ROSALIND FRANKLIN UNIVERSITY of MEDICINE AND SCIENCE

Institutional Review Board

GUIDANCE ON CONTINUING REVIEW (CR) FOR ONGOING STUDIES:

One of the major changes ushered in with the Revised Common Rule on January 21, 2019 *("New Rules")* concerns continuing review/renewal of IRB protocols.

What has <u>not</u> changed?

- Greater than minimal risk studies (<u>Full Board review category</u>) that are either federally or non-federally funded are still required to submit CR applications annually. Once a Full Board category study moves into a data analysis only stage, the investigator may petition the full board to transition that study to expedited review status.
- Any federally funded, non-exempt, minimal risk studies (<u>Expedited review category</u>) that were initially approved *prior to January 21, 2019* are still required to submit CR applications annually.

What <u>has</u> changed?

Under the new federal rules IRB protocols that meet one of the following conditions *might not* require continuing review by the IRB:

- Research protocols (federally or non-federally funded) which are eligible for expedited review,
- Research that is limited to data analysis of identifiable private information or identifiable biospecimens, or
- Research that only accesses follow-up clinical data which subjects undergo as a part of their normal clinical care.

Determining the Need* for Continuing Review

- All expedited review category NEW protocols approved *after January 21, 2019 (New Rules)* will automatically be released from continuing review requirement unless there are extenuating circumstances. Investigators do not need to take any action if they receive a letter from the IRB that states: "No further Continuing Review applications are needed for this project". Such a letter will supersede any previous determination letters concerning the project's expiration date.
- For expedited review category protocols that were originally approved *prior to January 21, 2019* (Old Rules), **action from the Investigator is required** to transition the study to the new rules. This can be done at any time while the protocol is in compliance, but no later than 30 days prior to the current expiration date of the protocol, to allow for IRB review and formal approval. The text and table below provide guidance on how you should proceed to get your protocol transitioned to the New Rules (and thus be removed from the continuing review requirement).
- *If data collection for your expedited review study is ongoing*, transitioning requires: the submission of a <u>new IRB Protocol Form</u> (not the continuing review form) and a <u>new Informed Consent Form</u> (using the current forms on the IRB website), as well as electronic copies of all study related materials and personnel CITI completion certificates. Once this is reviewed and approved, the study will be considered transitioned to the New Rules and it will be "Released from CR".

- *If your expedited review category study has progressed to the stage of data analysis only and all interactions with subjects are completed*, the Investigator should provide this information in a formal letter to the IRB and request a "Release from CR". This includes both studies involving identifiable data or biological specimens.
- *If your expedited review category study that does not involve the collection or storage of biological specimens has progressed to the stage of "data analysis only", and you have de-identified the data*, the Investigator should submit a voluntary closure form to the IRB. That closure should describe in detail how the data were de-identified. Note that "coded" data is not the same as "de-identified" data (see the IRB website for more information about what constitutes de-identified data).
- *If you have a study involving deidentified biological specimens that is in "data analysis only"* the Investigator may request a "Release from CR" by submitting a letter to the IRB. That letter should describe in detail how the data were de-identified. Note that "coded" data is not the same as "de-identified" data (see the IRB website for more information about what constitutes de-identified data).

**Note that the IRB will make the final determination on the need for CR.*

Status	Funding Source	Risk Level	IRB Action+
Ongoing data collection and/or participant interaction	Federal or Non-Federal	Minimal / Expedited	Release from CR
Data Analysis Only - Identifiable Data or *Biological Specimens	Federal or Non-Federal	Minimal	Release from CR
Data Analysis Only - Deidentified Data *(not including Biological Specimens)*	Federal or Non-Federal	Minimal	Close Study
Data Analysis Only - Deidentified Biological Specimens	Federal or Non-Federal	Minimal	Release from CR

+ "Action" refers to a formal IRB decision after the PI makes the request (this will not happen automatically)

** Biological specimens include any material derived from a human such as blood, urine, tissues, organs, saliva, DNA/RNA, hair, nail clippings, or any other cells or fluids whether collected for research purposes or as residual specimens from human diagnostic, therapeutic, or surgical procedures.*

Issues that may prevent a release from Continuing Review by the IRB

Protocols eligible for release from Continuing Review will be granted a release unless a valid reason to require renewal applications is documented by the IRB. Issues that may prevent release from Continuing Review include, but are not limited to, the following situations:

- Additional regulatory or ancillary oversight is required (e.g. COI)
- Study is FDA regulated
- Study includes international or non-local sites
- New findings require additional oversight
- Investigator has a history of non-compliance

Other Investigator Requirements

A protocol's release from CR does not release the Investigator from other requirements such as:

- submitting modifications/amendments for review and approval *prior to* implementation.
- submission of reportable events
- submission of a project Closure Report upon completion of the study

Failure to meet these other regulatory requirements may result in a finding of non-compliance.