APPENDIX A: CRITERIA FOR IRB APPROVAL

§II.111 CRITERIA FOR IRB APPROVAL OF RESEARCH

The IRB shall determine that all of the following requirements are satisfied:

(1) Risks to subjects are minimized:

   (i) By using procedures that are consistent with sound research design and that do not unnecessarily expose subjects to risk, and

   (ii) Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

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

(3) Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted. The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.

(4) Informed consent will be sought from each prospective subject or the subject’s legally authorized representative, in accordance with, and to the extent required by, §II.116.

(5) Informed consent will be appropriately documented or appropriately waived in accordance with §II.117.

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

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

(8) For purposes of conducting the limited IRB review required by §II.104(d)(7)), the IRB need not make the determinations at paragraphs (1) through (7) of this section, and shall make the following determinations:

   (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §II.116(a)(1)–(4), (a)(6), and (d);

   (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §II.117; and
(iii) If there is a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

THE KEY ELEMENTS OF A STUDY THAT MEET THESE GOALS

[1] THE INFORMED CONSENT PROCESS. Informed consent is not just a signed form, but also a process of communication between researchers and participants that conveys respect for the individual.

For adults able to exercise full autonomy in making choices about participating in a research study, the informed consent process should include the following:

- a statement that the study involves research, an explanation of the purposes of the research, and a description of what participation in the study will involve;
- a description of any reasonably foreseeable risks and benefits to the participant;
- if the study involves health treatments, the participant must be informed of alternative procedures or courses of treatment;
- a statement describing the extent to which confidentiality of records or data identifying the subject will, or will not, be maintained;
- for research involving more than minimal risk (see below), an explanation of the treatment or resources available if any harm occurs;
- identification of whom to contact for further information about the study (e.g., the Principal Investigator), and about participants’ rights in the event of research-related harm (usually the Committee for the Protection of Human Subjects [IRB]);
- a statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time.

For a checklist of informed consent requirements, see this link.

New informed consent requirement. The Final Rule (45 CFR 46.116(a)(5)(i)) requires that informed consent forms begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research (referred to as a “preamble” or “summary” by some). This part of the informed consent must be organized and presented in a way that facilitates comprehension.

Written consent. Informed consent should usually be obtained in writing (“writing on a tangible medium (e.g., paper) or in an electronic format”). However, the IRB can sometimes waive the written consent requirement (e.g., under conditions of minimal risk, or where written consent would jeopardize the benefits of the study).

Parental Consent/Child Assent. For individuals with “diminished autonomy” (for example, children), informed consent procedures typically involve obtaining consent from an individual who has the legal authority to make decisions about the individual’s participation in research. In the case of children, The Ethical Standards for Research with Children of the Society for Research in Child Development suggest that informed consent should be obtained from parents, legal guardians or those who act in loco parentis (e.g., teachers, school superintendents). Where feasible, children should also be given the opportunity to assent to participate, even if they do not fully comprehend the full significance of such assent, as well as the opportunity to refuse to participate.
[2] IDENTIFICATION OF THE RISKS AND BENEFITS OF THE STUDY. “Risk” is defined as the probability of physical, psychological, social or economic harm or injury as a result of participation in a research study. “Minimal risks” are those where the probability of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily experienced in daily life or during the performance of routine psychological or physical examinations or tests. The investigator has three responsibilities: one is to reduce the risks (and maximize the benefits); the second is to explain the risks to potential participants so that participants can decide for themselves whether or not they want to take the risk; the third is to provide appropriate remedies or treatments for individuals who are harmed by the research. Where the risks are more than minimal, the investigator must provide evidence to the IRB that the benefits justify the risk.

[3] SAMPLE SELECTION. Sample selection is important because it addresses the third ethical principle of The Belmont Report: justice. Much of the research that has been done to date can be criticized on two different grounds. First, when research involves only white, middle-class males, the benefits of that research are only available to white, middle-class males (both to those who participate in the study, and to those whose health care, employment or other benefits are improved as a result of the study). A related problem associated with samples limited to white, middle-class males is that the results of those studies have been presumed, often inaccurately, to apply to men of color, women, and working class or poor individuals -- such an assumption potentially deprives these groups of the benefits of research. Second, when research uses readily available subjects, such as soldiers, prisoners, or institutionalized individuals, or uses subjects who are disenfranchised in other ways, such as the poor, the risks of those studies fall disproportionately on the disenfranchised. Therefore, investigators are encouraged to use sampling designs that allow the benefits and risks to be fairly shared among those populations appropriate for inclusion in the study on scientific grounds.