Making Sense of the New Common Rule

The USC Office for the Protection of Research Subjects has compiled these materials preparatory to implementing the New Common Rule on January 19, 2019.

Where no change is noted, the existing rules remain in effect.

Some changes are a reduction of burdens while others will present additional work for investigators and the IRB. Details about challenging items are provided.

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VIII. Elements of Broad Consent: for storage, maintenance or, secondary use

*NOT USED AT USC*

identifiable private information
## I. New Common Rule Summary of Changes

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<th>TOPIC</th>
<th>CHANGE</th>
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<tr>
<td>Applicability of the Common Rule</td>
<td>- The New Common Rule applies to research “conducted, supported, or otherwise subject to regulation by any Federal department or agency”</td>
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<td>New/revised definitions</td>
<td>- Human Subject</td>
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<td>- Research</td>
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<td>- Clinical trial (matches NIH)</td>
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<td>- Legally authorized representative</td>
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<td>- Vulnerable</td>
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<td>- Benign behavioral intervention</td>
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<td>- Intervention</td>
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<td>- Interaction</td>
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<td>- Private information</td>
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<td>Exemption categories</td>
<td>- Broad consent for exempt 2(iii), 3(i), 7 &amp; 8</td>
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<td>- “Limited IRB” review for exempt 2(iii), 3(i)(C), 7, and 8 (see attached)</td>
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<td>Expedited</td>
<td>- No continuing review unless the IRB documents a rationale for requiring it</td>
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<td>- No continuing review for projects conducting data analysis only (Full Board studies become expedited and no longer undergo continuing review)</td>
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<td>sIRB mandate</td>
<td>- All federally funded cooperative research in US must use single IRB beginning 2020</td>
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<td>- New Rule uses the term “cooperative research” (.114)</td>
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<td>- Federal agency/sponsor can opt out</td>
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<td>- sIRB review required for all NIH funded multi-site clinical trials</td>
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# I. New Common Rule Summary of Changes

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<tr>
<td>Informed Consent New elements</td>
<td>- New basic element of consent for collection of identifiable info/biospecimens: ICF must state whether or not data/specimen will be used for future research</td>
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<td>- “Key information” must be presented foremost on consent forms and on consent short forms</td>
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<td>- Broad consent required for certain exemption categories 7 &amp; 8 (<a href="#">Not used at USC</a>)</td>
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<td>- No consent required for screening procedures that are oral, written, or access records of identifiable private information or identifiable biospecimens (IRB approval still required)</td>
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<td>- Broad consent required for exempt 7 (storage and maintenance of identifiable data/specimen) &amp; 8 (secondary research with identifiable data/specimen)</td>
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<td>- Once consent form for each federally funded clinical trial must be posted on federally designated website no later than 60 days after the last study visit by any subject</td>
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<td>Waiver of consent criteria/</td>
<td>- Existing options for waiver of consent remain unchanged. I.e. the IRB may waive the consent requirement provided the research involves no greater than minimal risk and could not practically be carried out without the requested waiver</td>
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<td>waiver of documentation of consent</td>
<td>- Waiver of documentation of consent: new additional exception for subjects for whom signing documents is not the cultural norm</td>
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<td>- If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements at paragraph (d) of this section, and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.</td>
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II. New/Revised Definitions

- **Human subject**: a living individual about whom an investigator conducting research obtains
  (1) information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
  (2) uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

- **Research**: a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

- **Activities deemed not to be research**:
  - Scholarly and journalistic activities
  - Government functions with separately mandated protections

- **Clinical trial**: research study in which human subjects are prospectively assigned to interventions to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

- **Legally Authorized Representative**: individual/judicial/body authorized under applicable law to consent on behalf of prospective subject

- **Benign behavioral intervention**: interactions that are brief harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing

- **Interaction**: communication or interpersonal contact

- **Intervention**: physical procedures/environmental manipulations by which information or biospecimen are gathered

