RUTGERS UNIVERSITY
Office for Research

WORKSHEET – Preliminary Administrative Review		
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3.202 (HRP-308b)	4/29/2024	1 of 4

Protocol Number:	Pro20	PI Name (Last):	Meeting Date:
PI Requested:	☐ Exempt ☐ Expedited ☐ FB	Admin Pre-Reviewer:	Pre-Review Date:

	Y	N	N/A	
Funding (Section 3.0) If NIH is funded, does the consent and protocol include the required CoC language (if applicable)?	☐	☐	☐	
Study Sites (Section 4.1): ~~a.~~ Rutgers serve as the IRB of record for any non-Rutgers sites	☐	☐	☐	Note: Reliance Committee Member review required if Single IRB is being requested. Note: If **EU/EAA sites listed**, then **GDPR applies** Confirm if the research is conducted in the EU sites and add a note to the reviewer if additional information in the protocol section and necessary documents are required.
b. International	☐	☐	☐	
Protocol (section 6.0):				
a. Title of the project	☐	☐		
b. Name of the Investigator/Co-Investigators	☐	☐		
c. Study purpose	☐	☐		
d. Study duration	☐	☐		
e. Subject selection and enrollment	☐	☐		
f. Consent procedures	☐	☐		
g. Research sites	☐	☐		
h. Research significance	☐	☐		
i. Research design	☐	☐		
j. Data analysis	☐	☐		
k. Potential risks	☐	☐		
l. Potential benefits	☐	☐		
m. Minimizing risks of harm	☐	☐		
n. Bibliography	☐	☐		
Drugs / Devices / Biologicals (Section 7.0):	☐	☐	☐	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 Requirements (Check if "Yes". At least one must be "Yes" **If all are "No" IND information is not complete.)**				Please make a note for the reviewer.
a. The drug has a valid IND.	☐	☐	☐	
b. The drug is exempt from the IND requirements	☐	☐	☐	
c. The research is conducted outside of the United States and is conducted under ICH-GCP.	☐	☐	☐	
IND Validation (Check if **"Yes"**. If all are **"No"** IND cannot be validated.)	☐	☐	☐	Please make a note for the reviewer.
a. Sponsor protocol imprinted with the IND number.	☐	☐	☐	
b. Written communication from the sponsor documenting the IND number.	☐	☐	☐	
c. Written communication from the FDA documenting the IND number. *(Required if the investigator holds the* IND.*)*	☐	☐	☐	
d. 1572 submitted	☐	☐	☐	
1. **Recruitment of Subjects:**				Please make a note for the reviewer
Refer to the Required Recruitment Elements: https://orra.rutgers.edu/subjectrecruitmenthttps://orra.rutgers.edu/subjectrecruitment	☐	☐	☐	
2. Consent Forms& Process of Consent (Section 8.0):	☐	☐	☐	If any of these are missing, please make a note for the reviewer.
a. Consent will be signed by the subject	☐	☐	☐	
b. Consent is paginated	☐	☐	☐	
c. Consent has version date listed				
Process of Consent (Section 8.5):	☐	☐	☐	
a. Includes a Waiver of documentation?	☐	☐	☐	
b. Includes a Waiver of Elements of Consent	☐	☐	☐	
c. Includes a Waiver of Consent?	☐	☐	☐	
d. Includes a Waiver of HIPAA?				
Consent document (Section 10): Includes required elements below?	☐	☐	☐	If any of these are missing, please make a note for the reviewer.
a. Study summary	☐	☐	☐	
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	☐	☐	☐	
c. A description of any reasonably foreseeable risks or discomforts to the subject	☐	☐	☐	

d. A description of any benefits to the subject or to others which may reasonably be expected from the research	☐	☐	☐	
e. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject	☐	☐	☐	
f. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained	☐	☐	☐	
g. One statement below that the research involves the collection of identifiable private information or identifiable biospecimens **is written in the consent form**: 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	☐	☐	☐	
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.	☐	☐	☐	
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)	☐	☐	☐	
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	☐	☐	☐	
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:				
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	☐	☐	☐	
b. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent	☐	☐	☐	
c. Any additional costs to the subject that may result from participation in the research	☐	☐	☐	
d. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject	☐	☐	☐	
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	☐	☐	☐	
f. The approximate number of subjects involved in the study	☐	☐	☐	
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.	☐	☐	☐	

h. A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.	☐	☐	☐	
Consent Disclaimers: a. RU-Injury Disclaimer included, if study is more than minimal risk?	☐	☐	☐	
b. Child Abuse/Self-Harm Disclaimer Included?	☐	☐	☐	
16. **Consent will be signed by a Surrogate/LAR:**	☐	☐	☐	Submission needs review by Executive Committee
Non-English Speaking Participants: **a.** Includes an English Short form or a statement in protocol that the translated version of consent form will be provided in the future?	☐ ☐	☐ ☐	☐ ☐	
18. **PAR Conclusion**				Please make a note/s for the reviewer.
a. Incomplete submission -> Request changes	☐	☐	☐	
b. Forward to reviewer	☐	☐	☐	
19. Is the Review Type Correct?	☐YES	☐NO		If **NO**, then please make a note for the reviewer.

Administrative Review Additional Comments: