**NIH Human Subjects and Clinical Trial Information Study Record**

## The Study Record consists of five sections:

* [**Section 1 - Basic Information:**](https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/StdyRcrd_Sect_1.htm) Title, Exemptions, and Clinical Trial information
* [**Section 2 - Study Population Characteristics:**](https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/StdyRcrd_Sect_2.htm) Focus, Demographics, IERs, etc.
* [**Section 3 - Protection and Monitoring Plans:**](https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/StdyRcrd_Sect_3.htm#top) Information regarding PHS issues, data and safety monitoring, and team structure.
* [**Section 4 - Protocol Synopsis:**](https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/StdyRcrd_Sect_4.htm) Study design, purpose, interventions, metric parameters, etc.
* [**Section 5 - Other Clinical Trial-related Attachments:**](https://era.nih.gov/erahelp/assist/Content/ASSIST_Help_Topics/3_Form_Screens/PHS_HS_CT/StdyRcrd_Sect_5.htm) Area used for any additional attachments that do not fit the other sections (if requested by the FOA).

**Sections 1-5 below reflects the NIH Study Record which is populated in ASSIST**

**Section 1 – All studies must answer Exempt Research and Clinical Trial questions below. The NCT # is ONLY required for clinical trials.**

* **Is this study Exempt** from Federal Regulations? Yes or No (refer to IRB determination letter for exemption category or review exempt criteria at [here](https://grants.nih.gov/policy/humansubjects/research.htm)
* **If yes,** indicate the Exemption Number.
* **Is this study a Clinical Trial?** To determine if your project is a [Clinical Trial](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#1.4), answer the 4 questions below. (Note that the revised NIH definition of "clinical trials" is broader than in the past and can be found [here](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html).) If the answers to all 4 questions are Yes, then the study meets the definition of a Clinical Trial and additional documentation is required in Section 3 below.

1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect that will be evaluated a health-related biomedical or behavioral outcome?

* **NCT #** - only for clinical trials. If not available at time of grant submission, can enter at later time.

**Section 2 – Items 1-9 are required for all human subject research projects EXCEPT for those studies determined by the IRB to be Exempt category 4**

1. **Condition or Focus of Study**: 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. **Eligibility Criteria**: List the study’s inclusion & exclusion criteria. (max. 10,000 characters)
3. **Age Limits**: Provide the minimum and maximum age for study participants.
4. **Recruitment Status**: Select the status that best describes the proposed study.

* Not yet recruiting,
* Recruiting
* Enrolling by invitation
* Active, not recruiting
* Completed
* Suspended
* Terminated (halted prematurely)

**Provide the following information in PDF format. Use a naming convention that identifies the file content, PI name, date (e.g.,** *InclusionWomen\_PI Last Name\_Date).*

**5.  Inclusion of Individuals Across the Lifespan**

Individuals of all ages are expected to be included unless there are scientific or ethical reasons not to include them. Discuss whether individuals will be excluded based on age and provide a rationale for the age of study participants. Include a description of the expertise of the team for working with individuals of ages included and how age distribution of participants will contribute to a meaningful analysis relative to the purpose of the study. (See NIH instructions for preparing section 2.3.a [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.3.a)).

**Note**: If your research is Exempt Category 4, you don’t need to submit this item.

**6. Inclusion of Women and Minorities**

Provide inclusion plans for women and minorities. Describe if participant enrollment will be restricted based on sex, race, or ethnicity and if so, justify any exclusions. (See NIH instructions for preparing this section [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.4)).

**Note**: If your research is Exempt Category 4, you don’t need to submit this item.

**7. Recruitment and Retention Plan**

Describe how you will recruit and retain participants in your study. You should address both planned recruitment activities as well as proposed engagement strategies for retention. (See NIH instructions for preparing this section [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.5)).

**Note**: If your research is Exempt Category 4, you don’t need to submit this item.

**8. Study Timeline**

Provide a description or diagram describing the study timeline. The timeline should be general (e.g., "one year after notice of award"), and should not include specific dates. (See NIH instructions for preparing section 2.7 [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.7)).

