HRP Consulting is providing this sample SOP addendum to assist organizations in the event that the revised Common Rule goes into effect on January 19, 2018. This sample SOP addendum does not address every aspect of the revised Common Rule but rather attempts to capture those provisions most critical to compliance. Likewise, this SOP does not include any of the recommendations provided to date by SACHRP because they are recommendations that OHRP may choose to accept, modify, or reject when formulating formal guidance. This SOP addendum is intended as a **temporary solution** to facilitate compliance while organizations develop permanent materials and works from the assumption that the organization's current SOPs include content that this addendum supplements or replaces when research is subject to the revised Common Rule. Please review carefully and modify appropriately for your organization.

Standard Operating Procedure
IRB Review of Research Subject to the Revised Common Rule

This Standard Operating Procedure (SOP) is an addendum to the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual] and describes the variations in requirements and procedures that [INSERT ORGANIZATION] HRPP/IRB, and investigators, will adhere to for research subject to the revised Common Rule that is IRB-approved, or determined exempt, on or after January 19, 2018. This SOP also applies to any studies subject to the pre-2018 version of the Common Rule that [INSERT ORGANIZATION] decides to transition to comply with the new rule. When the research invokes multiple regulatory frameworks (e.g., Common Rule, FDA, HIPAA), all will be applied following the procedures described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual] and this addendum. This SOP addendum will remain in effect until such time as the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual] has been fully updated to incorporate the revised Common Rule.

1. Definitions [§__.102]:

The following definitions will be applied when [INSERT ORGANIZATION] IRB reviews research subject to the revised Common Rule, and for exempt determinations and evaluations regarding whether a proposed activity is human subjects research when the research (or activity) is conducted or supported by a Common Rule agency. Likewise, the definitions will be applied, as applicable, to the conduct of the research, investigator responsibilities, and organizational responsibilities. Some of these definitions are unchanged from the pre-2018 rule but are included here for context.

Clinical trial means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Human subject means a living individual about whom an investigator (whether professional or student) is conducting research:

(i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
(ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction includes communication or interpersonal contact between investigator and subject.

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).

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.

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

Legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, legally authorized representative means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Minimal risk means that that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this rule, the following activities are deemed not to be research:

(i) Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.

(ii) Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

(iii) Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.

(iv) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Written, or in writing, refers to writing on a tangible medium (e.g., paper) or in an electronic format.

2. IRB Composition

The requirements for the composition of the IRB under the revised Common Rule vary slightly from the pre-2018 rule. The composition of the [INSERT ORGANIZATION] IRB complies with both rules. The following excerpt describes the requirements for the composition of the IRB under the revised Common Rule:

> *Each IRB shall have at least five members, with varying backgrounds to promote complete and adequate review of research activities commonly conducted by the institution. The IRB shall be sufficiently qualified through the experience and expertise of its members (professional competence), and the diversity of its members, including race, gender, and cultural backgrounds and sensitivity to such issues as community attitudes, to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects. The IRB shall be able to ascertain the acceptability of proposed research in terms of institutional commitments (including policies and resources) and regulations, applicable law, and standards of professional conduct and practice. The IRB shall therefore include persons knowledgeable in these areas. If an IRB regularly reviews research that involves a category of subjects that is vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, consideration shall be given to the inclusion of one or more individuals who are knowledgeable about and experienced in working with these categories of subjects.*
>
> *The IRB shall include at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas.*
>
> *The IRB shall include at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution.*
>
> *No IRB may have a member participate in the IRB's initial or continuing review of any project in which the member has a conflicting interest, except to provide information requested by the IRB.*

An IRB may, in its discretion, invite individuals with competence in special areas to assist in the review of issues that require expertise beyond or in addition to that available on the IRB. These individuals may not vote with the IRB. [§__.107]

