**STUDY RECORD: PHS Human Subjects and Clinical Trials Information**

For additional guidance for what to include in each of the sections below, see <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-h/research-forms-h.pdf>

**Section 1 – Basic Information**

|  |  |
| --- | --- |
| 1.1. Study Title (insert text) |  |
| 1.2 Exempt from Federal Regulations (Y/N) |  |
| 1.3 Exemption Number 1-6 (if applicable) |  |
| 1.4 Clinical Trial Questionnaire |  |
|  1.4a. Involve human participants? (Y/N) |  |
|  1.4b. Prospectively assigned to intervention? (Y/N) |  |
|  1.4c. Evaluate the effect? (Y/N) |  |
|  1.4d. Health-related biomedical or behavioral outcome? (Y/N) |  |
| 1.5 ClinicalTrials.gov Identifier (optional, if available) |  |

**Section 2 – Study Population Participants** (not required for exempt category 4)

|  |  |
| --- | --- |
| 2.1 Conditions/focus of study (255 characters each, up to 20) | Identify the name(s) of the disease(s) or [condition](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.1)(s) you are studying, or the focus of the study. If available, use appropriate descriptors from [NLM's Medical Subject Headings](https://www.nlm.nih.gov/mesh/) so the application can be categorized. (At least 1 entry is required, up to 20 are allowed).  |
| 2.2 Eligibility criteria (15,000 characters) |  |
| 2.3 Age limits (minimum, maximum) | Enter age range for study population (minimum and maximum) in years, months, weeks, days or miniutes |
| 2.3.a. Inclusion of Individuals Across the Lifespan | File Required **[attachment]**Describe age groups (including children and elderly) that will be involved in research; provide justification for exclusions of any age  |
| 2.4 Inclusion of women and minorities | File Required **[attachment]**Describe plans for Inclusion of Women and Minorities  |
| 2.5 Recruitment and retention plan | File Required **[attachment]**Describe recruitment plan: Advertise and Screen for eligibility; Retention of study subjects  |
| 2.6 Recruitment status (see dropdown: not yet recruiting, recruiting, enrolling, etc.) |  |
| 2.7 Study timeline | File Required **[attachment]**Insert Table of Study Timeline over grant period Example:

|  |  |
| --- | --- |
|  | **Table 5**. Study Timeline |
| Activities (in months) | FY01 | FY02 | FY03 | FY04 | FY05 |
|  |  |  |  |  |  |  |  |  |  |
| Master study contract agreements, sIRB processes/IRB approval | X |  |  |  |  |  |  |  |  |  |
| Patient and Provider  |  | X |  |  |  |  |  |  |  |  |
| Agreement on final study measures |  | X |  |  |  |  |  |  |  |  |
| Recruitment and Intervention  |  |  | X |  |  |  |  |  |  |  |
| Site level data collection training  |  | X |  |  |  |  |  |  |  |  |
| Recruitment begins |  |  |  |  |  |  |  |  |  |  |
| Analysis |  |  |  |  |  |  |  | X |  |  |
| Dissemination |  |  |  |  |  |  |  |  | X |  |
| Annual & final reports  |  |  |  |  |  |  |  |  |  |  |
| Data Safety and Monitoring Board meetings |  |  |  |  |  |  |  |  |  |  |

 |
| 2.8 Enrollment of first participant (date) | Enter date of first participant enrollment and pick from drop down – anticipated or actual |
| Inclusion Enrollment Report (up to 20 enrollment reports can be added) | Upload numbers into Planned Enrollment TableExample:

|  |
| --- |
| **Planned Enrollment Table** |
| **Inclusion Enrollment Report Title (project title):** |
| **Racial Categories**  | **Ethnic Categories**  |
| **Not** **Hispanic or Latino**  | **Hispanic or Latino**  | **Total**  |
| **Female**  | **Male**  | **Female**  | **Male**  |
| **American Indian / Alaska Native**  |  |  |  |  |  |
| **Asian**  |  |  |  |  |  |
| **Native Hawaiian or other Pacific Islander**  |  |  |  |  |  |
| **Black or African American**  |  |  |  |  |  |
| **White**  |  |  |  |  |  |
| **More than one race**  |  |  |  |  |  |
| **Total**  |  |  |  |  |  |

 |
| Using existing dataset (Y/N) |  |
| Enrollment location (Domestic or International; if International need country(ies))  |  |
| Comments (up to 500 characters if needed to explain planned enrollment) |  |

