Approved Changes to IRB Processes 2024
(Approved 11/17/2023)

Relevant Precipitating Conditions

- The IRB has a high volume combined with low staffing
- We have not taken advantage of the flexibility that 2018 revisions to the Common Rule (45 CFR Part 46) afforded IRBs
- 45 CFR 46 applies only to research conducted by federal agencies and federally funded projects

Determinations of not Research or not Human Subjects Research

There will be two processes for determinations of *not human subjects research* (Not HSR), one formal/ the other informal. The formal process is for investigators who need or desire a formal determination letter from the IRB. The informal process is for those not needing such documentation.

The primary criteria for such determinations will be that the study does not include (a) collection of data through interaction or intervention with human subjects or (b) does not collect or include identifiable data from or *about* individuals (e.g., identifiable patient records). Not HSR protocols will receive the designation of "review not required" in Streamlyne.

Under this criterion, studies that are secondary analyses of anonymized data, publicly available or otherwise, are not human subjects research and will also be designated "review not required" in Streamlyne.

For informal determinations, PIs must complete and submit the IRB determination form via email to ric_admin@nmsu.edu. For faster attention, PIs should cc the IRB Coordinator (mgavin@nmsu.edu) and IRB Chair (tomaka@nmsu.edu). The IRB Admin Team (Chair, Vice-Chair, and Staff Coordinators) will review these requests, decide, and notify the PI via email with ric_admin@nmsu cc'd. In affirmative decisions, this email will serve as a record of the official determination.

For formal determinations, PIs must complete and submit the same IRB determination form via a Streamlyne protocol following the directions provided at the top of the determination form. (Eventually, this will become available directly in Streamlyne.) The IRB Admin Team will review these requests and render a decision in streamlyne. Streamlyne will communicate the decision to the PI. The official determination letter will be generated and housed within Streamlyne and is available to download.

Exempt and Expedited Research

NOTE: As the requirements and processes for review of exempt and expedited research have changed under the 2018 revisions to the common rule (45 CFR Part 46; https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-46?toc=1), the IRB encourages investigators to become familiar with these changes, the types of review, and their respective categories. Investigators can find a helpful guide at https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html.

Exempt Review

Research that fits within one of the exempt review categories—as determined by IRB Administrators[1]--will be reviewed by the IRB Admin team. If and when the protocol satisfies NMSU requirements (e.g., for informed consent, fair compensation, privacy protection, data storage, etc.), the protocol will receive

[1] The IRB Administrative Team, not individual investigators, will make all such decisions.

approval for five years, with no need for annual continuing review or renewal within the approval period. The project will be closed at the end of the five years unless the PI requests a further extension. There is no requirement for a "final" or "close-out" report.

There are no changes regarding the necessity of, expectations for, or processes related to submitting amendments. It is important to note that modifications that take the protocol out of exempt category status will require submitting a new protocol and engaging in an expedited or full board review process.

NMSU requires exempt research to provide informed consent. The minimum information required for exempt informed consent forms, statements, cover letters, etc., is attached.

Expedited Review

Research that fits within one of the expedited review categories—as determined by IRB Administrators--will be reviewed by at least one IRB member. If or when the protocol satisfies NMSU requirements (e.g., informed consent, fair compensation, privacy protection, data storage, etc.), the protocol will receive approval for five years, with no requirement for annual continuing review or renewal within the approval period unless the IRB determines otherwise.[2] The project will be closed at the end of the five years unless the PI requests a further extension. There is no requirement for a "final" or "close-out" report. There are no changes to the required consent elements, which remain consistent with 45 CFR Part 46

Full Board Review

There are no changes to the full-board review process other than the assignment of at least two "primary" reviewers to each protocol from the IRB committee. Final or close-out reports are required.

Other Miscellaneous

- *Study Closure. I*nvestigators may close a study when data collection has ceased and they have removed identifying information from the working data (i.e., made anonymous). There is no need to maintain an active protocol beyond this point unless the PI anticipates collecting additional data.
    - Investigators must request to close a study in Streamlyne through *Protocol Actions*

Summary of proposed changes

1. Exempt protocols will be reviewed and approved by the IRB Administrative Team.
2. Exempt protocols will have modified requirements for informed consent
3. Unless otherwise required by the IRB, exempt and expedited protocols will have five-year approval periods.
4. The IRB will automatically close exempt and expedited protocols at the end of the approval period unless the investigator requests an extension.
5. An investigator can close a study once the data have been made anonymous.

[2] The IRB, PI, or funding agency may request/require continuing review as frequently as annually according to 45 CFR Part 46.

NMSU-Required Elements of Exempt Consent Forms, Letters, Statements[3]

(1) A statement that the study involves research, the purposes of the research and the expected duration of the subject's participation, a description of the procedures, identification of any procedures that are experimental, and a description of how the data will be used;

(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 statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained; **or** that the study is anonymous (i.e., does not collect any personally identifying information)

(5) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights

(6) 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.

NOTE: Participants may give consent by written signature, checkbox, or passively by continuing with the study procedures (e.g., completing a survey).

[3] Adapted from 45 CFR Part 46 general requirements for infomed consent

(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 about any research that involves the collection of identifiable private information or identifiable biospecimens:

a. (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

b. (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.

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