



Changes to the Common Rule

Jeanette Gommel, MPH, CIP
Office of Research Compliance, Integrity and Safety



General Comments

- Three “developmental phases” of revised Common Rule: ANPRM (2011), NPRM (Sept. 2015), and final approved version (Jan. 18, 2017)
- The most controversial aspects of the NPRM are not part of the final version of the revised Common Rule
- Some changes that will make minimal risk research administration less burdensome
- Some surprises; ANPRM , NPRM, and final version of Common Rule all quite different
- Changes go into effect on January 19, 2018 (except for single IRB, not until Jan. 2020)

Belmont Principles

The preamble to the revised Common Rule clearly indicates that The Belmont Report's three principles must guide the IRB's decisions :

1. Respect for persons – voluntary, informed decision about whether to participate
2. Beneficence – risks minimized and benefits maximized
3. Justice –populations that bear the risks of the research should also be able to gain the benefits, vulnerable populations should not be unfairly targeted.

7 criteria for IRB approval of research which is not exempt in 45 CFR 46 are unchanged

Changes in Common Rule definitions

- Term “vulnerable” updated in the Common Rule: vulnerability is a function of the possibility of coercion or undue influence in making an informed decision about participating in research.
- New version of the final rule no longer includes pregnant women or handicapped or physically disabled individuals as examples of populations that are potentially vulnerable.
- Assessment of equitable subject selection should include factors like societal marginalization or discrimination.
- Term “mentally disabled persons” has been replaced with “individuals with impaired decision-making ability.”

Key changes:

- No longer an option to “check the box.” 45CFR46 applicable only to federally funded research. Institutions can (and probably will) voluntarily use the Common Rule to guide their IRBs, but no federal oversight if not federally funded.
- Changes in consent requirements, addition of broad consent option for storage and maintenance of identifiable data, identifiable biospecimens
- Annual continuations no longer required for expedited projects or when only analyzing identifiable data for protocols approved after January 18, 2018.
- Extensive revisions to exempt review categories; now there are two kinds of exemptions: exempt from all review criteria, and exempt with limited review
- In Jan. 2020: requirement for single IRB review for domestic cooperative research. If research is federally funded, and more than one institution is involved, one IRB must be selected to provide review, rather than review by multiple IRBs.

Changes in consent requirements

- New provision allows an IRB to approve screening for recruitment or to determine eligibility without informed consent if:
 - (i) Investigator obtains screening information through oral or written communication with subject or LAR or
 - (ii) The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens

Changes in consent requirements

- “Informed consent must begin with a concise and focused presentation of the key information” most likely to assist prospective subject (or LAR) in making decision about participation
- Consent information must be organized in a way that “facilitates comprehension” of why one might or might not want to participate, not just a “list of isolated facts”
- “Reasonable person” standard for information that should be provided- what a reasonable person would want to know when deciding whether or not to participate in the research.

Changes in consent requirements

- **Additional required statement: consent must include one of two choices, whichever is appropriate:**

(1) Identifiers may be removed from your identifiable private information or identifiable biospecimens, and 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.

OR

(2) Your identifiable private information or identifiable biospecimens collected as a part of the research will not be used or distributed for future studies, even if the identifiers are removed.

Changes in consent requirements

- **Additional elements to be added (when appropriate)**
 - (1) subject's biospecimens may be used for commercial profit and whether the subject will share in this profit
 - (2) Whether clinically relevant research results, including individual results, will be disclosed to subjects, and if so, under what conditions
 - (3) Where the research involves biospecimens, whether the research might include whole genome sequencing

Changes in consent requirements

- New criterion for waiver or alteration of some or all of consent requirement: for research that uses identifiable private information or biospecimens: the research could not practicably be carried out without using such information in an identifiable format. (In other words, justify why using deidentified data is not feasible.)
- Now explicitly allows waiver of signature of consent where subjects are from a cultural group or community where signing forms is not the norm; must be minimal risk and alternative method of documenting consent process must be used
- Specifically states that consent signatures may be in an electronic format
- Written copy of consent must be given to person signing the form (written can mean an electronic copy that can be saved or printed)

Exempt Research

- OHRP still recommends that exempt determinations be made by someone other than the researcher
- All exemptions applicable to research with pregnant women, human fetuses and neonates
- Exemptions do not apply to research with prisoners *except* for research aimed at broader subject population that only incidentally includes prisoners
- Some exemptions apply for research with children. As before, survey and interview research with persons under 18 is not exempt (exempt 2), nor are benign behavioral interventions (exempt 3).
- The exemption for survey and interview research with elected or appointed officials (former exempt 3) has been eliminated.

Exempt Categories overview

1. Educational research
2. Surveys, observation of public behavior, educational tests – i, ii, iii
3. Benign behavioral interventions (new) – i, ii, iii
4. Secondary research for which consent is not required
5. Federal research and demonstration projects (not normally used other than by federal agencies or research that they fund)
6. Taste and food quality
7. Storage or maintenance of identifiable data for which broad consent is required (new, optional)
8. Secondary research using identifiable data for which broad consent is required (new, optional)



Exempt Categories overview

- In the current version of the Common Rule, the IRB did not have to apply any review criteria to research that was determined to be exempt.
- Under the revised Common Rule, some exempt categories do require *limited IRB review* for specific criteria. Exempt categories requiring limited review are 2 iii, 3 iii, 7, and 8.

