**Exempt research must be submitted in** [**NJH IRB Manager**](https://njhealth.my.irbmanager.com/) **for an official Exempt determination prior to beginning the research. Use this checklist as a guide for preparing your submission.**

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

**If unsure whether your research falls into an exempt category, please reference** [**OHRP’s decisions charts**](https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts-2018/index.html) **for exempt research.**

|  |  |  |  |
| --- | --- | --- | --- |
|  | **Yes** | **No** | **N/A** |
| Study Protocol | **[ ]**  | **[ ]**  |  |
| Information Sheet/Consent form if there is interaction with subjects.A template can be found on the NJH website.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Other subject materials: recruitment materials, scripts, questionnaires, diaries, or surveys (if applicable) | **[ ]**  | **[ ]**  | **[ ]**  |
| 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) | **[ ]**  | **[ ]**  | **[ ]**  |
| 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 required by the sponsor, grant or contract)
 | **[ ]**  | **[ ]**  | **[ ]**  |
| 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 | **[ ]**  | **[ ]**  | **[ ]**  |
| 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 #). | **[ ]**  | **[ ]**  | **[ ]**  |
| Request for Waiver or Alteration of HIPAA (if applicable). For example:* You plan to use or disclose PHI for recruitment purposes (e.g., “pre-screen” or review of medical records to identify prospective research participants)
* You plan to use or disclose PHI for research purposes and there is no plan to obtain consent and authorization from subjects of the research (e.g., retrospective review of existing medical records).
* You plan to obtain authorization to use or disclose PHI for research purposes but want elements of the authorization to be waived (e.g., a request to waive signature because you are obtaining verbal consent over the phone).
 | **[ ]**  | **[ ]**  | **[ ]**  |
| **Ancillary Reviews** | **Yes** | **No** | **N/A** |
| 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.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve sending data/specimens outside of NJH or receiving data/specimens from an outside institution/entity?If Yes, this study will need to be reviewed by the Contracts Office to ensure the appropriate agreements are in place.  | **[ ]**  | **[ ]**  | **[ ]**  |
| 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> | **[ ]**  | **[ ]**  | **[ ]**  |
| 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> | **[ ]**  | **[ ]**  | **[ ]**  |
| Will this study involve Twilio to send and/or collect research data for this study?If Yes, please complete the following REDCap survey:<https://redcap.njhealth.org/redcap/surveys/?s=YNWRM8EX9C> | **[ ]**  | **[ ]**  | **[ ]**  |
| 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. | **[ ]**  | **[ ]**  | **[ ]**  |
| 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, include documentation of Institutional Biosafety Committee approval with your submission. If you are unsure whether you protocol requires IBC review, please refer to the IBC Flowchart and/or reach out to the IBC Office.  | **[ ]**  | **[ ]**  | **[ ]**  |
| Have any study personnel undergone COI Review for this project? If Yes, provide documentation of COI review. Any conflict management plans must be included with your submission. | **[ ]**  | **[ ]**  | **[ ]**  |