- **Private information**: 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

- **Identifiable private information**: private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

- **Identifiable biospecimen**: a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

- **Vulnerable Subjects**: vulnerable to coercion/undue influence
### III. Exemption Categories

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<tr>
<th>Vulnerable populations in exempt research</th>
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<tr>
<td><strong>Subpart B</strong></td>
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<td><strong>Subpart C</strong></td>
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<td><strong>Subpart D</strong></td>
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<tr>
<th>Exemption Category</th>
<th>Exemption Description</th>
<th>Conditions/Allowances/Limitations</th>
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<tbody>
<tr>
<td><strong>1</strong></td>
<td>Research in established or commonly accepted education settings that involves normal educational practices</td>
<td>Not likely to adversely impact students’ opportunity to learn or assessment of educators</td>
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<td>Research only includes educational tests, surveys, interviews, public observation if at least one of the following criteria met:</td>
<td>Data collection only; May include visual or auditory recording; May NOT include Intervention</td>
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<tr>
<td>(i)</td>
<td>Recorded information cannot readily identify the subject (directly or indirectly/linked)</td>
<td>Surveys &amp; interviews: no children; Educational tests or observation of public behavior can only include children when investigators do not participate in activities being observed</td>
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<td>(ii)</td>
<td>Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)</td>
<td>Surveys &amp; interviews: No children; Educational tests or observation of public behavior can only include children when investigators do not participate in activities being observed</td>
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<td>(iii)</td>
<td>Information is recorded with identifiers &amp; IRB conducts Limited Review</td>
<td>No children</td>
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<td><strong>2</strong></td>
<td>(i) Research involving Benign Behavioral Interventions through verbal, written responses, (including data entry or audiovisual recording) from adult subject who prospectively agrees and ONE of following met:</td>
<td>No children; May not include medical interventions; subject prospectively agrees;</td>
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<tr>
<td></td>
<td>A. Recorded information cannot readily identify the subject (directly or indirectly/linked)</td>
<td>Benign Behavioral Intervention must be:</td>
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<td>B. Any disclosure of responses outside of the research would NOT reasonably place subject at risk (criminal, civil liability, financial, employability, educational advancement, reputation)</td>
<td>• Brief in duration</td>
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<td>C. Information is recorded with identifiers &amp; IRB conducts Limited Review</td>
<td>• Painless/Harmless</td>
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<td>• Not physically invasive</td>
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<td>• Not likely to have a significant adverse lasting impact on subjects</td>
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<td>• Unlikely that subjects will find interventions offensive or embarrassing</td>
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<td>No deception unless participant prospectively agrees</td>
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### III. Exemption Categories

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<tr>
<th>Exemption</th>
<th>Description</th>
<th>IRB Requirements</th>
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<td><strong>4</strong></td>
<td>Secondary research for which consent is not required: use of identifiable Information or identifiable biospecimen that have been or will be collected for some other ‘primary’ or ‘initial’ activity, if <strong>ONE of following criteria met:</strong>&lt;br&gt;&lt;br&gt;<strong>(i)</strong> Biospecimens or information is publically available&lt;br&gt;<strong>(ii)</strong> Information recorded so subject cannot readily be identified (directly or indirectly/linked); Investigator does not contact subjects and will not re-identify the subjects&lt;br&gt;<strong>(iii)</strong> Collection and analysis involving Investigators Use of Identifiable Health Information when use is regulated by HIPAA “health care operations” or “research” or “public health activities and purposes”&lt;br&gt;<strong>(iv)</strong> Research information collected by or on behalf of federal government using government generated or collected information obtained for non-research activities</td>
<td>No primary collection from subjects for the research; Allows both retrospective and prospective secondary use&lt;br&gt;Must be publically available&lt;br&gt;HIPAA still applies; HIPAA protections include authorization or waiver of authorization;&lt;br&gt;If research generates identifiable private information it is subject to specified federal privacy laws (see iv for list)</td>
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<td><strong>5</strong></td>
<td>Research and demonstration projects supported by a Federal Agency/Dept. AND designed to study, public benefit or service programs.</td>
<td>Must be posted on a federal web site</td>
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<td><strong>6</strong></td>
<td>Taste and Food Quality</td>
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**EXEMPTION 7 AND 8 WILL NOT BE IMPLEMENTED AT USC**