**Note**: If your research is Exempt Category 4, you don’t need to submit this item.

**9.  Inclusion Enrollment Report or Table**

Upload a planned Inclusion Enrollment Report or Table. Provide in this table your best guestimate of the number of subjects to be enrolled or population to be studied according to race, ethnicity and gender. This is also required for retrospective chart reviews and database research. Click here ([PDF](https://tracs.unc.edu/docs/pilotprogram/inclusion-enrollment-report-template.pdf) – [Word](https://tracs.unc.edu/docs/pilotprogram/planned_enrollment_table.docx)) for an Enrollment Table template and click [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#2.9) for instructions on completing the table. Include the following enrollment location information:

1. Type (domestic or foreign)
2. Country / countries
3. Locations (be specific)

**Note**: If your research is Exempt Category 4, you do not need to submit an enrollment table item.

**SECTION 3: Items 10-12 below are required for all human studies including EXEMPT research. Only clinical trials are required to address those items described in 13-15 below.**

**10. Protection of Human Subjects**

Upload a “Protection of Human Subjects” document for the pilot grant that clearly describes the risk, protections, benefits and importance of the knowledge to be gained by the research activities (see NIH instructions for preparing section 3.1 [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.1)). **If the IRB determined the research to be exempt, provide a justification of exemption.** The justification should explain how the proposed research meets the criteria for the exemption claimed, and not merely repeat the criteria or definitions.

**11. Single IRB Plan (if applicable)**

Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

**Note**: This requirement is not applicable to any category of Exempt research.

**12. If yes, describe the single IRB plan**

See NIH instructions [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.2). See UNC guidance for single IRB [here](https://tracs.unc.edu/index.php/services/regulatory/grant-submission-guidance).

**Note**: This requirement is not applicable to any category of Exempt research.

**13. Data and Safety Monitoring Plan (DSMP)**

If an NIH-defined clinical trial is proposed, upload a Data and Safety Monitoring Plan (DSMP). See NIH instructions for preparing section 3.3 [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#3.3).

**14. Indicate if a** [**Data and Safety Monitoring Board**](https://tracs.unc.edu/index.php/services/regulatory/data-and-safety-monitoring-board/when-is-a-dsmb-needed) **(DSMB) will be appointed for this trial.**

Yes or No

**15. Overall Structure of the Study Team**

Provide a brief overview of the organizational/administrative structure and function of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers. The attachment may include information on 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. If you have a multi-PI leadership plan, describe it here.

**Section 4 – This item is ONLY required for NIH defined clinical trials (see definition** [**here**](https://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-015.html)**).**

**Protocol Synopsis**

Complete all of section 4 (Protocol Synopsis) of the NIH Human Studies Study Record if you are conducting a clinical trial. This section has content with word/character limits, drop downs to choose from and sections with required attachments. Topics covered include study design, purpose, study phase, interventions, masking & allocation, outcome measures, statistical design and power, FDA regulated products, and dissemination plan. See NIH instructions for preparing this section [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#4).

**Section 5** – **Other Clinical Trial-related Attachments**

**If you answered “Yes” to all the questions in the “Clinical Trial Questionnaire:”** Include an attachment only if your FOA specifies that an attachment(s) is required or permitted; otherwise, do not include any Other Clinical Trial-related attachments. See NIH instructions for preparing this section [here](https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#5).

**References:**

NIH Forms G Guidance for Human Subject Sections: <https://grants.nih.gov/grants/how-to-apply-application-guide/forms-g/general-forms-g.pdf>

[NIH Human Subjects and Clinical Trials Study Record Template (V3)](file:///\\ad.unc.edu\med\tracs\groups\Regulatory\Human%20Subject%20Protection%20for%20NIH%20grants\DSM%20Plan%20&%20HSP%20guidance%20for%20grants\NIH%20Grant%20guidance%20docs\HumanSubjectStudyRecord_V3.0.pdf)

NC TraCS DSMB: <https://tracs.unc.edu/index.php/services/regulatory/data-and-safety-monitoring-board/when-is-a-dsmb-needed>

NIH Clinical Trial Definition, Decision Tree and Case Studies: <https://grants.nih.gov/policy/clinical-trials/definition.htm>

NIH Definition of Human Subject Research Decision Tool <https://grants.nih.gov/policy/humansubjects/research.htm>

NC TraCS Regulatory Guidance Documents for NIH Grants: <https://tracs.unc.edu/index.php/services/regulatory/grant-submission-guidance>