Office for Human Research Protections (OHRP)
Revised Common Rule Q&As

Definitions

Has the revised Common Rule changed the definition of research?

The revised Common Rule adds a provision that identifies four types of activities as not being "research" as defined in the Rule. In other words, the revised Common Rule does not apply to the following types of activities because they do not meet the regulatory definition of research:

Certain scholarly and journalistic activities
Certain public health surveillance activities
Collection and analysis of information, specimens, or records, by or for a criminal justice agency for certain criminal justice or investigative purposes
Certain authorized operational activities for national security purposes

Has the revised Common Rule changed the definition of human subject?

The regulatory definition of human subject remains substantively unchanged in the revised Common Rule. The definition has not been expanded. However, there have been clarifications to the wording that make explicit OHRP's current interpretation of the definition included in the pre-2018 Common Rule.

1. The pre-2018 Common Rule referred to "data" obtained by an investigator through intervention or interaction with the individual, but in the revised Common Rule "data" is replaced with "information or biospecimens" for clarity.

2. In addition, language has been added related to "using, studying, or analyzing individuals' information or biospecimens or generating identifiable private information or identifiable biospecimens" to clarify OHRP's understanding of the meaning of "obtaining" in the pre-2018 Common Rule's definition of human subjects.

3. The definition also now specifies what is meant by an identifiable biospecimen, and includes a requirement for Common Rule departments and agencies to reexamine the meaning of "identifiable private information" and "identifiable biospecimen."

4. In addition, the revised definition includes a provision requiring the Common Rule departments and agencies to assess whether there are analytic technologies that should be considered by investigators to generate "identifiable private information."

Exemptions

How has Exemption 1 for research involving educational practices changed with the revised Common Rule?

Exemption 1 applies to research in established or commonly accepted educational settings that involves certain normal educational practices, such as research on instructional techniques already in use or classroom management. The 2018 revisions to the Common Rule have added a new restriction to the applicability of Exemption 1: the research must also not be likely to adversely impact the student's opportunity to learn required educational content or the assessment of educators who provide the instruction.

How has Exemption 2 for research involving educational tests, surveys, interviews or observation of public behavior changed with the revised Common Rule?

There have been three primary changes to Exemption 2 in the revised Common Rule:

1. First, the word “only” has been added to clarify that Exemption 2 applies to research that “only includes interactions” involving educational tests, surveys, interviews, and observation of public

What type of research is covered by the new Exemption 3 in the revised Common Rule?

The new Exemption 3 applies to research involving benign behavioral interventions with adults who prospectively agree to the research, when the information collected is limited to verbal or written responses, including data entry or audiovisual recordings. The criteria for when Exemption 3 applies to such research is the same as for Exemption 2, in summary: (1) the information recorded cannot be readily linked back to the subjects in such a manner that subjects' identity can be readily ascertained, directly or through identifiers linked to the subjects; or (2) any disclosure of this information would not place the subjects at risk of certain harms; or (3) the information is recorded in an identifiable manner, even if sensitive, provided that an IRB determines through limited review that, when appropriate, there are adequate privacy and confidentiality protections in the study.

The new Exemption 3 applies to behavioral interventions only. It is not applicable to biomedical research.

What types of limited IRB review are described in the revised Common Rule, and which exemptions require it?

There are four exemptions that may require limited IRB review: Exemptions 2, 3, 7*, and 8* (* not currently used at Skidmore)

Exemption 2 is for research that only includes interactions involving educational tests, survey or interview procedures, or observation of public behavior if at least one of the three provisions included in this exemption is met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subjects can readily be ascertained either directly or through identifiers. For this provision of Exemption 2, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

Exemption 3 is for research involving benign behavioral interventions in conjunction with specified data collection methods if the criteria listed in one of three possible provisions are met. Limited IRB review is required only if the third provision of the exemption is being used—that the information obtained is recorded by the investigator such that the identity of the subject can readily be ascertained either directly or through identifiers. For this provision of Exemption 3, the limited IRB review serves to determine that adequate provisions are in place to protect the privacy of subjects and maintain confidentiality of the data.

Exemption 7 (not currently used at Skidmore) is for the storage and maintenance of identifiable private information or identifiable biospecimens for potential secondary research use, for which broad consent is required. This exemption requires limited IRB review to determine that the requirements for broad consent are met; that broad consent is appropriately documented or documentation of broad consent is appropriately waived; and that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, if there will be a change made for research purposes in the way the identifiable private information or identifiable biospecimens are stored or maintained.

Exemption 8 (not currently used at Skidmore) is for secondary research involving identifiable private information or identifiable biospecimens, for which broad consent is required. This exemption requires an IRB to determine through limited review that there are adequate provisions in place to protect the privacy of subjects and maintain confidentiality of the data, and that the research to be conducted is within the scope of the obtained broad consent.

Who may conduct limited IRB review?

The limited IRB review process may be done either via the expedited review mechanism, that is, by the Chair or an experienced IRB member designated by the Chair, or by the convened IRB.

Do studies for which limited IRB review is required also require continuing review?

No, studies for which limited IRB review is required in order to meet an exemption do not require continuing review.

Broad Consent in the Revised Common Rule (not currently used at Skidmore)

What is broad consent?

Broad consent is a new type of informed consent provided under the revised Common Rule pertaining to storage, maintenance, and secondary research with identifiable private information or identifiable biospecimens. Secondary research refers to research use of materials that are collected for either research studies distinct from the current secondary research proposal, or for materials that are collected for non-research purposes, such as materials that are left over from routine clinical diagnosis or treatments.

Broad consent does not apply to research that collects information or biospecimens from individuals through direct interaction or intervention specifically for the purpose of the research.

Is broad consent required?

There is no requirement to use broad consent. Other options for doing secondary research remain, such as conducting secondary research with non-identifiable private information and non-identifiable biospecimens, since this is not human subjects research. In addition, Exemption 4 has two new provisions under the revised Common Rule that may be applicable to secondary research. For many researchers, using the options that are available under the pre-2018 Common Rule, and that continue to be available in the revised Common Rule, may be preferable to using broad consent for future secondary research use.

Informed Consent

What are the changes to the general requirements for informed consent under the revised Common Rule?

There are several major changes to the general requirements for informed consent in the revised Common Rule. The intent of these changes is to promote prospective subjects' autonomy. Informed consent serves several purposes, but an important one is letting people make their own decisions about what they really want and what best serves their interests. To do this, they need to have the necessary information conveyed in an appropriate way.

One of the new standards is that the consent form, and the consent process, should provide subjects with the information needed to make an informed decision about whether to participate. One change is introducing the requirement that informed consent must give prospective subjects the information that a reasonable person would want to have in order to make an informed decision about whether to participate. Using this standard, informed consent remains focused on what information a reasonable person would want to have to make an informed choice about participation.

An additional change is that the information needs to be presented in sufficient detail and organized and presented in a way that facilitates an understanding of why one might, or might not, want to participate.

Moreover, the informed consent should not merely be a list of isolated facts. Many consent forms are not as good as they could be in terms of aiding decision-making. The goal is to help people process the complicated information they're being given and make it easier for them to make a more informed decision.

There is also a new requirement that key information about the study must be provided at the beginning. Because consent forms can be very long, sometimes 25-30 pages, the aim is to put the really important information up front. This will likely include information about the purpose, the risks, the benefits, and alternatives, and it will explain to the person how to think about these pieces of information in terms of making a decision. It should be presented in a concise and focused manner. That way people will at least have what's most important right at the beginning. As with the other changes, the goal of this is to help participants think about why they might or might not want to participate in a study and make a decision that reflects their interests. Of note is that if information included in the key information section also satisfies the elements of informed consent under §46.116(b) and (c), this information need not be repeated later in the body of the informed consent.

Are there changes to the basic elements of informed consent in the revised Common Rule?

There is one new element that has been added to the basic elements of informed consent at §116(b). This new element requires a notice about whether participants' information or biospecimens collected as part of the current research might be stripped of identifiers and used for other research in the future. The

purpose of this is to increase transparency by letting participants know that it might happen. If potential participants find it objectionable, they may not want to participate in the study.

Consent forms will need to say either that information or biospecimens collected for the research might be stripped of identifiers and used in other research in the future, or that this will not happen. Note that this is only about future research use of information and biospecimens that will be stripped of identifiers. Consent for the future use of identifiable private information and identifiable biospecimens for future unspecified research is covered under the section for “broad consent,” or could also occur under conditions where an IRB determines that a waiver of informed consent is appropriate.

Are there changes to the additional elements of informed consent in the revised Common Rule?

There are three new additional elements of informed consent at section 116(c). Note that these are additional elements; they may not be relevant to all studies, in which case, they wouldn’t need to be included. These new additional elements are all notices. One is a notice about possible commercial profit, the second is a notice about whether clinically relevant research results will be returned to the subjects, and the third is a notice about whether research activities will or might include whole genome sequencing.

Are there changes to the conditions for waiving informed consent by the IRB in the revised Common Rule?

There is a change regarding the waiver and alteration of informed consent in the revised Common Rule. There is one new waiver criterion, which applies to research with identifiable private information or

What changes did the revised Common Rule make to the definition of legally authorized representative?

The definition of legally authorized representative has been changed to address jurisdictions in which there is no applicable law for allowing a legally authorized representative to provide consent on behalf of a prospective research subject. Under the revised Common Rule, in these jurisdictions, an individual who is recognized by institutional policy as acceptable for providing consent in the non-research context to the procedures involved in the research will be considered a legally authorized representative for the purposes of research.

What consent form must be posted?

This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. Under the revised Common Rule, the term "clinical trial" refers to research studies in which one or more human subjects are prospectively assigned to one or more interventions to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes. For such studies, one IRB-approved version of a consent form that has been used to enroll participants must be posted on a public federal website designated for posting such consent forms. The form must be posted after recruitment closes, and no later than 60 days after the last study visit. Federal departments or agencies may permit or require redactions as appropriate. The purpose of this requirement is to be more transparent about the consent forms being used and, over time, improve the quality of consent forms.

Does the posted informed consent have to be reposted after every change to the form?

No. Only one IRB-approved version of a consent form that has been used in the course of the study to enroll participants needs to be posted on a public Federal website designated for posting such consent forms.

Are social, behavioral, and educational (SBER) research studies also required to post an informed consent form?

The provision for posting informed consent forms applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. The revised Common Rule defines clinical trial as "a research study in which one or more human subjects are prospectively assigned to one or more interventions … to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes." SBER research studies that are conducted or sa] ɔ ported by a Common Rule department or agency and that fit the definition of clinical trial as stated in 45 CFR 46.102(b) of the revised Common Rule must also comply with the posting requirement.