**Section 3 – Protection and Monitoring Plans**

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| --- | --- |
| 3.1 Protection of human subjects (no character, word or page limitations) | File Required **[attachment]**Describe the following:Risks to Human Subjects:* Human Subjects Involvement, Characteristics (I/E)
* Study Design (enrollment #s, randomization)
* Study Procedures
* Materials
* Potential Risks

Adequacy of Protection Against Risk:* Informed Consent and Assent
* Protections against risk
* Vulnerable Subjects

Potential Benefits Importance of Knowledge to be Gained **For exempt studies**, provide an explanation / justification for the exempt category |
| 3.2 Multi-site study (Y/N; if Yes describe the single IRB plan and site locations) | File Required if a multicenter clinical trial **[attachment]**Include a plan with the following elements:* Describe compliance with [NIH Policy on the Use of sIRB for Multi-Site Research](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html).
* Provide name of IRB that will serve as the sIRB of record.
* Indicate that all identified participating sites have agreed to rely on the proposed sIRB and that any sites added after award will rely on the sIRB.
* Describe how communication between sites and the sIRB will be handled
* Indicate that all participating sites will, prior to initiating the study, sign an authorization/reliance agreement that will clarify the roles and responsibilities of the sIRB and participating sites.
* Indicate which institution or entity will maintain records of the authorization/reliance agreements and of the communication plan.
* **Note:** Do not include the authorization/reliance agreement(s) or the communication plan(s) documents in your application.

If your study does not fall under the NIH single IRB policy for any reason you should answer “No” to question 3.2. This includes studies that involve multiple sites that are conducting different protocols.  |
| 3.3 Data and safety monitoring plan (include description of DSMB if applicable) – section applicable only to clinical trials | File Required if study involves a clinical trial **[attachment]**All clinical trials supported by NIH should have some form of monitoring based on a Data and Safety Monitoring plan (DSMP). The level of monitoring should be commensurate with the size and complexity of the trial, the level of risk to study participants, and phase of the trial. Describe (see guidance from specific NIH Institute on DSMPs)* The individual(s) or group that will be responsible for trial monitoring (i.e., PI, ISM, SMC or DSMB) and advising the study team. The roles and responsibilities of everyone on the team involved in monitoring to include the entity responsible for submitting necessary reports to NIH.
* Procedures for 1) monitoring study safety to include monitoring schedule, auditing selected cases for compliance with IRB requirements, conformance with informed consent requirements, verification of source documents, and investigator compliance; 2) minimizing research-associated risk, and 3) protecting the confidentiality of participant data.
* If applicable, the type and number of events that would halt accrual and would generate a review of eligibility, monitoring, assessments, intervention, and how the resumption of accrual would occur (i.e., study wide stopping rules).
* Procedures for identifying, reviewing, and reporting [Adverse Events (AEs)](https://www.fda.gov/ForPatients/ucm410359.htm), including [Serious Adverse Events (SAEs)](https://www.fda.gov/safety/medwatch/howtoreport/ucm053087.htm), and unanticipated problems to the IRB, NIH (i.e., program officer), and FDA (if applicable). For further information, see:
	+ OHRP Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/reviewing-unanticipated-problems/index.html>
	+ NIH Guidance on Reporting Adverse Events to Institutional Review Boards for NIH-Supported Multicenter Clinical Trials (<http://grants1.nih.gov/grants/guide/notice-files/not99-107.html>)
* For multi-site studies, procedures to ensure compliance with the monitoring plan and reporting requirements across study sites.
* An assessment of external factors or relevant information (e.g., developments in the literature, results of related studies) that may have an impact on the safety of participants or on the ethics for the research study.
* The frequency of monitoring activities (review of data for safety, efficacy, futility) including plans for interim and/or futility analysis as appropriate.
* Another aspect of trial monitoring is the review of data to ensure the reported trial data are accurate, complete and verifiable. This aspect of trial monitoring is required when an investigator holds an IND or IDE. Describe that a qualified monitor will review trial data at regular intervals throughout the conduct of the study.

