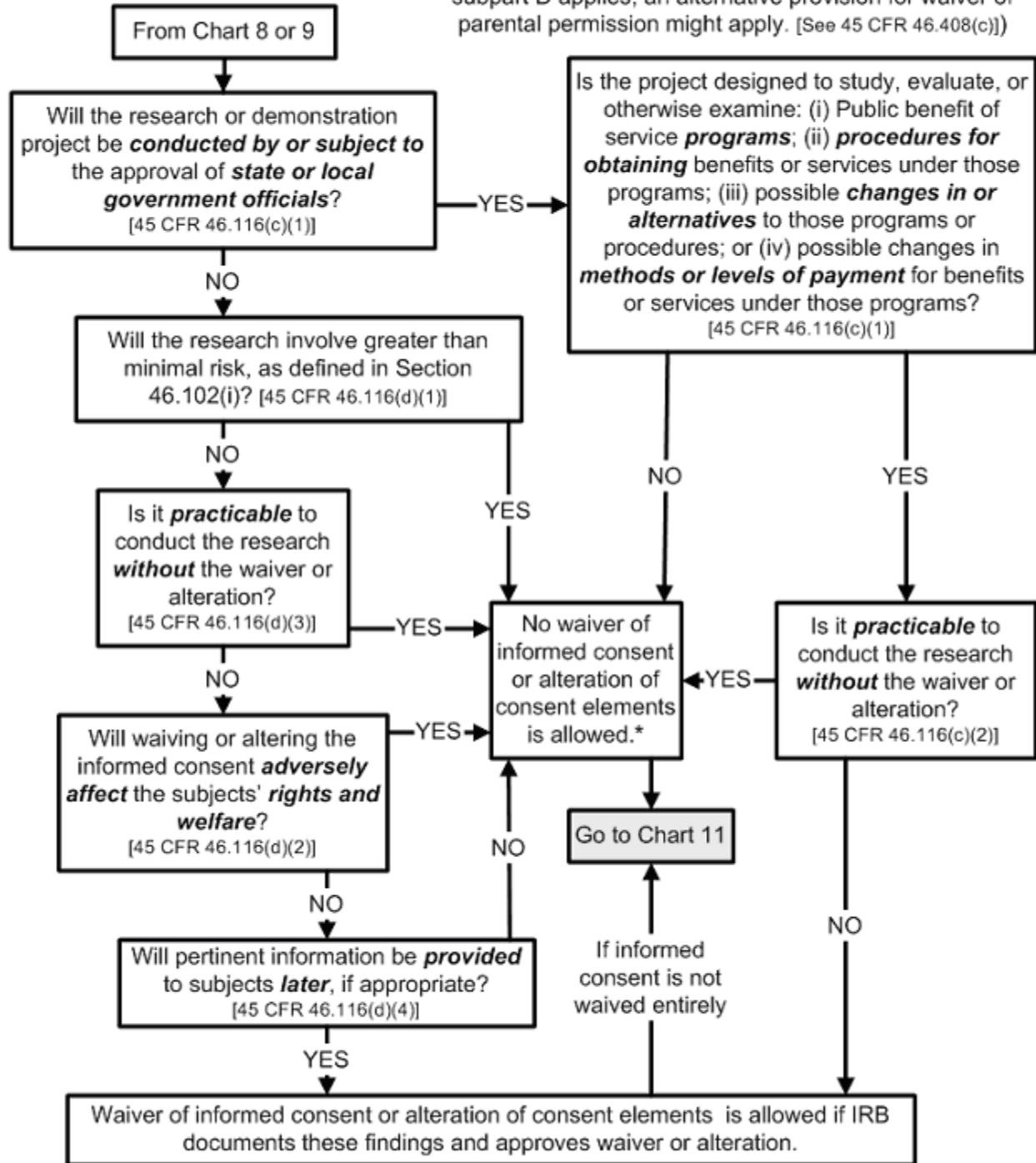
* Note: See expedited review categories, OHRP guidance on the use of expedited review procedures and on continuing review at <http://www.hhs.gov/ohrp/policy/index.html#expedited> and #continuing for further information on expedited review.