3. Exempt Determinations and Limited IRB Review

Determinations regarding whether research subject to the revised Common Rule qualifies for exempt status will be made by [RESPONSIBLE PARTIES]. When the research requires limited IRB review or a HIPAA determination (i.e., waivers or alterations of the requirement for HIPAA authorization), the review will be conducted by the IRB Chair or a Chair-designated member of the IRB and may be conducted using expedited review procedures. As with all other research subject to IRB review requirements, when conducting limited IRB review the IRB has the authority to approve, require modifications in (to secure approval), or disapprove all research activities. [§__.109(a)]

Proposed modifications to the aspects of research subject to limited IRB review must be submitted to and approved by the IRB prior to implementation, except when necessary to eliminate apparent immediate hazards to the subject(s), in which case the change must be promptly reported to the IRB (i.e., within X business days). [§__.108(a)(3)(iii)]

Continuing review is generally not required for research determined to be exempt, even when that research is subject to limited IRB review. However, the IRB may determine that continuing review is required for a particular study subject to limited IRB review, in which case it shall document the reasons for its determination in the IRB record and communicate the requirement to the investigator in the IRB determination letter. [§__.109(f)(ii), §__.115(a)(3)]

3.1. Limitations on Exemptions

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. [§__.104(b)(3)]

Prisoners: Exemptions do not apply EXCEPT for research aimed at involving a broader subject population that only incidentally includes prisoners. [§__.104(b)(2)]

3.2. Exempt Categories [§__.104(d)]

Unless otherwise required by law or a federal agency or department, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from the additional requirements of the revised Common Rule, except as specified.

Note: Other than exempt category 6, these categories do not apply to research that is also FDA-regulated.

1. Research, conducted in established or commonly accepted educational settings, that specifically involves 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.

2. 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 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."*

3. 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. 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.

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) The identifiable private information or identifiable biospecimens are publicly available;
    (ii) Information, which may include information about biospecimens, 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, the investigator does not contact the subjects, and the investigator will not re-identify subjects;
    (iii) The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164 ['HIPAA'], subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b); **or**
    (iv) The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq.

5. Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

    (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal website or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

    (i) If wholesome foods without additives are consumed, **or**
    (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the

level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Note: Exempt categories 7 & 8 always require limited IRB review and are only available when broad consent will be (or has been) obtained. *(If an organization is not adopting the option for broad consent or only permitting under limited circumstances, these exemptions may be eliminated, or a statement describing any organizational requirements or constraints may be added.)*

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 §__.111(a)(8):

    (i) Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1) – (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
    (ii) Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117 (See Sections 8.6 and 8.7); **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.

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 §__.116(a)(1) through (4), (a)(6), and (d) (See Sections 8.1 and 8.3);
    (ii) Documentation of informed consent or waiver of documentation of consent was obtained in accordance with §__.117 (See Sections 8.6 and 8.7);
    (iii) An IRB conducts a limited IRB review and makes 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"* and makes the determination that the research to be conducted is within the scope of the broad consent referenced in 8.i above; **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.

4. Expedited Review

Expedited review of research subject to the revised Common Rule will be conducted using the procedures described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual] with the following variations:

1. The IRB shall apply the most current list of categories of research published in the Federal Register that may be reviewed using expedited review procedures [§__.110(a)]

2. Research that falls within the list of categories is presumed to be minimal risk unless the IRB determines and documents that the research involves more than minimal risk. [§__.110(b)(1)(i)] If the reviewer determines that the research involves more than minimal risk, it will be referred for review by the convened IRB

3. The limited IRB review that is required for certain exempt research (See Section 3) may be conducted using expedited review procedures [§__.110(b)(1)(iii)]

4. Continuing review of research is not required for research that qualifies for expedited review unless the IRB determines that is required and documents the rationale within the IRB record

5. Modifications to IRB-approved Research [§__.108(3)(iii)]

Investigators must promptly report proposed changes in a research activity to the [INSERT ORGANIZATION] IRB, and must conduct the research activity in accordance with the terms of the IRB approval until any proposed changes have been reviewed and approved by the IRB, except when necessary to eliminate apparent immediate hazards to the subject.

