Administrative Review Guidance Process

First, please confirm with the lead site that they are willing to serve as the IRB of Record for Rutgers University.

Next, if the lead site agrees to be the IRB of Record, an Administrative Review submission should be created in eIRB.

- 1) Please login to eIRB (<u>https://eIRB.rutgers.edu</u>) and create a new study.
- 2) In eIRB application section 1.0 Submission Type, select "Administrative Review."
- 3) In **eIRB application section 1.1 Study Identification**, please list any Rutgers personnel involved in the project (all Rutgers personnel must complete required CITI and eCOI).
- 4) In eIRB application section 1.5 Administrative Review:
 - a) Please provide the IRB approval letter from the IRB of Record. There should be documentation indicating that the Rutgers PI and/or Rutgers University has been added to the research protocol.
 - b) Please provide the Institutional Authorization Agreement (IAA)/reliance agreement from the lead site (IRB of Record)

If SMART IRB is being utilized to establish the reliance agreement, please provide the SMART IRB ID number such so that the Reliance Team can review appropriately.

SMART IRB guidance link: https://smartirb.org/assets/files/Reliance-Checklist.pdf

5) In eIRB application section 7.0 Research Protocol/Summary:

- a) Please upload <u>all</u> study documents approved by the IRB of Record. Examples of documents include protocol, study instruments, other study materials, recruitment materials, etc.
- b) Please upload the Rutgers Local Context Supplement (HRP-508 Form). Link: <u>Local Context</u> <u>Supplement form</u>. This Form should be filled out to outline only the <u>research activities</u> that the <u>Rutgers study team</u> will be involved with at the <u>Rutgers site</u>.
- 6) In **eIRB application section 13.17 Consent Forms & Process of Consent**, if applicable, please upload the consent form used in this study.
- 7) In **eIRB application section 15.0 Additional Supporting Information**, please upload any other pertinent materials (i.e., grant/Notice of Award, etc.).
- 8) If Rutgers data will be shared, please contact Rutgers Research Contract Services (<u>ru-researchcontracts@research.rutgers.edu</u>). Research Contract Services are the Data Use Agreement subject matter experts; they will be able to clarify and assist with any potential formalized agreements that may be required.
- 9) When all items have been uploaded, please submit the request to eIRB.