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

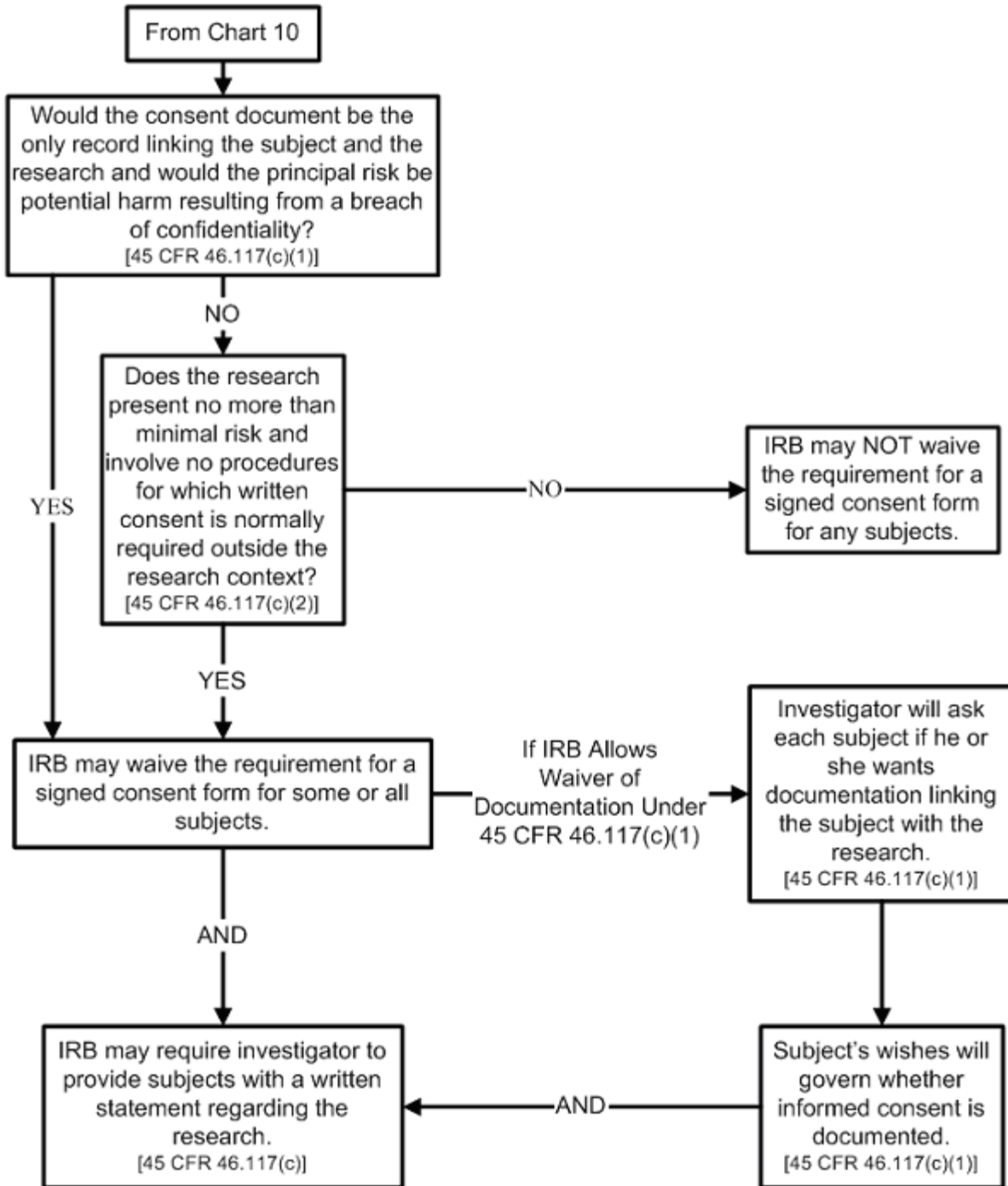
** (Note: If subjects include children to whom 45 CFR part 46, subpart D applies, an alternative provision for waiver of parental permission might apply. [See 45 CFR 46.408(c)])



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

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



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XII. RESEARCH INVOLVING SPECIAL OR VULNERABLE POPULATIONS

The federal regulations require that IRBs give special consideration to protecting the welfare of particularly vulnerable subjects, such as **children, cognitively impaired persons, pregnant women, prisoners, or economically or educationally disadvantaged persons** [Federal Policy §____.111]. For research to which the DHHS regulations are applicable, the DHHS regulations set forth specific provisions on research involving **pregnant women, fetuses, and neonates; human in vitro fertilization [45 CFR 46 Subpart B]; prisoners [45 CFR 46 Subpart C]; and children [45 CFR 46 Subpart D]**. In general, these special regulations allow IRBs to approve research that is of minimal risk or that will benefit the subjects directly. Investigations involving these subjects that present significantly greater than minimal risk without direct benefit to them must be reviewed and approved by the Secretary of Health and Human Services, in consultation with appropriate experts.

Institutions with DHHS-approved Assurances on file must abide by the provisions of 45 CFR 46 Subparts A-D. Some of the other departments and agencies have incorporated all provisions of 45 CFR 46 into their policies and procedures as well. The exemptions at 45 CFR 46.101(b), however, do not apply to research involving prisoners, fetuses, pregnant women, or human in vitro fertilization (*i.e.*, research to which Subparts B and C apply). Also, the exemption at 45 CFR 46.101(b)(2), for research involving survey or interview procedures, or observation of public behavior, does not apply to research involving children (*i.e.*, research to which Subpart D applies), except for research involving observations of public behavior when the investigator(s) do not participate in the activities being observed. [See Federal Policy §____.101, footnote 1.]

A. Children

Federal regulations [Title 45 CFR Part 46, Subpart D] require that the researchers explicitly address the measures taken to protect the welfare and rights of children participating in research projects. At the University of Tennessee at Martin, the adequacy of the protection measures is assessed by the IRB during the approval process. Because of the potential vulnerability of children, a higher standard of protection must be demonstrated for approval. As a result, almost all research involving children requires expedited or full-IRB review of IRB Applications. The only exception to this rule (discussed in [Section XI.A.](#)) occurs when the research involves observation of public behavior. All other minimal risk projects that would normally be considered exempt from IRB review are not exempt when children are involved.

Researchers may not initiate contact with potential child-participants, or begin data collection, before they have received **final approval from the IRB and the Authorized University Official assigning an IRB docket number**. Only after permission from the appropriate authorities has been granted in writing may potential child-participants' identifies be obtained from school classrooms, care-giving programs, or other agencies. For example, researchers wishing to study students in public school systems must obtain written permission from the school board or its authorized representative before student can be contacted. This approval cannot be used to require teachers or students to participate.