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<tr>
<th>Exemption</th>
<th>Description</th>
<th>IRB Requirements</th>
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<tr>
<td><strong>7</strong></td>
<td>Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research for which broad consent is required</td>
<td>IRB may waive consent requirement; or; All requirements for Broad Consent must be met and refusals to consent must be tracked; the IRB may not waive consent for use of identifiable material for any individual who refuses</td>
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<tr>
<td><strong>8</strong></td>
<td>Secondary research involving use of Identifiable Private Information or Identifiable Biospecimens for Which Broad Consent was Required</td>
<td>Privacy and confidentiality protections adequate; Broad Consent was obtained; Documented or documentation waived return research results not allowed; Refusals to consent must be tracked; the IRB may not waive consent for use of identifiable material for any individual who refuses</td>
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IV. Expedited Review

Changes: No continuing review required of expedited research unless the IRB documents a rationale for requiring it

Summary of Expedited Categories (unchanged):

1. Clinical studies of drugs and medical devices only when certain conditions are met
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture in certain populations and within certain amounts
3. Prospective collection of biological specimens for research purposes by noninvasive means
4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.
5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes
6. Collection of data from voice, video, digital, or image recordings made for research purposes
7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies
V. Updated Elements of Informed Consent: Basic + Additional

**CHANGES BOLDEDED BELOW**

**Basic elements of informed consent. § 46.116 (b)**

Except as provided in paragraph (d), (e), or (f) of this section, in seeking informed consent the following information shall be provided to each subject or the legally authorized representative:

1. 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 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; and

9. One of the following statements is required 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.
V. Updated Elements of Informed Consent: Basic + Additional

**CHANGES BOLDED BELOW**

*Additional elements of informed consent. § 46.116 (c)*

Except as provided in paragraph (d), (e), or (f) of this section, one or more of the following elements of information, when appropriate, shall also be provided to each subject or the legally authorized representative:

1. 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) that are currently unforeseeable;

2. Anticipated circumstances under which the subject’s participation may be terminated by the investigator without regard to the subject's or the legally authorized representative’s consent;

3. Any additional costs to the subject that may result from participation in the research;

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

5. A statement that significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject;

6. The approximate number of subjects involved in the study;

7. A statement that the subject’s 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 regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions; and

9. For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
General waiver or alteration of consent (.116(f))

1. **Waiver.** An IRB may waive the requirement to obtain informed consent for research under paragraphs (a) through (c) of this section, provided the IRB satisfies the requirements for waiver and alteration of consent (below). If an individual was asked to provide broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens in accordance with the requirements of broad consent (.116(d)), and refused to consent, an IRB cannot waive consent for the storage, maintenance, or secondary research use of the identifiable private information or identifiable biospecimens.

2. **Alteration.** An IRB may approve a consent procedure that omits some, or alters some or all, of the elements of informed consent provided the IRB satisfies the requirements for waiver and alteration of consent. An IRB may not omit or alter any of the general requirements for informed consent (.116(a)). If a broad consent procedure is used, an IRB may not omit or alter any of the elements of broad consent (.116(d)).

