Simmons
UNIVERSITY

FORM FOR REQUESTING TRANSITION TO THE REVISED COMMON RULE

When to Use this Checklist: The federal government changed the Common Rule (45 CFR 46) that governs human subjects research, with an effective date of January 21, 2019.

Submit this form with your IRB continuing review application to request that an existing study is to be transitioned to the revised Common Rule.

Note:

- A transition can only be requested at the time of your protocol's renewal.
- Consult the Simmons IRB website ***Key Changes*** document and under the IRB Manual and Forms banner to learn more about the changes. You will also find guidance for preparing informed consent documents and more.

Section 1. PROTOCOL INFORMATION

A. Principal Investigator: _____

B. Advisor (Student Protocols): _____

C. Protocol Number: _____

D. Project Title: _____

Section 2. STUDY STATUS

A. Is your study reviewed annually by a fully convened Board? ☐ Yes ☐ No ☐ Unsure

B. Are you still collecting data from participants? ☐ Yes ☐ No

C. If no to **B**, are you still analyzing identifiable data or biospecimens? ☐ Yes ☐ No

Section 3. CITI TRAINING

A. Have you taken the required CITI training after January 20, 2019? ☐ Yes ☐ No

4. REQUIRED CHANGES TO CONSENT DOCUMENTS

A. Key information needs to be added to the top of all consent forms still being used to enroll participants. Action taken:

☐ Consent form modified to include key information
☐ No action required; *please select reason why*
  ☐ A waiver of informed consent is in place for this research
  ☐ Enrollment is no longer taking place for this study

B. A specification of future use of data needs to be added to all consent forms still being used to enroll participants. Action taken:

☐ Consent form modified to indicate that de-identified information and/or biospecimens may be used for future research without additional consent
☐ Consent form modified to indicate that information and/or biospecimens will not be used for any future research
☐ No action required; *please reason select why*
  ☐ A waiver of informed consent is in place for this research
  ☐ Enrollment is no longer taking place for this study
  ☐ This information is already included on the consent form

C. When applicable, a specification of whether or not clinically relevant research results will be disclosed to participants and under what conditions needs to be added to consent forms. Action taken:

☐ Consent form modified to include information about disclosure of clinically relevant research results
☐ No action required; *please reason select why*
  ☐ A waiver of informed consent is in place for this research
  ☐ Enrollment is no longer taking place for this study
  ☐ This study does not have clinically relevant research results
  ☐ This information is already included on the consent form

D. Are the revised consent forms attached? ☐ Yes ☐ No ☐ Not Applicable

E. Is this study longitudinal in nature? (Are the same participants being followed for years?)
☐ Yes ☐ No

If yes, in the research team's opinion, do participants consented with the pre-transition consent form who are still active in the study need to be re-consented? ☐ Yes ☐ No
If yes, has a plan for re-consenting participants been added to the application? ☐ Yes ☐ No

F. Is this project registered as a clinical trial? ☐ Yes ☐ No

NOTE: If yes, when the study transitions to the revised Common Rule an informed consent form must be posted on the Federal Web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit.

Section 5. OTHER CHANGES

A. Do you currently have a Waiver or Alteration of Informed Consent in place for this project?
☐ Yes ☐ No

NOTE: Be sure to request a new waiver or alteration of informed consent in your continuing review application.

B. Do you currently get consent for screening procedures for this project? ☐ Yes ☐ No

If yes, are you requesting to no longer receive consent for screening procedures? ☐ Yes ☐ No
If yes, has the application been updated accordingly? ☐ Yes ☐ No