Federal law recommends the assent of the child and requires the permission of the parent(s), or guardian(s), in place of consent of the child before a child may be involved in a

research project. Research involving emancipated minors may not need parental permission, but full IRB committee approval must be obtained to waive the parental permission requirement. (See [Section IX – Definitions](#) - above for discussion of **Assent, Permission, and Guardian.**)

1. Use of Educational Records: Federal law [34 CFR 99, 99.03 through 99.37] governs the privacy and access to elementary and secondary school records. The primary rights of access to these records are given to parents, guardians, and to students (once they have reached 18 years of age). Except for administrative purposes, schools must withhold access to personally identifiable information from education records except with the written permission of the students; parents, or students once they have reached 18 years of age. To be valid, a written consent for disclosure of educational records must include three items: (1) a specification of the records to be disclosed, (2) the purpose(s) of the discloser, and (3) the party or class of parties to whom the disclosure will be made. The requirement for written permission applies to all research, except that conducted by or for educational agencies or institutions developing, validating, or administering predictive tests, administering student aid, or improving instruction (provided such studies will not permit the identification of individual students and that personally identifying data will be destroyed upon completion of the study).

2. Exempt Research Involving Children: The only research involving child-participants exempt from expedited or full IRB review is observation of public behavior. The definition of observation of public behavior requires that researchers not interact in anyway with the children, record their identities (including use of video- and audio-taping procedures), or place the children at risk. However, the observation of public behavior exemption does not apply when (1) the child-participants have a reasonable expectation of privacy (e. g., a private conversation in a public park); (2) survey instruments are used (this would constitute an interaction, even if conducted by an independent third-party, such as a teacher); and (3) the researcher rearranges or changes the setting/environment in which the public observation occurs.

3. Expedited Research Involving Children: Research projects that involve children may be eligible for expedited review if they present no more than minimal risk to children and involve only procedures listed in one or more of the nine (9) listed categories (See [Section XI.B.](#) of this Guide). The nine categories activities listed should not be considered to be of minimal risk simply because they are listed. Inclusion on this list means that the activity is eligible for review through expedited review procedures when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

Wards: Children who are wards of the State or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

- a. related to their status as wards; or
- b. conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

If the research is approved under paragraph (a) of this section, the IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual

acting on behalf of the child as guardian or in *loco parentis*. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization

B. Cognitively Impaired Individuals

The predominant ethical concern in research involving individuals with psychiatric, cognitive, or developmental disorders, or who are substance abusers is that their disorders may compromise their capacity to understand the information presented and their ability to make a reasoned decision about participation. Many individuals with disabilities affecting their reasoning powers may be residents of institutions responsible for their total care and treatment. The impact of institutionalization may further compromise their ability to exercise free choice (voluntariness). (These concerns apply both to voluntary patients and those committed involuntarily.) The eagerness for release may induce an institutionalized person, especially one who is involuntarily confined, to participate in research out of a desire to appear "rational" and "cooperative" to those who will make decisions about his or her release.

It is important to protect the privacy of all subjects and the **confidentiality** of information gathered in research exploring emotionally sensitive topics. Many patients do not want even the fact of their institutionalization divulged.

The recommendations of the National Commission for the Protection of Human Subjects resemble the recommendations made with respect to children. More recently, Annas and Glantz (1986) have argued that research should involve cognitively impaired subjects only where: (1) they comprise the only appropriate subject population; (2) the research question focuses on an issue unique to subjects in this population; and (3) the research involves no more than minimal risk. Levenson and Hamric (1989) argue that research involving greater than minimal risk may be acceptable where the purpose of the research is therapeutic with respect to individual subjects and where the risk is commensurate with the degree of expected benefit.

1. Selection of Subjects: It is now generally accepted that research involving persons whose autonomy is compromised by disability or restraints on their personal freedom should bear some direct relationship to their condition or circumstances. Persons who are **institutionalized**, particularly if disabled, should not be chosen for studies that bear no relation to their situation just because it would be convenient for the researcher. An institutional setting can be advantageous to the conduct of research - the population is easily accessible, close supervision to prevent extraneous influences is possible, and medical monitoring and emergency services are available. Some not uncommon characteristics of the institutional setting, however, create circumstances that may compromise the voluntary nature of participation in research. For example, institutionalized individuals may have become emotionally dependent on their caretakers and may acquiesce too readily to requests for their "cooperation." Persons who are totally dependent on an institution may be vulnerable to perceived or actual pressures to conform to institutional wishes for fear of being denied services or privileges. If medical care, staff attention, or living conditions are inadequate, an invitation to move into a special unit or research ward may be appealing.

Finally, with little or no opportunity to make decisions regarding their daily living, the ability of institutionalized subjects to make choices may be further diminished.

Nevertheless, IRBs should not make assumptions as to the effect of an institutional setting on **voluntariness** or **competence**. People do not automatically become incapable of competent and voluntary consent the moment they enter a mental institution. On the other hand, institutionalized individuals (particularly retarded persons) have been used as convenient research subjects in drug tests totally unrelated to their disorders or institutionalization. This exploitation of the vulnerable and the "voiceless" led the National Commission to recommend that, even in research on mental disabilities, subjects should be recruited from among noninstitutionalized populations whenever possible.

2. Degree of Risk. No clear consensus exists on the acceptable degree of risk when mentally compromised persons are involved in the research. One position holds that research that presents more than minimal risk should involve mentally compromised persons only if they will derive a direct and significant benefit from participation. The National Commission recommended that a minor increase over minimal risk may be permitted in research involving those institutionalized as mentally disabled, but only where the research is designed to evaluate an intervention of foreseeable benefit to their care. For research that does not involve beneficial interventions and that presents more than minimal risk, the National Commission recommended that the anticipated knowledge sought should be of vital importance for understanding or eventually alleviating the subject's disorder or condition. Finally, the National Commission recommended that there be additional ethical review at the national level for research projects the IRB believes should be supported - because the knowledge to be gained may be of major significance to the prevention, diagnosis, or treatment of mental disorders - but that would not otherwise be approved at the local level. The American College of Physicians has similarly recommended the creation of a national board to review research that involves more than minimal risk and that carries no direct benefit for the subjects [1989, p. 846]. Since the mechanism of a national board is not currently available, IRBs reviewing such research should consider obtaining assistance from expert consultants.

