**All non-exempt human subject research must be “registered” in** [**NJH IRB Manager**](https://njhealth.my.irbmanager.com/) **prior to submitting to an IRB for review. Use this checklist as a guide for preparing your registration submission.**

**All referenced documents, templates, etc. can be found here:** [**https://www.nationaljewish.org/research-science/support/compliance/irb/submissions**](https://www.nationaljewish.org/research-science/support/compliance/irb/submissions)

|  |  |  |  |
| --- | --- | --- | --- |
| **Basic Information**  | **Yes** | **No** | **N/A** |
| Name of the requested reviewing IRB If not requesting BRANY IRB, WIRB, Advarra, or NCI CIRB/SWOG:* IRB point of contact name and contact information
* Whether the IRB has agreed to be the reviewing IRB
* Whether the IRB is accredited (e.g., AAHRPP)
* Why you are requesting this IRB
 | **[ ]**  | **[ ]**  |  |
| Study sponsor/funding | **[ ]**  | **[ ]**  |  |
| Specific research activities to be performed locally at NJH | **[ ]**  | **[ ]**  | **[ ]**  |
| Subject population to be recruited locally at NJH | **[ ]**  | **[ ]**  | **[ ]**  |
| Recruitment plan for subjects recruited locally at NJH | **[ ]**  | **[ ]**  | **[ ]**  |
| Other research sites (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| Clinicaltrials.gov identifier (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| IND/IDE numbers (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| **Required Documents** |  |  |  |
| For internally funded projects: Completed Internal Research Review (IRR) FormFor externally funded projects: A Sponsored Projects Proposal Form in Cayuse (upload a Word document with the proposal #). | **[ ]**  | **[ ]**  |  |
| Financial interest disclosures in NJH COI system for all members of the research team\*Non-NJH employees should complete the NJH Human Research Financial Interest Form; include this form with your submission | **[ ]**  | **[ ]**  |  |
| Current CITI training for all members of the research team:* Biomedical (or Social Behavioral) Research
* Health Information Privacy and Security (HIPS) for Clinical Investigators
* 3 Conflicts of Interest courses (in Healthcare, Public Health Service, **AND** Other Federal Sponsors)
* GCP (if a federally-funded clinical trial, or are otherwise required to do so by an industry sponsor, or as a condition of a grant or contract)

\*Each course has a 3 year expiration | **[ ]**  | **[ ]**  |  |
| Study Protocol | **[ ]**  | **[ ]**  |  |
| Consent/assent form(s). (if applicable)\*If the study is going to BRANY IRB, be sure to use the consent/assent template on our website. \*For studies going to other IRBs, be sure to incorporate NJH required consent language into the consent/assent forms. This language can be found on our website.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Other subject materials: recruitment materials, scripts, questionnaires, diaries, or surveys (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| Request for Waiver of Alteration of HIPAA Form (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| Investigator Brochures and/or package inserts (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| IND/IDE Supporting Documentation (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| Device manuals (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| NJH Pharmacy Exception Form (if applicable)\*An approved version of this form is required if you **will not** use NJH Pharmacy for storing, dispensing, etc. Investigational Product. \*If you **will** use NJH Pharmacy for this purpose, you must submit an NJH Pharmacy Service Request Form to NJH Pharmacy. This form does not need to be included in the registration submission.  | **[ ]**  | **[ ]**  | **[ ]**  |
| **Ancillary Reviews****\*It is highly recommended that study teams contact applicable ancillary groups as early as possible to avoid delays in the registration process.** **\*Please refer to the NJH Ancillary Review Contact List for ancillary group contact information** | **Yes** | **No** | **N/A** |
| Does this study involve research-related radiation? If Yes, prior approval must be received from the Radiology Research Committee before your registration submission will be approved.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Does your study involve any of the following;* Human materials (blood, cells, cell lines, tissues, body fluids, organs)
* 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)

If Yes, prior approval from the Institutional Biosafety Committee must be uploaded in the registration submission before your registration will be approved.If you are unsure whether you protocol requires IBC review, please refer to the IBC Flowchart and/or reach out to the IBC Office.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Will you be obtaining services, data, or specimens from NJH’s Advance Diagnostic Laboratories (ADx)?If Yes, prior approval must be received from ADx before your registration submission will be approved. | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study require a full or partial waiver (or alteration) of HIPAA? If Yes, prior approval must be received from BRANY IRB before your registration submission will be approved (unless BRANY is the Reviewing IRB). If you have already obtained this approval, please upload the approval letter with your Request for Waiver of Alteration of HIPAA Form. Otherwise, the NJH HRPP will submit the waiver request to BRANY IRB on your behalf.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve using or purchasing new software, hardware, cloud storage or cloud services and/or wearable devices, phone apps, etc,?If Yes, this study will need to be reviewed by IST. This review will not hold up approval of the registration submission.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve receiving data from an outside institution/entity or sending data outside of NJH?If Yes, this study will need to be reviewed by the Contracts Office to ensure the appropriate agreements are in place. This review will not hold up approval of the registration submission. | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve obtaining data from the Research Database/dataSCOUT or to use REDCap to store data?If Yes, this study will need to be reviewed by Research Informatics Services (RIS). Please request services here: <https://redcap.njhealth.org/redcap/surveys/?s=7XF8RCWAE4>This review will not hold up approval of the registration submission. | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve obtaining human samples from the Biobank?If Yes, this study will need to be reviewed by the NJH Biobank Committee. Please request services here: <https://redcap.njhealth.org/redcap/surveys/?s=7XF8RCWAE4>This review will not hold up approval of the registration submission. | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve Twilio to send and/or collect research data for this study?If Yes, this study will need to be reviewed by the NJH HRPP. Please complete the following REDCap survey:<https://redcap.njhealth.org/redcap/surveys/?s=YNWRM8EX9C>This review will not hold up approval of the registration submission. | **[ ]**  | **[ ]**  | **[ ]**  |
| **Post-Approval Submission Requirements****\*Post-Approval Submission Requirements must be submitted in NJH IRB Manager using the appropriate xForm:**Modification xForm: change in PI and study team personnelInterim/Event Report xForm: UAPs, non-compliance, complaintsPost Approval Submission xForm: Continuing review/status report submissions and local-site modifications (including any updated protocols, updated consent forms, etc.) and corresponding IRB approval notification. DSMB, auditor, monitor, inspector reportsNote: This form does not require PI sign off.Closure xForm: Study closure |  |  |  |
| **Studies reviewed by BRANY IRB**Submit the following in NJH IRB Manager concurrent with submission to BRANY IRB:* Removal of any study team member responsible for contributing medical or psychological expertise to the conduct of the study.
* Local unanticipated problems, complaints, and any serious and continuing noncompliance.
* Notices about, and reports from, DSMB’s, external monitors, auditors, or inspectors.
 |  |  |  |
| **Studies reviewed by other external IRBs:**Submit the following in NJH IRB Manager concurrent with submission to the IRB of record* Local unanticipated problems, complaints, and any serious and continuing noncompliance.
* Notices about, and reports from, DSMB’s, external monitors, auditors, or inspectors.
* Study closures.

Submit the following in NJH IRB Manager once documentation of approval from the IRB of Record is received:* Copies of approved continuing review/status report submissions, approved local-site modifications/amendments (including any updated protocols, updated consent forms, etc.), and corresponding IRB approval notification.

Submit the following in NJH IRB Manager regardless of Reviewing IRB requirements:* Changes in PI and all study team member additions.
* Removal of any study team member responsible for contributing medical or psychological expertise to the conduct of the study.
 |  |  |  |