This requirement applies to all research approved by the [INSERT ORGANIZATION] IRB, including any aspects of exempt research subject to limited IRB review (See Section 3), and research for which continuing review is not required (See Section 6).

The [INSERT ORGANIZATION] IRB will follow the procedures described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual], and any applicable requirements and procedures in this SOP addendum, when reviewing modifications to IRB-approved research subject to the revised Common Rule.

6. Continuing Review [§__.109(e) and (f)]

The revised Common Rule modifies when continuing review is required. Unless [INSERT ORGANIZATION] IRB determines otherwise, continuing review of research is not required for research subject to the revised Common Rule in the following circumstances:

1. Research eligible for expedited review in accordance with §__.110;

2. Research reviewed by the IRB in accordance with limited IRB review as described in Section 3;

3. Research that has progressed to the point that it involves 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

[INSERT ORGANIZATION] IRB may determine that continuing review is required for any research protocol that falls within the above criteria. *(The following is not required but provided as an example of factors an IRB may take into consideration.)* For example, the IRB may determine that continuing review is required when:

1. Required by other applicable regulations (e.g., FDA);

2. The research involves topics, procedures, or data that may be considered sensitive or controversial;
3. The research involves particularly vulnerable subjects or circumstances that increase subjects' vulnerability;
4. An investigator has minimal experience in research or the research type, topic, or procedures; and/or
5. An investigator has a history of noncompliance

When the [INSERT ORGANIZATION] IRB determines that continuing review is required for such research, it will document the rationale in the IRB record and communicate the requirement to the investigator in the IRB determination letter.

(If the organization will require a status report when continuing review is not required, describe the requirement and procedures here (e.g., what to submit, when to submit, and any corresponding reviews or requirements (e.g., verification of human subjects training, COI review).)

7. Criteria for IRB Approval of Research

The [INSERT ORGANIZATION] IRB will apply the criteria for IRB approval described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual] to research subject to the revised Common Rule with the following variations:

Within criterion §__.111(a)(3), the text describing vulnerable subjects is replaced with the following:

> *The IRB should be particularly cognizant of the special problems of research that involves a category of subjects who are vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.*

Likewise, within criterion §__.111(b), the description of vulnerable subjects is updated and now reads:

> *When some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, additional safeguards have been included in the study to protect the rights and welfare of these subjects.*

While pregnant women are no longer described as vulnerable within the above criteria, the IRB shall continue to apply Subpart B "Additional Protections for Pregnant Women, Human Fetuses and Neonates" as described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual]. The revised Common Rule does not eliminate or modify Subpart B.

For **exempt research** subject to **limited IRB review**, the following criteria shall be applied:

1. For exempt categories 2(iii) and 3(iii) (See Section 3.2), the IRB may approve the research when it determines that there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data.

2. For exempt category 7, the IRB may approve the research when it determines that the following criteria are satisfied:
    a. Broad consent for storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens is obtained in accordance with the requirements of §__.116(a)(1) - (4), (a)(6), and (d) (See Sections 8.1 and 8.3 below);
    b. Broad consent is appropriately documented or waiver of documentation is appropriate, in accordance with §__.117 (See Sections 8.6 and 8.7 below); and
    c. 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.

3. For exempt category 8, the IRB may approve the research when it determines that the following criteria are satisfied:
    a. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data; and
    b. The research to be conducted is within the scope of the broad consent obtained from subjects.

8. Informed Consent

When reviewing research subject to the revised Common Rule, the [INSERT ORGANIZATION] IRB will evaluate the provisions for informed consent as described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual] with the below variations. Investigators conducting research subject to the revised Common Rule must adhere to these requirements.

8.1. General Requirements for Informed Consent [§__.116(a)]

In addition to the requirements for obtaining informed consent and the consent process described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual], the following specific requirements for consent, whether written or oral, apply to research subject to the revised Common Rule:

(Note: an alternative to this approach (stating that these requirements are "in addition") would be to specify which requirements in the organization's current SOPs are replaced or modified by the following. A grey-highlighted note has been added after each of the following to assist organizations in identifying whether a requirement is new or has been modified.)

1. Before involving a human subject in research, an investigator shall obtain the legally effective informed consent of the subject or the subject's legally authorized representative (LAR) *(reworded slightly for clarity that consent must be obtained before involving a subject in research)*

2. An investigator shall seek informed consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence *(importantly, added "to discuss"; reworded slightly)*

3. The information that is given to the subject or the LAR shall be in language understandable to the subject or the LAR *(slight rewording – added "legally authorized" to "representative")*

4. The prospective subject or the LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information *(new requirement)*

5. Except for broad consent (See Section 8.3):
    a. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR 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 a way that facilitates comprehension *(new requirement)*

        i. Generally, the beginning of an informed consent should include a **concise** explanation of the following:

            1. The fact that consent is being sought for research and that participation is voluntary;
            2. The purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
            3. The reasonably foreseeable risks or discomforts to the prospective subject;
            4. The benefits to the prospective subject or to others that may reasonably be expected from the research; and
            5. Appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject.

        However, based upon the facts of an individual protocol, the IRB may require that different (or additional) information be presented at the beginning of an informed consent to satisfy this requirement.

    b. 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 facilitates the prospective subject's or LAR's understanding of the reasons why one might or might not want to participate *(new requirement)*

6. No informed consent may include any exculpatory language through which the subject or the LAR is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. *(reworded slightly, removed "whether oral or written" as this has been elevated to the beginning of the section (applies to all), added "legally authorized" to "representative")*

8.2. Elements of Consent

In addition to the elements of informed consent described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual], the following additional elements are required for research subject to the revised Common Rule. The requirements for Broad Consent are described in Section 8.3.

Basic Elements [§__.116(b)]

1. One of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:

    a. 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

    b. 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.

Additional Elements (must be included when appropriate) [§__.116(c)]

1. 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;

2. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

3. 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).

8.3. Broad Consent [§__.116(d)]

(If an organization is not adopting the option for broad consent or only permitting under limited circumstances, this section may be eliminated, or language added to reflect the organization's constraints or requirements for use.)

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted under the revised Common Rule. Broad consent is not currently recognized in FDA regulation or guidance.

When obtaining broad consent, the general requirements for informed consent described in Section 8.1 apply except as noted. The following elements of broad consent [§__.116(d)] shall be provided to each subject or the subject's LAR:

1. A description of any reasonably foreseeable risks or discomforts to the subject;

2. A description of any benefits to the subject or to others which may reasonably be expected from the research;

3. A statement describing the extent, if any, to which confidentiality of records identifying the subject must be maintained;

4. 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;

5. For research involving biospecimens, 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;

6. 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);

7. 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;

8. 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;

9. 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);

10. 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, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

11. 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

12. 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.

(The following two paragraphs are examples of procedures an organization could choose to adopt, organizations should customize as appropriate to reflect their own practices.)

Investigators must include information regarding the circumstances under which broad consent will be obtained, the proposal for tracking of responses, and the proposed consent form(s) (or oral script if a waiver of documentation of consent is sought) and any other consent materials (e.g., information sheet, audiovisual materials, etc.) in their submission to the IRB. The [INSERT ORGANIZATION] IRB will review the information provided with the aid of a checklist to ensure that all requirements are satisfied. The outcome of the IRB's review will be communicated to the investigator in writing following the procedures described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual].

When investigators propose research involving the use of identifiable private information and/or identifiable biospecimens research for which broad consent was obtained, the investigators must include

documentation of the IRB approval for the storage or maintenance of the information or specimens and a copy of the consent form and/or other materials. The [INSERT ORGANIZATION] IRB will review the information provided with the aid of a checklist to ensure that all requirements are satisfied. The outcome of the IRB's review will be communicated to the investigator in writing following the procedures described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual].

8.4. Waiver or Alteration of Informed Consent [§__.116(e) and (f)]

When reviewing research subject to the revised Common Rule, the [INSERT ORGANIZATION] IRB will evaluate requests for waivers or alterations of informed consent in accordance with the requirements and criteria specified in the revised rule and summarized below. The IRB's determination will be documented in the IRB record and communicated to the investigator as described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual].

8.4.1. General Waiver or Alteration of Consent

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the [INSERT ORGANIZATION] IRB must determine and document that the below criteria are satisfied.

1. The research involves no more than minimal risk to the subjects;
2. The research could not practicably be carried out without the requested waiver or alteration;
3. 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;
4. The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
5. Whenever appropriate, the subjects or LARs will be provided with additional pertinent information after participation.

Investigators may be asked to provide justification, or additional information or documentation, to support that the above criteria are satisfied.

Restrictions:

1. Waivers –
    a. 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 in Sections 8.1 and 8.3, 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. Alterations –
    a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in Section 8.1
    b. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 8.3

8.4.2. Waiver or Alteration of Consent in Research Involving Public Benefit and Service Programs

In order to approve a request from an investigator to waive the requirement for informed consent, or to omit or alter one or more basic or additional element of consent (an "Alteration"), under this provision the [INSERT ORGANIZATION] IRB must determine and document that the below criteria are satisfied.

1. The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
    a. Public benefit or service programs;
    b. Procedures for obtaining benefits or services under those programs;
    c. Possible changes in or alternatives to those programs or procedures; or
    d. Possible changes in methods or levels of payment for benefits or services under those programs; **and**
2. The research could not practicably be carried out without the waiver or alteration.

Restrictions:

1. Waivers –
    a. 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 in Sections 8.1 and 8.3, 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. Alterations –
    a. An IRB may not approve a request to alter or omit any of the general requirements for informed consent described in Sections 8.1 and 8.3
    b. If a broad consent procedure is used, an IRB may not alter or omit any of the elements described in Section 8.3

8.5. Screening, Recruiting, or Determining Eligibility [§__.116(g)]

The revised Common Rule removes the requirement for partial waivers of consent for the use of information or specimens for the purposes of screening, recruiting, or determining the eligibility of prospective subjects for inclusion in the research. Pursuant to the revised rule, the [INSERT ORGANIZATION] IRB may approve a research proposal in which an investigator will obtain information or biospecimens for these purposes without the informed consent of the prospective subject or the subject's LAR if either of the following conditions is met:

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

When research is subject to the revised Common Rule, and the above conditions are met, investigators do not have to request waivers of consent for the purposes of screening, recruiting, or determining eligibility but do have to describe the activities in the application or protocol submitted to the IRB. The

above does not negate the requirements of other rules, such as HIPAA, when applicable. It also does not negate the requirement to obtain consent, or a waiver of consent, before involving a subject (including the use of their identifiable private information or biospecimens) in other research activities.

8.6. Documentation of Consent [§__.117]

The revised Common Rule modifies the requirements for documentation of consent as described below. When reviewing research subject to the revised Common Rule, the [INSERT ORGANIZATION] IRB will apply the requirements summarized below.

Unless the requirement for documentation of consent is waived by the IRB, informed consent must be documented by the use of written informed consent form (ICF) approved by the IRB and signed (including in an electronic format) by the subject or the subject's LAR. A written copy must be given to the person signing the ICF.