3. Limiting Risks. IRBs must be sure that investigators have included a description of appropriate psychological or medical screening criteria to prevent or reduce the chances of adverse reactions to the therapeutic and research procedures. When appropriate, IRBs might want to require that other health care providers be consulted to ensure that proposed research procedures will not be detrimental to ongoing therapeutic regimens. Specific diagnostic, symptomatic, and demographic criteria for subject recruitment should be described in the research proposal.

4. Problems of Consent and Competence. Consent to research involving cognitively impaired subjects through any of the intramural programs of the National Institutes of Health (*e.g.*, the National Institute of Mental Health, the National Institute of Neurological and Communicative Disorders and Stroke, the National Institute on Aging, and the National Institute on Alcohol Abuse and Alcoholism) is guided by NIH policy on consent to research with impaired human subjects. This policy sets out, in matrix form, conditions under which cognitively impaired subjects may participate in research of varying risk.

As a general rule, all adults, regardless of their diagnosis or condition, should be presumed competent to consent unless there is evidence of serious mental disability that

would impair reasoning or judgment. Even those who do have a diagnosed mental disorder may be perfectly able to understand the matter of being a research volunteer, and quite capable of consenting to or refusing participation. Mental disability alone should not disqualify a person from consenting to participate in research; rather, there should be specific evidence of individuals' incapacity to understand and to make a choice before they are deemed unable to consent.

Persons formally adjudged incompetent have a court-appointed guardian who must be consulted and consent on their behalf. Officials of the institution in which incompetent patients reside (even if they are the patient's legal guardians) are not generally considered appropriate, since their supervisory duties may give rise to conflicting interests and loyalties. Family members or others financially responsible for the patient may also be subject to conflicting interests because of financial pressures, emotional distancing, or other ambivalent feelings common in such circumstances. IRBs should bear this in mind when determining appropriate consent procedures for cognitively impaired subjects.

Some individuals may be incompetent and have no legal guardian. One such example would be mentally retarded adults whose parents "voluntarily" institutionalized them as children and have never subsequently gone through formal proceedings to determine incompetence and have a guardian appointed. Another example would be geriatric patients with progressive cognitive disorders (*e.g.*, senile dementia of the Alzheimer type). Typically, a spouse or adult child of such patients consents to their medical care, but no one is a "legally authorized representative." The extent to which family members may legally consent to the involvement of such patients in research (especially if no benefit to the subjects is anticipated) is not clear. According to a position paper published by the American College of Physicians (1989), surrogates of cognitively impaired persons should not consent to research that holds out no expected benefit if such research presents more than minimal risk of harm or discomfort. As mentioned earlier, the ACP also, however, recommended the creation of a national board to review research that involves more than minimal risk and that carries no direct benefit for the subjects [1989, p. 846].

Because no generally accepted criteria for determining competence to consent to research (for persons whose mental status is uncertain or fluctuating) exist, the role of the IRB in assessing the criteria proposed by the investigator is of major importance. The selection of an appropriate representative to consent on behalf of those unable to consent for themselves must be accomplished without clear guidance from statutes, case law, or regulations. Within the boundaries of existing legal precedents, IRBs can be creative in helping investigators formulate appropriate procedures in these uncertain areas. IRBs should be sure, however, to seek legal advice to determine the applicability of state laws that might affect the participation of legally incompetent persons in research. [See also Levine 1986, 270-76.]

Research projects that plan to enroll cognitively impaired participants must be submitted as expedited or full IRB review applications. The participation of mentally disabled individuals in research that would typically fall in exempt categories cannot be reviewed using exempt procedures. Researchers should clearly describe their informed consent and assent procedures in their Applications.

5. Points to Consider

- a. Does the IRB need to include a member knowledgeable about and experienced with the mentally disabled or cognitively impaired?
- b. Does the research pertain to mental disabilities so that it is necessary to involve persons who are mentally disabled as subjects?
- c. If the investigator proposes to involve institutionalized individuals, has he or she provided sufficient justification for using that population? Are noninstitutionalized subjects appropriate for the research and reasonably available? Does the research pertain to aspects of institutionalization?
- d. Are adequate procedures proposed for evaluating the mental status of prospective subjects to determine whether they are capable of consenting? Are these procedures appropriate both to the subject population and the nature of the proposed research?
- e. Is more than minimal risk involved? If so, is the risk justified by anticipated benefits to the participating subjects and the importance of the knowledge that may reasonably be expected to result?
- f. Is it possible to identify persons authorized to give legally valid consent on behalf of any individuals judged incapable of consenting on their own behalf? Should assent of the prospective subjects also be required? If incapable of giving valid consent, can subjects' objection to participation be overridden? Under what circumstances?
- g. Should an advocate or consent auditor be appointed to ensure that the preferences of potential subjects are elicited and respected? Should someone ensure the continuing agreement of subjects to participate, as the research progresses?
- h. Should the patient's physician or other health care provider be consulted before any individual is invited to participate in the research? Is the research likely to interfere with ongoing therapy or regimens? Is it possible that the request to participate itself might provoke anxiety, stress, or other serious negative response?

6. Applicable Laws and Regulations: IRBs should be aware of any applicable law in their state, particularly those relating to consent by family members on behalf of persons incapable of consenting on their own. Note that consent to participation in research may differ from consent to medical treatment. In addition, it should be noted that some federal agencies (including components of the Department of Defense) prohibit the participation of mentally disabled persons in research conducted under their auspices.

