

RUTGERS UNIVERSITY FORM: Local Site Information – Clinical Site – RWJBarnabas Health Office for Research Sites ONLY

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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) Numb | er: | | | | |
| FWA Expiration: Does the institution have an internal In | stitution | nal Review Board? 🗆 Yes 🗆 N | lo | | |
| IRB registration Number (If Ar | plicab | | 10 | | |
| Is the Relying Site's IRB AAH | RPP a | le): ccredited (If Applicable)? Yes ⊏ |] No □ | | |
| Full Study Title: | | | | | |
| Relying Site Details: | | | | | |
| Local PI: Enter the name, email address and PI Name: | telepho | one number of the local site Prir | ncipal Inve | stiga | tor. |
| PI Name. PI Email Address: | | | | | |
| PI Telephone Number: | | | | | |
| Local IRB: Enter the name, email address an | d telep | hone number of the person to c | contact who | o is re | esponsible for answering any |
| questions from the local IRB. | • | | | | |
| Local IRB Point Of Contact Na | | | | | |
| Local IRB Point Of Contact En Local IRB Point of Contact Te | | e Number: | | | |
| | | ? (i.e. Healthcare Entity) Yes 🗆 | | | |
| Are there any investigations, audits, or | finding | is (e.g., OHRP, FDA, or local au | udits) over | the p | ast three years that would be relevant |
| to the conduct of new human subject re | esearc | n proposed at the site? Yes | No 🗆 | e p | |
| If the answer to guestion abo | ve was | s "Yes", please provide addition | al informat | ion r | egarding investigations, audits or |
| findings that may be relevan | | | | | |
| | | | | | |
| 2. Description of the Research Facility (Ch | eck All | That Apply): Section to be | completed | d by | Participating Site study team |
| | | Outpatient | - | | Long Term Care |
| □ Rehabilitation | | Residential Care | | | Psychiatric Care |
| Geriatric Care | | Imaging Center | | | Private Practice Center |
| Pediatric Clinic | | Primary Care | | Π | 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 guestion above is "no", please describe how the recruitment process will be different at this site: | | | | | |
| 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 outli | ned in t | the approved multi-site protocol | ? Yes □ N | lo 🗆 | |
| □ If the answer to question above is "no", | | | | | |
| | p.5000 | | | anne | |
| Research procedures (including implementation/administration of research intervention) | | | | | |
| Will all research procedures be conducted as c | | | , | ⊐ No | |
| ☐ If the answer to question above is "no", | | | | | |
| Standard of Care (as it relates to the proposed clinical research intervention | | | | | |



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| 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 D No D | | | | |
| □ 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; Section to be completed by Participating Site IRB | | | | |
| please reference item #7 in this form to determine which subject | | | | |
| populations apply): 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 \Box No \Box | | | | |
| □ 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 not permitted to be | | | | |
| embedded in the consent form)? Yes | | | | |
| □ Genetic Testing: | | | | |
| Research Related Injury: Please provide any other consent form language required by site policy or state law: | | | | |
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| Stan Des | signation of Responsibilities | | Degree(s) | e complete | | ting Site study | |
|---|---|---|---|---|--|---|--------|
| <u>Name</u> | | | | | | Task Coo | 1e(s) |
| | | | | | | | |
| Desi | ignated Task Codes | | | | | | 1 |
| | r task codes 1 through 15 for | | udy staff as stated b | elow. Indic | ate ALL applica | ble codes for |] |
| | <i>riduals performing multiple tasl</i> Obtain Informed Consent | | | 2 Dh | sical Examinati | ion | |
| | Assess Capacity to Consent | 0() | ce Accountability | | rt Review | ION | - |
| | Explain Study Procedures | | se Report Forms | | rpret Radiology | vor Lab | - |
| '· ' | | | | | sults | | |
| 10. [| Dispense drug(s)/device | 11. Determine Eli Participants | gibility of | 12. Dra | wlabs | | |
| 13. 1 | Report Adverse Events | 14. Medical Histo | ry | | iducts study pro ase describe | ocedures: | |
| Initial He | "I have verified that some study person the list until the red | ning, GCP Training an at all study personnel lis nnel have not complete quired training has bee | d HIPAA Training, sted have completed ed required training a n completed." | as applica d required t and will ens | raining. I have i sure that they ai | identified that re removed fror | m |
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| □ Refrigerated study drug(s) | | |
|---|---|--|
| Required annual certifications available on | request | |
| | Tequesi | |
| | | |
| | | |
| | | |
| 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 | |
| | | |
| □ On-site | | |
| Dedicated lab space | | |
| Required annual certifications available on | request | |
| 11. Community Considerations | Section to be completed by Participating Site IRB | |
| | form and identify whether there are any special characteristics/concerns of your aware for this specific study. Please also outline any steps that may be taken to address | |
| | | |
| 12. Affirmation | | |
| 12. Affirmation | | |
| Local Investigator Affirmation | | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and com | npleteness of the information provided herein. I will conduct the protocol in accordance | |
| Local Investigator Affirmation | | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and com | | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and com | | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and com with the IRB's requirements and any relevant loca | l requirements. | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and com with the IRB's requirements and any relevant loca Signature Name | l requirements. | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and corr with the IRB's requirements and any relevant loca Signature Name Institutional Official Affirmation | Date Title | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and corr with the IRB's requirements and any relevant loca Signature Name Institutional Official Affirmation | l requirements. | |
| Local Investigator Affirmation By signing below, I attest to the accuracy and corr with the IRB's requirements and any relevant loca Signature Name Institutional Official Affirmation | Date 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



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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.