The ICF may be either of the following:

1. A written consent document that embodies the basic and required additional elements of informed consent. The investigator shall give either the subject or the subject's LAR adequate opportunity to read the informed consent form before it is signed; alternatively, this form may be read to the subject or the subject's legally authorized representative; or

2. A short form written consent document stating that the elements of informed consent have been presented orally to the subject or the subject's LAR and that the key information required by §__.116(a)(5)(i) (See Section 8.1 #5.a) was presented first to the subject, before other information, if any, was provided. When this method is used:

    a. The oral presentation and the short form written document should be in a language understandable to the subject; and
    b. There must be a witness to the oral presentation; and
    c. The IRB must approve a written summary of what is to be said to the subject (the approved full consent document may serve as this summary); and
    d. The short form document is signed by the subject;
    e. The witness must sign both the short form and a copy of the summary; and
    f. The person actually obtaining consent must sign a copy of the summary; **and**
    g. A copy of the summary must be given to the subject or representative, in addition to a copy of the short form.

8.7. Waiver of Documentation of Informed Consent [§__.117(c)]

The revised Common Rule adds a third condition under which an IRB may waive the requirement for an investigator to obtain a signed informed consent form. When reviewing research subject to the revised Common Rule, in addition to the criteria described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual], the [INSERT ORGANIZATION] IRB may also approve a request for a waiver of documentation of consent if it finds that:

1. The subjects or LARs 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.

The IRB's determination will be documented in the IRB record and communicated to the investigator as described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual].

9. IRB Review of Grant Applications

The revised Common Rule removes the requirement that the IRB review the Federal grant application or proposal for consistency with the protocol submitted to the IRB. Unless required by the Federal department or agency conducting or supporting the research, or by foreign, state, or local laws or regulations (including tribal law), the [INSERT ORGANIZATION] IRB will no longer require submission of, or conduct review of, Federal grant applications or proposals when research is subject to the revised Common Rule.

10. Posting of Clinical Trial Consent Forms [§__.116(h)]

The revised Common Rule includes a requirement for the posting of one IRB-approved consent form to a publicly available Federal website for each clinical trial conducted or supported by a Common Rule department or agency after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject. This requirement may be satisfied by either the awardee or the Federal department or agency. If the Federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a Federal website (e.g., confidential commercial information), the department or agency may permit or require redactions to the information posted.

Federal guidance or instructions regarding the implementation of this requirement was not available at the time this SOP went into effect. Until federal guidance or instructions are available, when [INSERT ORGANIZATION] is the prime awardee, [insert responsible party, e.g., investigators, sponsored programs staff] should consult with the grant officer regarding how to satisfy this requirement.

11. IRB Records [§__.115]

The revised Common Rule includes additional requirements for IRB records. When [INSERT ORGANIZATION] is engaged in human subjects research subject to the revised Common Rule the following records will be maintained in addition to those described in the [INSERT ORGANIZATION] [HRPP/IRB SOP Manual].

1. Institutional Records –
    a. For nonexempt research involving human subjects covered by the Common Rule (or exempt research for which limited IRB review takes place as described in Section 5.5) that takes place at an institution in which IRB oversight is conducted by an IRB that is not operated by the institution, the institution and the organization operating the IRB shall document the institution's reliance on the IRB for oversight of the research and the responsibilities that each entity will undertake to ensure compliance with the requirements of this policy (e.g., in a written agreement between the institution and the IRB, by implementation of an institution-wide policy directive providing the allocation of responsibilities between the institution and an IRB that is not affiliated with the institution, or as set forth in a research protocol)

2. IRB Records –

a. The rationale for conducting continuing review of research that otherwise would not require continuing review (as described in Section 6)
b. The rationale for a determination that research appearing on the expedited review list published in the Federal Register is more than minimal risk

12. Additional SOP Content Considerations

(Organizations should review their current SOPs and include additional content as needed in this SOP addendum to address any other variations or changes related to the implementation of the revised Common Rule. For example, updated language may need to be included when current SOPs include:

- *A statement that the organization voluntarily extends the Common Rule or the Common Rule and subparts B, C, & D to all non-exempt human subjects research on their FWA*

Statements that research involving Newborn Dried Blood Spots is considered research involving human subjects and that waivers of consent may not be granted for the Newborn Dried Blood Spots when the res