|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Protocol Number:** | Pro202 | **PI Name (Last):** |  | **Meeting Date:** |  |
| **PI Requested:**  | [ ]   **Exempt** [ ]   **NHR**[ ]   **Expedited** [ ]  **FB** [ ]  **Admin Review**[ ]  **sIRB**  | **Admin Pre-Reviewer:** |  | **Pre-Review Date:** |  |
|  |
| **1.0 Study Identification** | **Y**  | **N** | **N/A** | **Comments/Changes** |
| 1. The type of submission selected is Humanitarian Use Device (HUD)\*
2. Research Data Bank or Biorepository \*\*
3. Involves Surrogate Consent \*\*
4. Submission type is Single IRB\*\*\*
5. Submission type is Administrative Review\*\*\*
 | [ ]  | [ ]  | [ ]  | \*This submission requires review by Full Board.  \*\*Route to the Sr. IRB Manager overseeing EC.\*\*\*Route to the IRB Reliance Administrator |
| 1. The principal investigator (PI), co-investigator (CI), or other study personnel (OSP) is restricted.
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** Inform the PI about the submission policy for investigators who are restricted.  |
| 1. The principal investigator (PI), co-investigator (CI), or other study personnel (OSP) institutional status is provided.
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** If NO, inform PI, CI or OSP to update their institutional status. Refer to the FUL document for reviewer note language |
| 1. The PI is a student:
2. Graduate/Doctoral Student\*
3. Undergraduate Student\*\*
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI about the policy on who may be a principal investigator and who may not. For example, \*Graduate/Doctoral students must have a full-time Rutgers faculty advisor (except GSAPP where Faculty are PT) listed on the eIRB application as Co-Investigator.\*\*Undergraduate students, Housestaff (Interns, Residents, Clinical Fellows) or Postdoctoral Fellows (ArtSci) cannot be the PI but can be listed as Co-I.  |
| 1. The PI is Robert Wood Johnson University Hospital or University Hospital staff.
 | [ ]  | [ ]  | [ ]  | Send an invoice for IRB fees |
| **1.2 IRB Researcher Training Records** |
| 1. The PI, Co-I, and all Other Study Personnel completed CITI within the past 3 years. (not applicable to Non-Human/QA/QI projects)
 | [ ]  | [ ]  |  | If NO, list names below and send email via eIRB to study coordinator/personnel informing them they will need to complete CITI for final approval. If YES, but expiring within 30 days, list names below |
| 1. If this is a clinical trial funded by NIH, please check if the PI, Co-I, and Other Study Personnel completed the GCP module within the past 3 years.
 | [ ]  | [ ]  | [ ]  | If NO, list names below and send email via eIRB to study coordinator/personnel informing them they will need to complete CITI for final approval. If YES, but expiring within 30 days, list names below.* Name
* Name
 |
| **1.3 Conflict of Interest (COI)** |
| 1. The PI, CI, and OSP completed, eCOI within the past year OR Non-Rutgers Financial disclosure for Non-Rutgers research personnel (not applicable to Non-Human/QA/QI projects)
2. If eCOI is under ‘Monitor Review’,

send email to COI Admin and upload in eIRB1. If COI under Mitigation/Management Plan, note added in eIRB system for the Analyst
 | [ ]  | [ ]  |  | If NO, describe what is missing below. |
| [ ]  | [ ]  | [ ]  |
| [ ]  | [ ]  | [ ]  |
| **1.4 Required Reviews** |
| 1. \*The Department approver for each Department/Division involved with this new study application provided administrative approval.
2. Section ***1.0 Study Identification*** to verify each Department/Division involved in the study.

\*Not Applicable for Arts Science | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to add Department/Division and then submit study application to the Department/ Division approver before resubmitting to the IRB.See [Department Approvers list](https://orra.rutgers.edu/eirb) at eIRB Department Approvers List |
| **4.0 Study Funding Information** |
| 1. The study is externally funded?
2. If YES, the Grant Application(s) or draft Contract/CTA Agreement(s) is uploaded.
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to upload the Grant Application(s) or draft Contract/CTA Agreement(s).  |
| [ ]  | [ ]  | [ ]  |
| **5.1 Study Sites : Required Approvals** |
| 1. Non-Rutgers performance site approval and/ or signoff sheet for UH, UBHC, or RUG is uploaded.
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to upload the appropriate documentation. |
| **6.03 Embryonic Stem Cell Review** |
| 1. The Embryonic Stem Cell Review Oversight (ESCRO) Committee approval Letter is uploaded (if this study involves the use of Embryonic Stem Cells).
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to upload the ESCRO Committee approval. |
| **6.04 Scientific Review Board (SRB)** |
| 1. The SRB approval Letter is uploaded (for any cancer related protocol involving a RWJMS/NJMS faculty member).
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to upload the SRB approval.For the **Department of Education (ED)** research ensure that a permission letter has been submitted attesting compliance with FERPA and PPRA. |
| **7.0 Study Summary** |
| 1. A separate research protocol document is uploaded.
2. Administrative Review Submission(s): Local Context document is uploaded.
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to upload the protocol**Add Reviewer Note** to inform the PI to upload the local context document for administrative review submissions only |
| **8.1 Study Drugs** |
| 1. The Investigator Brochure (IB) or Drug Insert (DI) is uploaded.
 | [ ]  | [ ]  | [ ]  | **Add Reviewer Note** to inform the PI to upload the IB/DI. |
| **13.0 Informed Consent** |
| 1. Written consent will be signed by subject.
2. If YES, consent is uploaded.
3. If written consent will NOT be signed by subject (waiver of documentation of consent).
4. Consent/Assent will not be obtained from all subjects to be enrolled for this study.
5. Written consent will be signed by surrogate.
6. Additional required documents for surrogate are uploaded
 |  | **Add Reviewer Note** in section 13.2 Consent Forms & Process of Consent to inform the PI to, request waiver of written documentation of consent or request waiver of consent.**Add Reviewer Note** in section **13.2 Consent Forms & Process of Consent** to inform the PI to upload surrogate consent and additional required documents. New study applications utilizing the surrogate consent process must be reviewed by the Executive IRB. Route the complete new study application (after the PI addresses all/ any requested changes) to the Sr. IRB Manager for processing. |
| [ ]  | [ ]  | [ ]  |
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| **14.0 Billing Information** |
| 1. Send Invoice.
 | [ ]  | [ ]  | [ ]  | Specify the reason for not sending the invoice when applicable |
| 1. Check conclusion

The new study application is complete as submitted.If YES, route to appropriate IRB team member as per the routing coverage guideIf no,select **Request Changes** to enter the following message in the text box provided.*Thank you for your recent submission. Necessary information and/ or documentation were not included with your submission and are required before the IRB will process your new study application. Please log in to eIRB to respond to the requested changes. Click the* **Reviewer Notes** *tab* *to view a summary of the change requests. A response must be provided in each section before you can submit the changes. Click* **Submit Changes** *under* **My Activities** *menu only after a response is provided for each required change identified in each section.* | [ ]  | [ ]  | [ ]  | **Please note, when reviewer note(s) are added, the study must be returned to the PI to address the requested changes before being assigned to an IRBA except for COVID submissions.** |

**Administrative Review Additional Comments:**