|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Protocol Number:** | Pro20 | **PI Name (Last):** | | | | | | | |  | | **Meeting Date:** |
| **PI Requested:** | **Exempt**  **Expedited**  **FB** | **Admin Pre-Reviewer:** | | | | | | | |  | | **Pre-Review Date:** |
| **nNN=** | | |  | | | | | | | | **Comments/Changes** | |
| **Y** | | | **N** | | | **N/A** | |
| 1. 1. Submission Type (section 1.0) 2. a. Administrative Review (for NCI-CIRB, Commercial or other non-Rutgers IRB Review Request) | | | |  | |  | | |  | |  | |
| 1. b. Research [Biospecimen or Data] Bank | | | | ☐ | | ☐ | | | ☐ | | Note: Research Bank SOP and consent (if applicable) is uploaded. | |
| 1. 2. **Study Funding Information** **(Section 4.1):** 2. a. The grant application includes a human use or human subject section? 3. b. If NIH funded, does the consent and protocol include required CoC language (if applicable)? | | | |  | |  | | |  | |  | |
|  | |  | | |  | |
| 1. 3. **Coverage of study related costs (Section 4.0):** If this is a greater than minimal risk, then standard Rutgers University injury disclaimer is included in the consent | | | |  | | |  | |  | |  | |
| 1. 4. **Study Sites (Section 5.1):** | | | |  | | | | | | |  | |
| * 1. a. Rutgers serve as the IRB of record for any non-Rutgers sites   2. b. International | | | |  | |  | | |  | | Please review for potential Single IRB Review for engagement or non-engagement of research. If sites are engaged re-assign to IRBA after PAR is completed  Note: If **EU/EAA sites listed**, then **GDPR applies** | |
|  | |  | | |  | |
| * 1. c. Study sites with special circumstances | | | |  | |  | | |  | | Please refer to the document listing non-Rutgers sites. | |
| 1. 5. **Biosafety** **(Section 6.01):** 2. a. RU-Institutional Biosafety Committee (IBC) Approval is uploaded? | | | |  | |  | | |  | | If IBC approval is not uploaded, please ask the PI to provide documentation from Biosafety Committee indicating that the submission is in review.  Please make a note for the reviewer.  If IBC approval is not provided, this submission can be processed with approval with stipulation. | |
| 1. 6. **Radiation Safety (Section 6.10)** 2. a. Radiation safety committee Approval is uploaded? | | | | ☐ | | ☐ | | | ☐ | | If radiation safety approval is not uploaded, please ask the PI to provide documentation from Biosafety Committee indicating that the submission is in review.  Please make a note for the reviewer and note that radiation safety approval letter is required to process the approval for this submission. | |
| 1. 6. **Research with Radioisotopes that don’t have an IND** 2. b. Is Radioactive Drug Research Committee (RDRC) 3. Approval required? 4. c. If yes, is RDRC Approval uploaded? | | | | ☐ | | ☐ | | | ☐ | | If RDRC approval is not uploaded, please ask the PI to provide documentation from the RDRC indicating that the submission is in review.  Please make a note for the reviewer and note that RDRC approval letter is required to process the approval for this submission. | |
| 1. 7. **Study Summary (section 7.0)**:    1. a. Protocol is paginated    2. b. Protocol has version date listed. | | | |  | |  | | |  | | If any of these are missing, please make a note for the reviewer.  Note: Please make sure that the protocol is on most current template. | |
|  | |  | | |  | |
| 1. 8. **Protocol (section 7.0):** | | | |  | | | | | | | Note: Check that there is a version date & Pagination  Please make a note for the reviewer. | |
| 1. a. Title of the project | | | |  | |  | | |  | |  | |
| 1. b. Name of the Investigator/Co-Investigators | | | |  | |  | | |  | |  | |
| 1. c. Study purpose | | | |  | |  | | |  | |  | |
| 1. d. Study duration | | | |  | |  | | |  | |  | |
| 1. e. Subject selection and enrollment | | | |  | |  | | |  | |  | |
| 1. f. Consent procedures | | | |  | |  | | |  | |  | |
| 1. g. Research sites | | | |  | |  | | |  | |  | |
| 1. h. Research significance | | | |  | |  | | |  | |  | |
| 1. i. Research design | | | |  | |  | | |  | |  | |
| 1. j. Data analysis | | | |  | |  | | |  | |  | |
| 1. k. Potential risks | | | |  | |  | | |  | |  | |
| 1. l. Potential benefits | | | |  | |  | | |  | |  | |
| 1. m. Minimizing risks of harm | | | |  | |  | | |  | |  | |
| 1. n. Bibliography | | | |  | |  | | |  | |  | |
| 1. 9. **Drugs / Devices / Biologicals (Section 8.0):** | | | |  | |  | | |  | | Includes: Investigator Brochure (IB), Drug Insert (DI), Non-significant risk documentation (e.g. FDA documentation or PI justification).  Please make a note for the reviewer. | |
| **IND Requirementsv (Check if “Yes”. One must be “Yes” If all are “No” IND information is not complete.)**   1. The drug has a valid IND. 2. The drug is exempt from the IND requirements 3. The research is conducted outside of the United States and is conducted under ICH-GCP. | | | |  | | | | | | | Please make a note for the reviewer. | |
| ☐ | | ☐ | | | ☐ | |
| ☐ | | ☐ | | | ☐ | |
| ☐ | | ☐ | | | ☐ | |
| **IND Validation** (Check if **“Yes”**. At least one must be **“Yes”**  If all are **“No”** IND cannot be validated.   1. Sponsor protocol imprinted with the IND number. 2. Written communication from the sponsor documenting the IND number. 3. Written communication from the FDA documenting the IND number. *(Required if the investigator holds the* IND*.)* | | | |  | |  | | |  | | Please make a note for the reviewer. | |
| ☐ | | ☐ | | | ☐ | |
| ☐ | | ☐ | | | ☐ | |
| ☐ | | ☐ | | | ☐ | |
