**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 * Conflicts of Interest * 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 | |  |  |  |
| Completed Internal Research Review (IRR) Form  \*Must have all required signatures and/or an IRR# at the bottom | |  |  |  |
| Request for Waiver or Alteration of HIPAA (if applicable) | |  |  |  |
| **Ancillary Reviews** | **Yes** | | **No** | **N/A** |
| 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 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 reach out to the IBC Office or 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 other groups outside of your department (e.g., pharmacy, ADx, or other NJH facilities where research activities will occur)?  If Yes, include documentation of support. |  | |  |  |
| **Additional Requirements for Exempt Research** | | | | |
| **Annual Progress Reports**  All exempt research will receive an “Annual Progress Report Due Date” upon approval. This date can be found on your approval letter and in the NJH IRB Manager system.  Study teams will be required to submit progress reports annually until study closure. If an annual progress report is not submitted within 30 days of the due date, the study will be administratively closed. | | | | |
| **Modifications**  Any change to the exempt research project must be submitted in NJH IRB Manager for approval prior to implementing that change. This includes all study team member additions/removals, changes in PI, and revisions to the protocol or other study materials. Implementing any change without prior approval is considered non-compliance. | | | | |
| **Study Closures** | | | | |