RUTGERS
THE STATE UNIVERSITY OF NEW JERSEY

FORM: Local Site Information – Clinical Site		
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The purpose of this form is to provide the Rutgers University IRB Office staff with local context information for Participating Sites that rely on the Rutgers University IRB to serve as the IRB of Record. This form must be completed by: (1) the Participating Site study team and (2) the Participating Site IRB; see notations throughout this form to determine who should complete the section. This completed form must be uploaded into the eIRB submission for each corresponding external clinical site.

IRB Protocol Number:	
Lead PI Name:	

1. Local Site and Study Information — **Section to be completed by Participating Site IRB, if available**

Name of Relying Site:
Federal Wide Assurance (FWA) Number:
FWA Expiration:
Does the institution have an internal Institutional Review Board? ☐ Yes ☐ No
IRB registration Number (If Applicable): _____
Is the Relying Site's IRB AAHRPP accredited (If Applicable)? Yes ☐ No ☐
Full Study Title:
Relying Site Details:

Local PI: Enter the name, email address and telephone number of the local site Principal Investigator.

PI Name:
PI Email Address:
PI Telephone Number:

Local IRB: Enter the name, email address and telephone number of the person to contact who is responsible for answering any questions from the local IRB.

Local IRB Point Of Contact Name:
Local IRB Point Of Contact Email:
Local IRB Point of Contact Telephone Number:
*Is the Relying Site a covered entity? (i.e. Healthcare Entity) Yes ☐ No ☐ N/A ☐

Are there any investigations, audits, or findings (e.g., OHRP, FDA, or local audits) over the past three years that would be relevant to the conduct of new human subject research proposed at the site? Yes ☐ No ☐

If the answer to question above was "Yes", please provide additional information regarding investigations, audits or findings that may be relevant.

2. Description of the Research Facility (Check All That Apply): — **Section to be completed by Participating Site study team**

	Inpatient		Outpatient		Long Term Care
	Rehabilitation		Residential Care		Psychiatric Care
	Geriatric Care		Imaging Center		Private Practice Center
	Pediatric Clinic		Primary Care		Specialty Care
	Other:				

3. Roles of the Participating Site (Check All that Apply):

Recruitment
Will the recruitment methods at this site be conducted as outlined in the approved multi-site protocol? Yes ☐ No ☐

If the answer to question above is "no", please describe how the recruitment process will be different at this site:

Consent process
Will the consent process be conducted as outlined in the approved multi-site protocol? Yes No

If the answer to question above is "no", please describe how the consent process will be different at this site:

Research procedures (including implementation/administration of research intervention)
Will all research procedures be conducted as outlined in the approved multi-site protocol? Yes ☐ No ☐

If the answer to question above is "no", please describe how the research procedures will be different at this site:

Standard of Care (as it relates to the proposed clinical research intervention
Is standard of care (as it relates to the proposed clinical research intervention) as outlined in the approved multi-site protocol consistent

with the standard of care at this site? Yes ☐ No ☐

If the answer to question above is "no", please describe how the standard of care at this site differs from what is outlined in the approved multi-site protocol:

Data storage and management

Will the confidentiality of the data be protected as outlined in the approved multi-site protocol? Yes ☐ No ☐

If the answer to question above is "no", please describe the how the confidentiality of the data will be protected at this site:

Subject compensation

Will subject compensation be conducted as outlined in the approved multi-site protocol? Yes ☐ No ☐

If the answer to question above is "no", please describe the how subject compensation will be different at this site:

4. Regulatory Requirements for this study (Check all that apply; please reference item #7 in this form to determine which subject populations apply)**:**	**Section to be completed by Participating Site IRB**

Age of Majority for Research (i.e. Age When One Is Considered An Adult In Your State):

Are There Any Tribal, State or Local Laws, non-US laws, regulations or institutional requirements that the Rutgers University IRB Will Need To Consider When Reviewing This Study? Yes ☐ No ☐

If the answer to question above is "yes", please describe the relevant state laws and provide a link to any key documents (e.g., institutional policy for applying state law or link to the statute).

What circumstances, if any, affect age of consent in your state (i.e. NJ does not allow emancipated minors to give consent for research purposes)?

Are there any state or local laws or institutional policies that require record keeping for longer than federal law requires under the Privacy Rule or Common Rule? Yes ☐ No ☐

If the answer to question above was "yes", please provide additional information regarding the record keeping requirements at your institution:

Please provide any local site policies for the following areas –if applicable (Please provide links to the relevant policy information):

Consent process for those with Impaired Decision-Making Capacity:

Use of Short Forms For Non-English Speaking Individuals:

Translation of consent forms for non-English speaking individuals:

Site-specific content or procedural information regarding the recruitment process:

Institutional Requirements: For each entry below, provide local template language for the following sections of the consent form (if applicable):

HIPAA Authorization Language:

Does this site require the use of a HIPAA waiver to review medical records solely for the purpose of identifying potential research subjects Yes ☐ No ☐

Does this site require the use of a stand-alone HIPAA authorization form (HIPAA authorization is <u>not</u> permitted to be embedded in the consent form)? Yes ☐ No ☐

Genetic Testing:

Research Related Injury: Please provide any other consent form language required by site policy or state law:

5. Staff Designation of Responsibilities for Research		Section to be completed by Participating Site study team
Name	**Degree(s)**	**Task Code(s)**

Designated Task Codes		
Enter task codes 1 through 15 for each member of the study staff as stated below. Indicate ALL applicable codes for individuals performing multiple tasks.		
1. Obtain Informed Consent	2. Drug(s)/Device Accountability	3. Physical Examination
4. Assess Capacity to Consent	5. Complete Source Documents	6. Chart Review
7. Explain Study Procedures	8. Complete Case Report Forms	9. Interpret Radiology or Lab Results
10. Dispense drug(s)/device	11. Determine Eligibility of Participants	12. Draw labs
13. Report Adverse Events	14. Medical History	15. Conducts study procedures:

Initial Here	**Please review the list of study personnel who will be engaged in human research and confirm that all have completed required training specific to your institution (i.e. Human Subject Protections Training, GCP Training and HIPAA Training, as applicable):** *"I have verified that all study personnel listed have completed required training. I have identified that some study personnel have not completed required training and will ensure that they are removed from the list until the required training has been completed."*
Initial Here	**Please review the list of study personnel who will be engaged in human research and indicate whether COI is present:** *"I have verified there are no financial interests to disclose. I have verified any relevant interests have been disclosed per my institutional policy and managed, as applicable."*

6. Recruitment Methods (Check All that Apply):				Section to be completed by Participating Site study team	
	Site investigator's own patients		Provider referrals		Chart Review
	Contacting Primary Care Physicians		Advertisements		Internet
	Tissue or blood bank		Admission to facility with eligible diagnosis		Posters
	Institutional electronic database		Institutional logbook/schedule		Other *describe:* _____.

7. Potential Study (Check All that Apply):				Section to be completed by Participating Site study team	
	Pregnant Women	☐	Children	☐	Prisoners
	Age 90 or over	☐	Cognitively impaired	☐	Non-English Speaking
☐	Males only	☐	Female only	☐	Transgender
☐	Employees of relying site	☐	Students of relying site	☐	Neonates

8. Emergency Procedures (Check All that Apply):				Section to be completed by Participating Site study team
☐	Code Cart	☐	*O2 Describe location:* _____	

9. Pharmacy (Check All that Apply):	Section to be completed by Participating Site study team
☐	Inpatient
☐	Outpatient
☐	Refrigerated study drug(s)
☐	Required annual certifications available on request
☐	Separate from supply for clinical use

☐	Refrigerate locked
☐	Limited access
☐	Ample/Adequate space
☐	Non-refrigerated study drug(s)
☐	Hood for preparation of drug(s)

10. Laboratory Services (Check All that Apply):	**Section to be completed by Participating Site study team**
☐ Outsourced	
☐ On-site	
☐ Dedicated lab space	
☐ Required annual certifications available on request	

11. Community Considerations	**Section to be completed by Participating Site IRB**
Please review the protocol and template consent form and identify whether there are any special characteristics/concerns of your community of which the reviewing IRB should be aware for this specific study. Please also outline any steps that may be taken to address these concerns:	

12. Affirmation

Local Investigator Affirmation

By signing below, I attest to the accuracy and completeness of the information provided herein. I will conduct the protocol in accordance with the IRB's requirements and any relevant local requirements.

Signature	***Date***
Name	***Title***

Institutional Official Affirmation

By signing below, I affirm to the training of the investigator(s) and accuracy of the information provided herein.

Signature	***Date***
Name	***Institutional Title***

**Covered entities are defined in the HIPAA rules as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards. Generally, these transactions concern billing and payment for services or insurance coverage. For example, hospitals, academic medical centers, physicians, and other health care providers who electronically transmit claims transaction information directly or through an intermediary to a health plan are covered entities. Covered entities can be institutions, organizations, or persons.*

Researchers are covered entities if they are also health care providers who electronically transmit health information in connection with any transaction for which HHS has adopted a standard. For example, physicians who conduct clinical studies or administer experimental therapeutics to participants during the course of a study must comply with the Privacy Rule if they meet the HIPAA definition of a covered entity.