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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Protocol Title: | |  | | | | | | | |
| PI Name: |  | | | Study ID: | |  | Date: | |  |
| Completed By: | | |  | |  | | |

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|  | | | **Yes** | | **No** | | **N/A** | |
| Exemption Request Form | | | |  | |  | |  | |
| Study Protocol | | | |  | |  | |  | |
| Subject materials, including recruitment materials, information sheets, consents, scripts, and questionnaires, diaries, or surveys | | | |  | |  | |  | |
| Letter(s) of permission from any non-NJH sites, or, when applicable, documentation of IRB approval or exemption from the external site | | | |  | |  | |  | |
| Grant application (if the project is federally-funded and NJH is the IRB or serving as the IRB of record for the prime awardee | | | |  | |  | |  | |
| Verification of current CITI training for all members of the research team:  \*Investigators and research staff who interact or intervene with subjects, or who use subject’s identifiable information or biological specimens for the purposes of research, must complete NJH’s CITI Basic Biomedical Course and HIPS Course\* | | | |  | |  | |  | |
| Internal Research Review Form | | | |  | |  | |  | |
| Information Sheet (i.e. information to be provided to participants to obtain prospective agreement as applicable) with the following points addressed:  • A statement that the activities involve research  • A description of the procedures to be performed  • A statement that participation is voluntary  • The investigator's name and contact information  • For Category 3 research that involves subject deception: A statement that subjects will be unaware of or misled regarding the nature or purposes of the research | | | |  | |  | |  | |
|  | | | **Yes** | | **No** | | **N/A** | |
| **Ancillary Reviews**  Has this study undergone Scientific Review? If Yes, include a copy of the scientific review evaluation with your submission. When scientific or scholarly review is conducted by an individual or entity external to the IRB, documentation of the outcome and details of that review must be provided to the IRB for review and consideration. | | |  | |  | |  | |
| Has this study undergone COI Review? If Yes, provide documentation of COI review and any conflict management plans must be included with your submission. | | |  | |  | |  | |
| Does this study involve research-related radiation? If Yes, include documentation of radiation safety review and any additional requirements or recommendations with your submission.  If approval is pending, check here: ☐ Note that your IRB approval will be withheld until it is submitted. If you are performing any research related radiation procedures, a radiation safety review must be completed. | | |  | |  | |  | |
| Does your study involve any of the following;   * Recombinant or synthetic nucleic acid molecules * Human, animal or plant pathogens, select agents (restricted human and animal pathogens and toxins that are considered by CDC to pose a potential threat to health, see [http://www.cdc.gov/od/sap/](http://www.cdc.gov/od/sap/%20) * Human/Primate materials (blood, cells, cell lines, tissues, body fluids, organs   If Yes, include documentation of Institutional Biosafety Committee approval with your submission.  If approval is pending, check here: ☐ Note: your IRB approval will be withheld until it is submitted.  If you are unsure whether you protocol requires an IBC review, please answer the following question to help guide your decision   * Where will the Human/Primate samples be kept and analyzed? * Who will be working with these materials? * Will this work be carried out in a laboratory that already has an approved IBC protocol that includes this work? If so, please list the IBC protocol number. In this case, you will need to be added to that protocol before your planned work can be approved   Please go to the following site for NJH IBC policies and documents: <http://spyderweb.njrc.org/safety/Read_Me_First_Guidelines.htm> | | |  | |  | |  | |
| Does this study involve resources from outside your department, such as pharmacy, pathology, or other NJH facilities where research activities will occur? If Yes, include documentation of support. Documentation of permission or approval may be required as a component of the IRB (NJH or external) application. The Director of RRA may request review or consultation with any of the above or other organizational committees or components even when such review or consultation is not technically required by policy. | | |  | |  | |  | |
|  |  | **Applicable HIPAA Forms** (applicable only if the research activity involves seeing, using or disclosing protected health information- PHI): |  | |  | |  | |
|  |  | Authorization to Use and Disclose PHI |  | |  | |  | |
|  |  | Request for Waiver or Alternation of Authorization |  | |  | |  | |
|  |  | De-identification Certification form |  | |  | |  | |
|  |  | Limited Data Set Certification Form |  | |  | |  | |