If a SMC or DSMB used, describe general composition of the Committee/Board without naming specific individuals. Describe their independence from the trial and study team members. Describe activities of the SMC/DSMB in providing oversight (frequency of reviews, reports provided, data to be reviewed, stopping rules). |
| 3.4 Will there be a DSMB (Y/N) | NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials. A DSMB may also be appropriate for Phase I and Phase II or other clinical trials if the studies are blinded (masked), employ high-risk interventions, or involve vulnerable populations.  |
| 3.5 Structure of the study team | File Required if study involves a clinical trial **[attachment]**If the study is a clinical trial, include information on the administrative structure and function of the study team.  The section may include study team composition and key roles (e.g. medical monitor, data coordinating center), the governance of the study, and a description of how study decisions and progress are communicated and reported. |

**Section 4 – Protocol Synopsis (only required for clinical trials)** File Required (pdf), can have refs

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| --- | --- |
| 4.1 Study design | No text here |
|  4.1.a. Detailed description (insert text, 32,000 character limit) | **Study design**: This is a 5-year Phase 2 clinical trial divided into…..The main objective of the study is to ….Our specific aims are:**Aim 1:****Aim 2**. **Aim 3.** **Study sites:** **Study subjects and eligibility criteria:****Screening, enrollment and informed consent:** : **Recruitment/enrolment visit**: **Study procedures and evaluations, including safety assessments.** **Overall study duration and duration of participant involvement.** **Retention of study subjects:** **Control condition:****Intervention**: **Fidelity Monitoring:****Measures:** The primary outcome is a **Summary of baseline variables:**  **Analysis overview:** **Aim 1****Aim 2****Aim 3**: |
|  4.1.b. Primary purpose (Treatment, Prevention, Diagnostics, Supportive Care, Screening, Health Services Research, Basic Science, Device Feasibility, or Other; if other please define) |  |
|  4.1.c. Interventions (If multiple interventions repeat c.1-c.3) |  |
|  c.1 Intervention Type (Drug w. Placebo, Drug w. sham, Biological/Vaccine, Procedure/Surgery, Radiation, Behavioral, Genetic, Dietary Supplement, Combination Product, Diagnostic Test, Other; if Other please explain) |  |
|  c.2 Intervention Name (insert text, up to 200 characters) |  |
|  c.3 Intervention Description (insert text, 1000 character limit) |  |
|  4.1.d. Study phase (Phase 0,1,1&2,2,2&3, 3,4,Other; if Other (please explain) |  |
|  d.1 NIH-defined Phase III clinical trial? (Y/N) |  <https://grants.nih.gov/policy/clinical-trials/glossary-ct.htm>  |
|  4.1.e. Intervention model (Single Group, Parallel, Cross- Over, Factorial, Sequential, Other; if Other please explain) |  |
|  4.1.f. Masking (Y/N) |  |
|  f. Masking (Participant, Care Provider, Investigator, Outcomes Assessor; indicate all that apply) |  |
|  4.1.g. Allocation (N/A, Randomized, or Non-Randomized) |  |
| 4.2 Outcome measures | The outcome measures section should include primary, secondary, and other important measures.  It is not expected that every outcome will be listed.  Furthermore, NIH recognizes that some studies may include exploratory analyses not specified in the application.Keep in mind that the outcomes listed on the Human Subjects Clinical Trials Form are expected to synchronize with your study’s Clinicaltrials.gov record. |
|  Primary (need name, type, timeframe, and brief description) |  |
|  Secondary (need name, type, timeframe, and brief description) |   |
|  Other  |  |
| 4.3 Statistical design and power | File Required **[attachment]**Analysis overview: Aim 1 analysis: Aim 2 analysis:Aim 3 analysis:Sample size calculation: |
| 4.4 Subject participation duration | The intervention period will last X years.  |
| 4.5 FDA-regulated intervention (Y/N) | File Required if Yes to FDA Regulated intervention **[attachment]**Describe the availability of investigational product and FDA IND (drug) or IDE (device) status |
| 4.6 Is this an applicable clinical trial under FDAAA (Y/N) | See <https://clinicaltrials.gov/ct2/manage-recs/fdaaa>  |
| 4.7 Dissemination plan | File Required **[attachment]**  The plan can be brief, but at a minimum, it must contain sufficient information to assure that:1. the applicant will ensure that clinical trials under the award are registered and results information is submitted to ClinicalTrials.gov as outlined in the policy and according to the specific timelines stated in the policy;
2. informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
3. the recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.
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