| 1. 10. **Subject Population (Section 10.0):** | | | |  | |  | | |  | | If there are vulnerable populations in this study (including children, prisoners, pregnant women, students, employees, etc), please check off “yes.” Otherwise, check off “no.” | |
| 1. 11. **Recruitment of Subjects (Section 11):** | | | |  | | | | | | |  | |
| Refer to the Required Recruitment Elements: [<https://orra.rutgers.edu/subjectrecruitment>](https://orra.rutgers.edu/subjectrecruitment) | | | |  | | |  | | |  | Please make a note for the reviewer | |
| 1. 12. **Consent Forms& Process of Consent** **(Section 13.2):** 2. a. Consent will be signed by the subject 3. b. Consent is paginated 4. c. Consent has version date listed | | | |  | | | |  |  | | If any of these are missing, please make a note for the reviewer. | |
|  | | | |  |  | |
|  | | | |  |  | |
| 1. 13. **Process of Consent** **(Section 13):** 2. a. Includes a Waiver of documentation? 3. b. Includes a Waiver of Elements of Consent 4. c. Includes a Waiver of Consent? 5. d. Includes a Waiver of HIPAA? | | | |  | | | | | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
| ☐ | | ☐ | | | ☐ | |
| 1. 14. **Consent document** **(Section 13): Includes required elements below?** | | | |  | |  | | |  | | If any of these are missing, please make a note for the reviewer. | |
| 1. a. Study summary | | | |  | |  | | |  | |  | |
| 1. b. 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 which are experimental | | | |  | |  | | |  | |  | |
| 1. c. A description of any reasonably foreseeable risks or discomforts to the subject | | | |  | |  | | |  | |  | |
| 1. d. A description of any benefits to the subject or to others which may reasonably be expected from the research | | | |  | |  | | |  | |  | |
| 1. e. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject | | | |  | |  | | |  | |  | |
| 1. f. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained | | | |  | |  | | |  | |  | |
| 1. **g. One statement** below that the research involves the collection of identifiable private information or identifiable biospecimens **is written in the consent form**: 2. 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 LAR, if this might be a possibility; OR 3. ii. A statement that 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. | | | |  | |  | | |  | |  | |
|  | |  | | |  | |
| 1. h. **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 (Standard Rutgers Injury Language) | | | |  | |  | | |  | |  | |
| 1. i. 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 | | | |  | |  | | |  | |  | |
| 1. j. 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 | | | |  | |  | | |  | |  | |
| **Additional Consent Elements:** | | | |  | |  | | |  | |  | |
| 1. a. 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) which are currently unforeseeable | | | |  | |  | | |  | |  | |
| 1. b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent | | | |  | |  | | |  | |  | |
| 1. c. Any additional costs to the subject that may result from participation in the research | | | |  | |  | | |  | |  | |
| 1. d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject | | | |  | |  | | |  | |  | |
| 1. e. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject | | | |  | |  | | |  | |  | |
| 1. f. The approximate number of subjects involved in the study | | | |  | |  | | |  | |  | |
| 1. g. A statement that the subject’s biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit and/or for research involving biospecimens, whether the research will or might include whole genome sequencing. | | | |  | |  | | |  | |  | |
| 1. h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions. | | | |  | |  | | |  | |  | |
| 1. 15. **Consent Disclaimers:** 2. a. RU-Injury Disclaimer included, if study is more than minimal risk? 3. b. Child Abuse/Self-Harm Disclaimer Included? | | | |  | |  | | |  | |  | |
|  | |  | | |  | |
| 1. 16. **Consent will be signed by a Surrogate/LAR:** | | | |  | |  | | |  | | Note: For HealthSci, submission needs review by Executive Committee | |
| 1. 17. **Non-English Speaking Participants (Section 13.1):** 2. **a. Includes an English Short form or a statement in protocol that the translated version of consent form will be provided in the future**? 3. b. Translated written consent will be signed by surrogate/LAR? 4. c. The content of surrogate consent is consistent with surrogate consent guidelines and includes required elements of consent listed above | | | |  | |  | | |  | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
|  | |  | | |  | |
| 1. 18. **PAR Conclusion** | | | |  |  | | | | |  | Please make a note/s for the reviewer. | |
| 1. a. Changes pending -> Request changes | | | |  | |  | | |  | |  | |
| 1. b. No changes pending -> Forward to reviewer | | | |  | |  | | |  | |  | |
| 1. 19. Is the Review Type/Risk Determination Correct? | | | | **YES** | | **NO** | | |  | | If **NO**, then please make a note for the reviewer. | |
| |  |  |  |  | | --- | --- | --- | --- | | **Requested ↓** |  | **Requires:** | | | **Full board** | **-->** | **Expedited** | **YES** | | **Expedited** | **** | **Full board** | **YES** | | **Expedited** | **** | **Exempt** | **YES** | | **Exempt** | **** | **Expedited** | **YES** | | **Exempt** | **** | **Full board** | **YES** | | | | | Please make a note for the reviewer here **& Forward to** **Full/ Expedited Reviewer** with a justification for the change in review type: | | | | | | | | |
| **Administrative Review Additional Comments:** | | | | | | | | | | | | |