C. Pregnant Women or fetuses (§46.204)

Pregnant women or fetuses may be involved in research if **all** of the following conditions are met:

1. Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been

- conducted and provide data for assessing potential risks to pregnant women and fetuses;
2. The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means.
 3. Any risk is the least possible for achieving the objectives of the research;
 4. If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means, her consent is obtained in accord with the informed consent provisions of subpart A of this part;
 5. If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest.
 6. Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate;
 7. For children as defined in §46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of [X.C.1-8](#) of this *Guide*;
 8. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
 9. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
 10. Individuals engaged in the research will have no part in determining the viability of a neonate

D. Prisoners (§46.302 - .306)

Inasmuch as prisoners may be under constraints because of their incarceration which could affect their ability to make a truly voluntary and uncoerced decision whether or not to participate as subjects in research, it is the purpose of this subpart to provide additional safeguards for the protection of prisoners involved in activities to which this subpart is applicable.

1. Composition of Institutional Review Boards Where Prisoners are Involved (§46.304)

In addition to satisfying the requirements in §46.107 of this part, an Institutional Review Board, carrying out responsibilities under this part with respect to research covered by this subpart, shall also meet the following specific requirements:

- a. A majority of the Board (exclusive of prisoner members) shall have no association with the prison(s) involved, apart from their membership on the Board.
- b. At least one member of the Board shall be a prisoner, or a prisoner representative with appropriate background and experience to serve in that capacity, except that where a particular research project is reviewed by more than one Board only one Board need satisfy this requirement.

2. Additional duties of the Institutional Review Boards Where Prisoners are Involved (§46.305)

a. In addition to all other responsibilities prescribed for Institutional Review Boards under this part, the Board shall review research covered by this subpart and approve such research only if it finds that:

1. the research under review represents one of the categories of research permissible under §46.306(a)(2);
2. any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the Board justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. the information is presented in language which is understandable to the subject population;
6. adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and

7. where the Board finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

b. The Board shall carry out such other duties as may be assigned by the Secretary.

c. The institution shall certify to the Secretary, in such form and manner as the Secretary may require, that the duties of the Board under this section have been fulfilled.

3. Permitted Research Involving Prisoners (§46.306)

a. Biomedical or behavioral research conducted or supported by DHHS may involve prisoners as subjects only if:

1. the institution responsible for the conduct of the research has certified to the Secretary that the Institutional Review Board has approved the research under §46.305 of this subpart; and

2. in the judgment of the Secretary the proposed research involves solely the following:

a. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

b. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

c. research on conditions particularly affecting prisoners as a class (for example, vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addiction, and sexual assaults) provided that the study may proceed only after the Secretary has consulted with appropriate experts including experts in penology, medicine, and ethics, and published notice, in the *Federal Register*, of his intent to approve such research; or

d. research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the subject. In cases in which those studies require the assignment of prisoners in a manner consistent with protocols approved by the IRB to control groups which may not benefit from the research, the study may proceed only after the Secretary has consulted with appropriate experts, including experts in penology, medicine, and ethics, and published notice, in the *Federal Register*, of the intent to approve such research.

e. Except as provided in paragraph (a) of this section, biomedical or behavioral research conducted or supported by DHHS shall not involve prisoners as subjects.

XIII. MOST FREQUENTLY ASKED QUESTIONS

DHHS receives many requests for assistance in interpreting and applying its human subjects research regulations, which are codified at 45 CFR 46. This Section provides answers to 18 most frequently asked questions that would be applicable to research conducted at UT Martin.

1. **Question:** What is the function of the Office for Protection from Research Risks (OPRR) in the DHHS regulations?

Answer: The Office for Protection from Research Risks (OPRR) is a unit within the Department of Health and Human Services (DHHS) that implements the regulations on behalf of the Secretary, HHS. It is located in the Office of the Director, Office of Extramural Research, National Institutes of Health (NIH), Bethesda, Maryland.

The Public Health Service Act required DHHS to issue regulations for the protection of human subjects of research and to implement a program of instruction and guidance in ethical issues associated with such research. The regulations are codified at Title 45 Part 46 of the Code of Federal Regulations, Protection of Human Subjects (45 CFR 46), last revised on June 18, 1991.

2. **Question:** How is 45 CFR 46 implemented?

Answer: DHHS regulations require institutions to assure their compliance with 45 CFR 46 before initiating participation in DHHS-conducted or - supported research involving human subjects. The terms of these written institutional assurances are negotiated with OPRR and constitute binding commitments to comply with the provisions of 45 CFR 46. Each negotiated commitment is called an **Assurance** document and is entered into by the institution and OPRR, representing DHHS. There is more than one type of Assurance document, depending on the nature of the research and other considerations. Each Assurance document stipulates the method(s) by which the institution will protect the rights and welfare of research subjects in accordance with the regulations [45 CFR 46.103].

3. **Question:** To what activities does 45 CFR 46 apply?

Answer: The regulations for the protection of human participants in research apply to all research involving human participants that is conducted or supported, in whole or in part, by DHHS in foreign or domestic settings. Note that **any** support provided by DHHS (*e.g.*, supplying a drug for research purposes) may trigger applicability of the regulations [45 CFR 46.101].

4. **Question:** If an IRB reviews a protocol that is closed to accruals before the institution initiates involvement in the research, must the IRB retain its records on the project for three (3) years beyond the completion of the research [45 CFR 46.115]?

Answer: While most records (*e.g.*, the protocols) need not be retained, some, (*e.g.*, any IRB minutes in which the project is discussed) should be preserved.