Exempt 1

- Research conducted in established or commonly accepted educational settings involving 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.**

* language in exempt descriptions that is in italics is new

Exempt 2

- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one of the following criteria is met:
 - (i) information recorded so that identity cannot be readily determined, either directly or through identifiers linked to subject
 - (ii) any disclosure of the subject's responses 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
 - (iii) *the information is recorded so that identity can be determined and the IRB conducts limited review to determine that privacy and confidentiality adequately protected* (**limited review; other review criteria need not be applied**)

Comment on Exempt 2 (iii)

- Implies that breach of confidentiality is only risk of survey/interview research
- In keeping with the principles of the Belmont Report, the NIU IRB *may* determine that where subjects are vulnerable to coercion or subject matter is very sensitive that this exemption may not be used.
- Confidentiality and privacy cannot be adequately protected when the researchers have a supervisory or evaluative role to participants.

Exempt 3 – new

- *Benign behavioral interventions with collection of information (verbal, written, audiovisual recording) from adult subjects if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:*
 - (i) information recorded so that identity cannot be readily determined, either directly or through identifiers linked to subject*
 - (ii) any disclosure of the subject's responses 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*
 - (iii) the information is recorded so that identity can be determined and the IRB conducts limited review to determine that privacy and confidentiality adequately protected (**Limited review; other review criteria need not be applied**)*

Exempt 3 (cont)

- Benign behavioral interventions: “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.”
- Can include deception IF the subject authorizes the deception.

Sample consent language: ““This consent form accurately describes the risks and benefits of the study. However, for the study to work, there are some things about this study that we won't tell you about until after you participate. At the end of your participation in the study, the researchers will fully explain the study, including the reasons for withholding certain information about the study.”.”

Exempt 4 – similar to existing exempt 4

- Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens if at least one of the following criteria is met:
 - (i) Information or biospecimens publicly available
 - (ii) Information is recorded in such a manner that identity of subjects not readily ascertained directly or through identifiers, *investigator does not contact subjects, and investigator will not re-identify the data*
 - (iii) *If the data is covered by HIPAA while being used for research purposes*
 - (iv) *Research by or on behalf of Federal dept./agency and covered by government privacy protections*



Exempt 5, 6

- Exempt 5: Research and demonstration projects conducted/supported by a Federal Dept or agency designed to study, evaluate, improve, or otherwise examine public benefit or service programs
- Exempt 6: Taste and food quality and evaluation and consumer acceptance studies

Exempt 7 – new - limited review

- *Exempt 7: Storage or maintenance of identifiable private information or biospecimens for potential secondary research use if the following criteria are met:*
 - (i) Broad consent is required*
 - (ii) and documented unless documentation is waived*
 - (iii) Adequate provisions to protect the privacy of the subjects and the confidentiality of the data*

Exempt 8 – new – limited review

- *Exempt 8: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use if the following criteria are met:*
 - (i) Broad consent was obtained*
 - (ii) and documented unless documentation was waived*
 - (iii) IRB makes limited review to determine that the research to be conducted is within the scope of the broad consent*
 - (iv) The investigator does not include returning individual research results to subjects as part of the study plan (unless there is a legal requirement to do so)*

Requirements for Broad consent - relevant to exempt 7, 8

- **The same general requirements as “regular consent:”**
 - (1) Prospective-obtained prior to research participation
 - (2) sufficient time to consider without coercion or undue influence
 - (3) in language understandable to participants (or their LARs)
 - (4) contains information that a reasonable person would want to have in order to make an informed decision
 - (5) No exculpatory language

Requirements for Broad Consent (cont)

- **Some of the same required elements as “regular” consent:**

- (1) Description of reasonably foreseeable risks or discomforts
- (2) Description of benefits to subject or others reasonably expected
- (3) Extent to which confidentiality of records identifying subjects will be maintained
- (4) Statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which subject is entitled, and subject may discontinue at any time
- (5) If appropriate: subject’s biospecimens (even if deidentified) may be used for commercial profit and whether the subject will or will not share in commercial profits
- (6) If appropriate: For research with biospecimens, whether research will or might include whole genome sequencing

Requirements for Broad consent (cont)

- **Required elements unique to broad consent:**

- (1) General description of types of research that may be conducted with the identifiable information or biospecimens sufficient so that reasonable person would understand what types of research might be expected
- (2) A description of the identifiable private information or identifiable biospecimens that might be used in the research
- (3) Whether sharing of the identifiable private data or biospecimens might occur
- (4) Types of institutions or researchers that might conduct research with the identifiable information or specimens

Requirements for Broad consent (cont)

- (5) Time period during which identifiable information or biospecimens may be stored and maintained (can be indefinitely)
- (6) Time period during which identifiable information or biospecimens may be used for research purposes (can be indefinitely)
- (7) Statement that subject (or LAR) will not be informed of any specific research studies their identifiable information or biospecimens may be used for, and that they might have chosen not to consent to some of those research studies (unless there are agreements to the contrary)
- (8) Statement that clinically relevant research results, including individual research results, may not be disclosed to the subject (unless it is known that they will be in all circumstances)
- (9) Contact information if they have questions about subject's rights and about storage and use of subject's identifiable information and biospecimens, who to contact in the event of a research-related harm

Broad consent comments

- If subject refuses broad consent for storage/maintenance of identifiable private information or biospecimens, IRB may not approve a waiver
- Elements of broad consent may not be eliminated or altered
- **Broad consent is an option; the existing methods of approving the use of previously collected identifiable data are still available**