

## Revised Common Rule Brief Summary for IRB Members

- Consent-Related Changes:
  - **New consent form required elements:**
    - Informed consent as a whole must present information in sufficient detail and organized in such a way that does not “merely provide lists of isolated facts, but rather facilitates the prospective subject’s ... understanding of the reasons why one might or might not want to participate”
    - The informed consent process **must begin with a concise and focused presentation** of the “key information” that is most likely to assist a prospective subject in understanding the reasons why one might or might not want to participate in the research. This subsection also requires that this part of the informed consent be “organized and presented in a way that facilitates comprehension.”
    - If study involves collection of **identifiable private info, or identifiable biospecimens**, consent **must contain one of two statements** (not necessarily verbatim):
      - Identifiers might be removed and the de-identified information or biospecimens used for future research or distributed to another investigator without additional informed consent from the subject; or
      - The subject’s information or biospecimens will not be used or distributed for future research studies even if identifiers are removed
    - If the study involves collection of **biospecimens**:
      - 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.
      - whether the research project **will or might** include **whole genome sequencing**.
    - If applicable, Whether clinically relevant research results, including **individual research results**, will be disclosed to subjects, and if so, under what conditions (i.e. only for studies related to physical or behavioral health)
  - New criteria for **waivers/alterations** of consent:
    - For research that involves using identifiable private information or identifiable biospecimens, **adds requirement** that the research could not practicably be carried out without using such information or biospecimens *in an identifiable format*
    - Screening: An IRB may approve research in which an investigator will obtain **information or biospecimens** for the purpose of **screening, recruiting, or determining the eligibility of prospective subjects without first obtaining informed consent**, if either of the following conditions are met (i.e. you still need consent for screening procedures that go beyond the following):
      - The information will be obtained through oral or written communication with the prospective subject, or
      - by accessing records or stored biospecimens.
  - **Electronic signatures** for consent documentation are specifically allowed; written (*can be electronic*) copy must be given to person signing
  - Consent form may be read to the subject

- **Continuing Review is no longer required** for studies that meet the below criteria, and reviewer **must justify rationale** for requiring continuing review:
  - Minimal risk (Exempt & Expedited)
  - Full Board: Have progressed to the point that they involve only one or both of the following, which are part of the IRB-approved study:
    - (A) Data analysis, including analysis of identifiable private information or identifiable biospecimens, or
    - (B) Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care
  - No longer required for IRB to **review proposal against the grant application** for federally-funded studies.

**Additional Info: whether they are “human subjects research” or Exempt:**

- Definition of **Research** has been expanded to list activities that are specifically deemed not to be research (e.g., oral history, journalism, public health surveillance, criminal justice or criminal investigative activities, and activities in support of intelligence, homeland security, defense, or other national security missions).
- Revised rules about applying Exemptions to Subparts:
  - Subpart C (Prisoners): Exemptions still do **not** apply, **except** all categories can apply to research aimed at involving a broader subject population that only *incidentally* includes prisoners
  - Subpart B (fetuses/non-viable neonates or neonates of uncertain viability): All exemptions apply
  - Subpart D (Children): Exemption #2(i) and (ii) for research involving survey or interview procedures or observations of public behavior does NOT apply to research in children, except for research involving observations of public behavior when the investigator does not participate in the activities being observed. Exemption #2(iii), where identifiable information is obtained and the IRB conducts a limited IRB review, is NOT applicable to research in children. Exemption #3 does NOT apply to research involving children.
- New exemptions
  - Educational research exemption revised: cannot be unless the practices being tested “are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction”
  - Research involving benign behavioral interventions in conjunction with the collection of information from adults through verbal or written responses (including data entry) or audiovisual recording (d)(3). Some restrictions apply – see guidance at end of this document.
  - Secondary research uses of **identifiable** private information or identifiable biospecimens where disclosure could be damaging but data security measures are adequate or already covered by HIPAA (d)(4) (**Limited IRB Review** is required!)

- Storage or maintenance for secondary research use of private information or identifiable biospecimens (d)(7) (Limited IRB Review is required!)
- Research involving the use of private information or identifiable biospecimens that have been stored or maintained for research use (d)(8) (Limited IRB Review is required!)

**Benign Behavioral Interventions Exemption Category:**

- Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject 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:
  - (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 by § \_\_.111(a)(7): "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data."
- **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.
- **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.