Institutional policy, however, may stipulate that all IRB records are to be kept for three (3) years. (See Section [VI.A.4.](#) of this *Guide*)

5. **Question:** Must an IRB perform continuing reviews of protocols in which patient accruals have been closed and the research interventions are completed, but investigators are still collecting follow-up data?

Answer: Yes. So long as data are being collected for an organized research project, the IRB must continue to review the status of the protocols and the details of the continuing data gathering activity. If the continuing research meets the requirements for expedited review, the expedited review process may be used, if desired by the IRB.

6. **Question:** Why would a standard cooperative research protocol or a standard informed consent document need review at the local level when it has already been reviewed by another national organization (*e.g.*, the National Institutes of Health, the National Cancer Institute, or a cooperative research group), or even by the IRB of another institution with an approved Assurance?

Answer: Cooperative protocol requirements may be standard, but the research setting is not standard across institutions. In addition, one should not assume that because a protocol or informed consent document has been reviewed by another entity, it necessarily conforms to pertinent regulations, local laws, or the local research setting. For example, local laws, institutional policies and constraints, professional and community standards, and population differences are all factors that can influence the research setting. [See 45 CFR 46.103(d), 46.107(a), and 46.111(a)(3), noting the relevance of the particular setting in which the research is to take place.]

7. **Question:** Certain research involving prisoners or children can be approved only upon review by the Secretary, HHS, in consultation with a panel of experts (specified in the regulations) [45 CFR 46.306(2)(c)-(d) (prisoners) and 46.407 (children).] Also, certain research involving fetuses, pregnant women, and human in vitro fertilization requires review by an Ethics Advisory Board established by the Secretary [45 CFR 46.204 and 46.211]. When a Multiple Projects Assurances (MPA) -holding institution reviews research that is neither supported nor conducted by DHHS, does it have to meet these special review requirements?

Answer: The institution's Assurance requires the institution to protect the rights and welfare of human research subjects whether or not the research is supported or conducted by DHHS [Federal Policy §____.103(b)(1)]. Further, institutions are encouraged to treat all research involving human subjects with the same level of review, regardless of the source of funding. In the case of research that would receive a second level of review if it were DHHS-supported, institutions should appoint a special review panel composed of the same kinds and quality of experts who would likely have advised the Secretary.

8. **Question:** What role does an advocate play in the review of research involving children who are wards of the state?

Answer: An advocate for a child who is a ward of the state has a fiduciary relationship (one of trust and confidence) to the child. In other words, the advocate must act with the child's interest as the primary consideration.

9. **Question:** Exemption 4 [45 CFR 46.101(b)(4)] covers research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens. When are data, documents, records, and specimens considered to be **existing** for the purposes of this exemption? Can an investigator use, for instance, blood specimens that have been drawn for another purpose?

Answer: To qualify for this exemption the data, documents, records, or specimens must be in existence *before* the project begins. An example might be helpful. Suppose Investigator A wishes to screen blood samples at a rural hospital for incidence of HIV infection. She does not want to draw specimens specifically for this purpose; rather she proposes to use specimens that were drawn for some other purpose but which remain in the hospital laboratory. If Investigator A proposes to use specimens that had been drawn prior to the initiation of her research and are, for some reason, "on the shelf," the protocol will qualify as exempt under 46.101(b)(4), assuming the other requirements of 46.101(b)(4) are met (*i.e.*, the sources are either publicly available or the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects). If she proposes to use specimens that will be drawn after the start date of her project for reasons unrelated to her research, the protocol is not exempt from IRB review, even though the specimens will be drawn regardless of her use of the excess blood. The protocol may, however, qualify for expedited review.

In the behavioral sciences, suppose Investigator B wishes to examine court records of involuntary commitments to psychological institutions. If he uses court records that were on file before the initiation of his research, the protocol will qualify as exempt under 46.101(b)(4). If he proposes to use records filed after the initiation of the project, the protocol is not exempt from IRB review, although it may qualify for expedited review.

The principle behind this policy is that the rights of individuals should be respected; subjects must consent to participation in research. When specimens and other data or records have yet to be collected, consent may be more easily sought. Where circumstances warrant, however, the investigator may seek a waiver of informed consent in accordance with the regulations [Federal Policy §____.116(d)].

10. **Question:** If an investigator is conducting a "masked" study, are the exemptions of 46.101(b) applicable, since no identifiers will be used?

Answer: It is a misnomer that subjects are not identified in masked studies. Research records do reflect the identity of subjects, either directly or through identifiers (codes) that can be linked to them. What is "masked" in a single-masked study is the identity of the intervention the subject receives: the subject does not know whether she is receiving the investigational intervention or a standard intervention. In a double-masked study, neither the subject nor the investigator knows which intervention the subject receives.

11. **Question:** Do the exemptions apply to **XII.C** (fetuses, pregnant women, and human in vitro fertilization) **and XII.D.** (prisoners) of this *Guide*?

Answer: No. In addition, with respect to research involving **children (XII.A. of this Guide)**, the exemption provided in 46.101(b)(2) for research involving survey or interview procedures or observation of public behavior does not apply, except for research involving observations of public behavior when the investigator(s) does not participate in the activities being observed.

12. **Question:** Can IRBs use an expedited review procedure when applying for a Single Project Assurance (SPA) from OPRR [45 CFR 46.110]?

Answer: No. Since SPAs are used by institutions that do not regularly engage in DHHS-supported research involving human subjects, special care must be taken to ensure that the subjects' welfare is fully considered. Institutions holding MPAs have established records of experience in reviewing human subjects research that SPA institutions may not have. OPRR policy is therefore to require that all research activities requiring an SPA be reviewed by the full IRB.

