Summary of Changes in New Federal Regulations

**Single IRB**

Encourages the use of external IRBs, single IRBs (convened only for one project) and independent IRBs.

**Definitions**

Vulnerable populations – removed “pregnant women,” added “economically or educationally disadvantaged persons”

Human subjects now include biospecimens and clarifies that IRB oversight is required when obtaining, storing, using, studying, analyzing, or generating private information or identifiable data.

Activities that have been deemed not to be human subjects research include oral history, journalism, public health surveillance, criminal justice or criminal investigative activities authorized by law or court order by or for a criminal justice agency, and activities supporting intelligence, homeland security, defense, or other national security missions.

**Exempt Research**

Only requires official determination that it is exempt, which will be done administratively in REC. Informed consent and data security measures should still be followed when applicable.

Exempt 1 is reworded (new language is italicized):

Research, conducted in established or commonly accepted educational settings, that specifically involve normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

Exempt 2 now allows for some video/audio. Children are still excluded unless the research is educational testing or observation when the investigator doesn’t participate. There is new third component, limited review, covered in the review section of this document.

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory record) if at least one of the following criteria is met:

(i) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;
(ii) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required in section 111(a)(7).

Exempt 3 is new:

Research involving benign behavioral interventions in conjunction with the collection of information from an adult through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:

(A) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

(B) Any disclosure of the human subjects’ responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects’ financial standing, employability, educational advancement, or reputation; or

(C) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required in section 111(a)(7).

For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.
Exempt 4 is basically the same regarding secondary research uses, but prohibits the investigator from contact the subjects or reidentifying the subjects. Subsections also describe identifiable health information or research conducted on behalf of a Federal agency.

Exempt 5 still covers research and demonstration projects conducted for or on behalf of Federal departments or agencies.

Exempt 6 still covers taste and food quality evaluation and consumer acceptance studies.

Exempt 7 and 8 are new and cover research conducted subsequent to broad consent with a variety of stipulations.

IRB Review of Research

Added “limited IRB Review” that includes a lower level of review in for secondary use of data obtained under broad consent. Limited review may be done under Expedited Review. Expedited Review may also be used for minor changes to Full Board review protocols.

Informed Consent

The basics remain –
- consent must be obtained prior to involving a subject in research,
- the subject has to have sufficient opportunity to discuss and consider whether or not to participate,
- coercion and undue influence must be minimized, language used must be understandable to subjects,
- exculpatory language cannot be used.
- Wherever subjects are mentioned, legally authorized individuals are included as well.

New –

- Subjects must be provided with the information that a “reasonable person” would want to have in order to make an informed decision and subjects must be provided an opportunity to discuss that information.

- Informed consent must 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. This part of the informed consent must be organized and presented in such a way that facilitates comprehension.

- Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely
provide lists of isolated facts, but rather facilitate the prospective subject’s understanding of the reasons why one might or might not want to participate.

Basic elements have been expanded in 116(b). The existing elements remain:

(1) A statement that the study involves research, an explanation of the purposes of the research and expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

(2) A description of any reasonably foreseeable risks or discomforts to the subject;

(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject;

(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

A ninth required element was added:

(9) One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

(i) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or

(ii) A statement that the subject’s information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

Several new additional elements were added for use when appropriate in 116(c):

(7) A statement that biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
(8) a statement about whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

(9) a statement about whether the research project will or might include whole genome sequencing.

“Broad consent” in 116(d) – This is a new section intended to cover obtaining consent for future research using stored data. The consent still needs to have all of the standard elements, but in addition the researcher would include:

- A general description of the types of research that may be conducted in the future;
- A description of the identifiable information or identifiable biospecimens that might be used for the future research;
- Whether sharing with other researchers might occur, and the types of institutions or researchers that might conduct the research;
- The length of time that the identifiable information or biospecimens may be stored, maintained, or used;
- A statement that the subjects will not be informed of the purposes or details of any specific research studies that might be subsequently conducted, and that they might have chosen not to consent to some studies; and
- Participants must also be provided with contact information for their questions about rights, about storage and use, and in the event of a research-related harm.

Waivers

We have developed a form now uploaded into IRBNet and the website that will assist PIs with requesting and justifying waivers of informed consent or waivers of documentation of informed consent. If it used, the PI can just reference the form in section B.2.b.ii.

Waivers or alteration of consent (eliminating some or all of the required elements of informed consent):

Requires the IRB to find and document that:

- The research involves no more than minimal risk to subjects;
- The research could not practicably be carried out without the requested waiver or alteration;
- the waiver or alteration will not adversely affect the rights and welfare of the subjects; and
- Whenever appropriate, the subjects of legally authorized representatives will be provided with additional pertinent information after participation;
- (NEW) If the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

If broad consent has been included for the project, the new regulations state that if the subject refused to agree to broad consent in the original project, an IRB cannot waive
consent for the storage, maintenance or secondary research use for that subject. Researchers would have to locate the individual and reconsent them in order to maintain the data for secondary purposes. Also, no required elements can be waived related to broad consent.

The new regulations allow for screening, recruiting, or determining eligibility without the informed consent of the prospective subject if:

- The investigator will obtain information through oral or written communication with the prospective subject, or
- The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Waiver of documentation of informed consent (Waiving the requirement for a signature on the consent document).

- Signatures are still required, but the new regulations allow for electronic signatures. This will eliminate many of the requests we have receive for waiver.
- Added another criteria allowing waiver if the subjects are members of a distinct culture group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.