3. **Requirements for waiver and alteration.** In order for an IRB to waive or alter consent as described in this subsection, the IRB must find and document that:
   - (i) The research involves no more than minimal risk to the subjects;
   - (ii) The research could not practicably be carried out without the requested waiver or alteration;
   - (iii) 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;
   - (iv) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and

4. Whenever appropriate, the subjects or legally authorized representatives will be provided with additional pertinent information after participation.
Screening, recruiting, or determining eligibility (.116 (g))

An IRB may approve a research proposal in which an investigator will obtain information or biospecimens for the purpose of screening, recruiting, or determining the eligibility of prospective subjects without the informed consent of the prospective subject or the subject’s legally authorized representative, if either of the following conditions are met:

1. The investigator will obtain information through oral or written communication with the prospective subject or legally authorized representative, or

2. The investigator will obtain identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

Waiver of documentation of informed consent (.117)

(c)(1) An IRB may waive the requirement for the investigator to obtain a signed informed consent form for some or all subjects if it finds any of the following:

(i) That the only record linking the subject and the research would be the informed consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the subject wants documentation linking the subject with the research, and the subject’s wishes will govern;

(ii) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context; or

(iii) If the subjects or legally authorized representatives are members of a distinct cultural 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.

(2) In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.
VII. Limited IRB Review  .111(a)(8)

----- NOT USED AT USC -----

What is limited IRB review?

Limited IRB is established for review of research that will record, store, maintain or, make secondary use identifiable private information. It is an alternative to the IRB approval criteria otherwise used for review of research. Limited IRB review is designed by OHRP to:

- “ensure that there are adequate privacy safeguards for identifiable private information and identifiable biospecimens.”
- reduce the chances that the disclosure of identifiable private information will occur and lead to harm.
- respond to commenters who believe that IRB oversight should be retained for the secondary research use of identifiable private information and identifiable biospecimens.

How is limited IRB review conducted?

- For purposes of conducting the limited IRB review, the IRB need not apply the IRB approval criteria otherwise used for review of research, 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 required elements of broad consent
  (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with the requirements for documentation of consent; 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.

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1 §__.102(e)(5) Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information. (4) 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).

2 Final Rule, Federal Policy for the Protection of Human Subjects Executive Summary: Purpose of the Regulatory Action

3 §__.111.(a)(1)-(7)
VII. Limited IRB Review \(111(a)(8)\)

----- NOT USED AT USC -----

- Continuing review of research is not required for research reviewed in accordance with the limited IRB review\(^4\)

- As an alternative to limited IRB review, an IRB may use the expedited review procedure to review research for which limited IRB review is a condition of exemption\(^5\)

When to conduct limited IRB review:

- **Exempt 2(iii)\(^6\)**
  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 recording) if 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 \section{111(a)(7)}\(^7\).

- **Exempt 3(i)(C)**
  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 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 \section{111(a)(7)}.

- **Exempt 7**
  Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by \section{111(a)(8)}\(^8\).

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\(^4\) \section{109(f)(i)}

\(^5\) \section{110(b)(1)(iii)}

\(^6\) Exempt 2 now contains three sub categories (i), (ii), and (iii)

\(^7\) \section{111(a)(7)} When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. (i) The Secretary of HHS will, after consultation with the Office of Management and Budget’s privacy office and other Federal departments and agencies that have adopted this policy, issue guidance to assist IRBs in assessing what provisions are adequate to protect the privacy of subjects and to maintain the confidentiality of data.

\(^8\) Limited IRB review
VII. Limited IRB Review .111(a)(8)

----- NOT USED AT USC -----

cont’d, When to conduct limited IRB review:

- Exempt 8
  Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
  (i) Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with the required elements of informed consent;
  (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with the requirements for documentation of consent;
  (iii) An IRB conducts a limited IRB review and makes the determination required by §__.111(a)(7) and makes the determination that the research to be conducted is within the scope of the broad consent; and
  (iv) The investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
VIII. Elements of Broad Consent .116(d)

for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens.

----- NOT USED AT USC -----

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section;*

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject’s identifiable private information or identifiable biospecimens;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject’s rights and about storage and use of the subject’s identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

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

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

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

b(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; and

When appropriate:

c(7) A statement that the subject’s 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;

c(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).