13. **Question:** Must investigators provide subjects with all of the information listed in 45 CFR 46.115(a) (basic elements) and (b) (additional elements) as part of the informed consent process unless the IRB specifically provides otherwise?

Answer: The additional elements of informed consent listed in 45 CFR 46.115(b) are required when they are appropriate to the research being conducted. It is necessary for the IRB to determine explicitly their inapplicability.

14. **Question:** Why does DHHS not allow for an emergency exception to IRB review as does the FDA? [See 21 CFR 50.23 and 56.104(c).

Answer: DHHS regulations require that research involving human participants receive full IRB review and approval, except where expedited review is specifically permitted, before initiation of the research [45 CFR 46.103(b)]. Physicians, however, do retain the authority to provide emergency medical care to their patients [45 CFR 46.116(f)]. On May 15, 1991, OPRR issued the following statement clarifying emergency treatment of a patient by a physician when that patient is also a research subject:

Whenever emergency care is initiated without prior IRB review and approval, the patient may not be considered to be a research subject. Such emergency care may not be claimed as research, nor may the outcome of such care be included in any report of a research activity. Simply stated: [D]HHS regulations for the protection of human subjects do not permit research activities to be started, even in [an] emergency, without prior IRB review and approval.

If the emergency care involves drugs, devices, or biologics that are considered to be investigational by the Food and Drug Administration (FDA), then it may be necessary to meet FDA requirements to use the investigational article for emergency purposes.

Thus, the distinction for DHHS-supported or - conducted research is that while the physician may, without prior IRB approval, treat the patient/subject using a test article (if the situation meets the FDA requirements), the subject may not be considered a research subject; data derived from use of the test article may not be used in the study.

15. **Question:** What must be reported to DHHS?

Answer: Any of the following occurrences:

- IRB membership changes;
- serious or continuing noncompliance with 45 CFR 46 [§46.103(b)(5)(i)];
- any unanticipated problems involving risks to subjects or others [45 CFR 46.103(b)(5)(i)]; or
- any suspension or termination of IRB approval for a project [45 CFR 46.103(b)(5)(ii) and 46.113].

16. **Question:** Must the IRB itself report instances of noncompliance with the regulations to DHHS?

Answer: Not necessarily. Each institution must have in place written procedures that ensure that instances of serious or continuing noncompliance will be reported to the IRB, appropriate institutional officials, and the head of the department or agency supporting the research (here, DHHS) [45 CFR 46.103(b)(5)]. The IRB is only responsible for doing the reporting if it is required to do so under the institution's written procedures. [**NOTE:** FDA requires that the IRB report to FDA if such reporting would not otherwise occur (*Federal Register* 56 (June 18, 1991): 28026).]

17. **Question:** Can treatment of a single patient constitute "research"?

Answer: Yes, if there is a clear intent before treating the patient to use systematically collected data that would not ordinarily be collected in the course of clinical practice in reporting and publishing a case study. Treating with research intent should be distinguished from the use of innovative treatment practices.

18. **Question:** If the research is subject to both DHHS and FDA human subjects regulations, which regulations should the IRB follow?

Answer: Where a protocol is subject to review under more than one department or agency's regulations, the requirements of each set of regulations must be met. This situation may arise, for example, with Treatment INDs, or when applying the provisions on waiver of documentation of informed consent, in cases where both the FDA and DHHS have jurisdiction over the research.

XIV. STEPS FOR OBTAINING APPROVAL OF RESEARCH INVOLVING HUMAN SUBJECTS

1. All researchers and investigators (including students) with projects or activities involving the use of human subjects **must** submit an application for approval to the IRB, via UT Martin's Office of Research, Grants, and Contracts.
2. Read the handbook entitled *Faculty, Staff, and Student Guide to Research Involving Human Subjects*. Copies are available in the UT Martin Office of Research, Grants, and Contracts, 100 Administration Building; on the RGC Web page; or through calling 731.881.7015.
3. Assemble the following materials:
 - a. a completed **[Application to the University of Tennessee Martin Institutional Review Board for the Protection of Human Subjects in Research](#)**. This form can be completed on line and printed out at a local printer for signatures. The Researcher is to complete the form as concisely as possible so as not to slow up the review process. **NOTE:** A copy of the research proposal may be requested by the IRB. Signatures on the Application **must** be originals.
 - b. a copy of all questionnaires or other research instruments;
 - c. a copy of the **[Informed Consent Statement](#)** along with a written summary of the information that will be given to subjects orally or in writing (if appropriate). **The Consent Form must cover the Basic Elements of Informed Consent;**
 - d. when children are involved, a copy of the **[Minor Assent Document](#)**; and
 - e. Thesis Approval Form for master's degree candidates, as applicable. [Not required for candidates from other institutions.]
4. Bring or mail the original and one (1) copy of your application to the Office of Research, Grants, and Contracts, 100 Administration Building, Martin, TN 38238.
5. The researcher or investigator must not initiate the project until written notification is received that the application has been approved by the IRB. (Faculty supervisors will receive copies of such notification when the researcher is a UT Martin student.)

NOTE: The **[expedited](#)** IRB committee, composed of the IRB chair and secretary, can generally meet to approve most protocols within two (2) weeks of submission to the Office of Research, Grants, and Contracts. The UT Martin IRB meets once each month to review applications for approval that cannot be granted by the expedited committee. The researcher (the faculty supervisors for UT Martin students are sent copies) will receive written notification of approval or disapproval and, if approval is granted, the IRB's decision regarding the form and extent of documentation of informed consent. Students will need to

contact their respective departments for the guidelines for submitting an Application for Review of Research with Human Subjects (e. g., meeting time for DRC, Chair of DRC, etc.).

The Office of Research, Grants, and Contracts can assist with completing the IRB Application (731.881.7015) or answer questions concerning the review process. This does not mean, however, that the RGC will prepare the application for the researcher.

XV. DESCRIPTION OF THE REVIEW PROCESS

All research involving human participants, **including** projects considered to be “exempt” from full IRB review, must be reviewed and approved before commencement of the research. The UT Martin IRB does not review research proposals from individuals, organizations, or units not affiliated with the University, **unless** the proposal includes UT Martin students, faculty, or administrators;

- A. **Investigator’s Responsibilities:** It is the responsibility of investigators (students, faculty advisors, faculty, co/principal investigators, etc.) to:
1. design and implement research so as to exclude or minimize risks to human participants;
 2. adhere to the highest standards of research design and procedure within the discipline of the proposed research;
 3. provide the appropriate review documents (**Application, Consent Forms, Assent Forms, research instrument**) to their Departmental Review Committee (DRC) chairs as soon as they know the extent to which humans will serve as participants in their research;
 - a. adhere to the principles of the Belmont Report)and to applicable codes of professional ethics for the discipline of the proposed research;
 4. ensure the use of appropriate professional competence and adequate support facilities for all research involving human participants.
- B. **Departmental Review of Research Projects:** The Departmental Review Committee will review all research projects involving human participants initiated by faculty, staff, and students in its department for scientific merit and for compliance with legal, regulatory, and ethical provisions for the protection of research participants’ rights.
- C. **Center Reviews:** Principal investigators or project directors in Centers not contained in or who do not report to an academic department at UT Martin shall submit their research protocols to the UT Martin Office of Research, Grants, and Contracts.
- D. **Department Chair’s Responsibilities:** Department Chairs have the responsibilities to assist faculty, staff, and students in meeting the requirements of

law, regulations, policy, and procedures (as well as applicable standards of professional ethics) for research involving human subjects.

XVI. DEPARTMENTAL REVIEW COMMITTEE APPOINTMENTS

If research involving human participants is a normal activity of the discipline, however regular or irregular its occurrence within the Department, the Department Chair will appoint a DRC. The Department Chair will report the names of the members of the DRC to the UT Martin IRB on via memorandum annually. The size of the DRC may vary, but minimum recommended membership is three (3), with alternates available so that members may avoid reviewing their own research or projects in which they may have either an active role or a conflict of interest.

- A. **Important Departmental Files:** Each department shall maintain a file consisting of the following documents:
1. This *Guide*, which incorporates the tenets of the [Belmont](#) Report, and contains copies of current UT Martin IRB Forms (e. g., [Application](#), [Informed Consent Form](#), [Assent Form](#), [Change/Termination form](#)), and copies of the DHHS regulations presented in 45 CFR 46, and FDA regulations presented in 21 CFR 50 and 56;
 2. Copies of federal regulations relevant to research conducted in the department;
 3. Copies of standards of professional ethics applicable to departmental research.
- B. **Departmental Review Committee (DRC) Recommendations:** Before submission to the UT Martin IRB, a research proposal must have DRC approval. In addition to the project's research merit, project approval by a DRC is dependent on three factors: (1) the level of risk, (2) the characteristics of people who will be asked to participate, and (3) the funding source of the research, if applicable. Depending on these factors, a DRC shall require investigators to describe their projects using the Application for the Protection of Human Subjects in Research. **Note: The Office of Research, Grants, and Contracts (UT Martin Compliances) or the UT Martin IRB may question the eligibility of the Application's exemption and require a nonexempt review before research may begin.**
- C. **Process for Approval of Research Involving Human Subjects:** The following process is followed for approval of Applications from departmental review through being granted permission to conduct the study and receiving an IRB docket number:
1. Applications with appropriate signatures and attachments are submitted to the DRC in the time specified by the department to submit IRB Applications;
 2. The DRC reviews the Application and denotes whether the Application is "[exempt](#)," "[expedited](#)," or "[full convened](#)";

3. The DRC Chair signs the Application and submits same with attachments to the Office of Research, Grants, and Contracts;
4. The Authorized Institutional Official (AIO) reviews the Application, and if the Application is deemed “exempt,” authorizes the research to go forward through a letter and an assigned IRB docket number;
5. If the Application is deemed for “expedited” review, the AIO sends the Application to the Expedited Board (IRB Chair and Secretary) for review;
6. Expedited Reviews normally take 10 – 12 days;
7. In the event the Application is deemed “full convened,” the AIO sends out the Application with attachments to the IRB who then meets on a regularly scheduled published date and time to discuss the Application;
8. The IRB then approves the research to go forward as stipulated in the Application, approves the research with modifications, or disapproves the research;
9. The AIO notifies the researcher of the IRB’s decision and either issues a letter of approval with an assigned IRB docket number or issues a letter of disapproval of research.
10. The researcher may appeal the IRB decision (see [Appeals](#) section of this *Guide*)

XVII. SUSPENSION OR TERMINATION OF IRB APPROVAL OF RESEARCH (§46.113)

An 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 or 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. (Approved by the Office of Management and Budget under Control Number 9999-0020.)

XVIII. APPENDICES

- A. [Application to the UT Martin IRB for the Protection of Human Subjects in Research](#)
- B. [Instructions on How to Complete the IRB Application](#)
- C. [Sample Informed Consent Document](#)
- D. [Sample Minor Assent Document #1 and](#)
- E. [Sample Minor Assent Document #2](#)
- F. [Change and/or Termination Form](#)