PHS Human Subjects and Clinical Trials Information Form – Forms H

(Additional details on pages 95 – 131 of Application Guide, also identified per section below)

Required?	Independently of answering yes or no to human subjects on the Other Project Information Form	
CT HS	*Does any of the proposal research in the application involve human specimens and/or data?* *Page 100 of Application Guide*	If all human specimens and/or data is considered human subjects research, then the answer to this question should be "NO". If the project is using human specimens and/or data that is **not considered human subjects research by the NIH**, then the answer should be "YES" and an attachment with the following information must be provided: - information on who is providing the data/biological specimens and their role in the proposed research - a description of the identifiers that will be associated with the human specimens and data - a list of who has access to subjects' identities; and - information about the way the privacy of research participants and confidentiality of data will be protected.
	If YES to Human Subjects on the Other Project Information Form	
CT HS	Other Requested Information *Page 101 of Application Guide*	(if applicable, per FOA)
CT HS	Study Record – or – Delayed Onset Study Record *Page 103 of Application Guide*	Must attach either: • Delayed Onset Justification • Full Study Record

Delay Onset Study information:

If you anticipate conducting research involving human subjects but cannot describe the study at the time of application (i.e., your study is a delayed onset human subject study), enter a Delayed Onset Study Record as instructed below.

Generally, for any study that you include as a delayed onset study in this section, you will provide a study title, indicate whether the study is anticipated to include a clinical trial, and include a justification attachment. Since, by definition, information for a delayed onset study is not available at the time of application, you will not be given the option to complete a full Study Record for a delayed onset study. For delayed onset studies, the Delayed Onset Study Record is sufficient.

Please note:

- Delayed onset **does NOT** apply to a study that can be described but will not start immediately (i.e., delayed start). Refer to the NIH Glossary definition of Delayed Onset Study and Delayed Start. l If you anticipate multiple delayed onset studies, you can include them together in a single Delayed Onset Study Record.
- All delayed onset studies must provide a justification explaining why human subjects study information is not available at the time of application.

Full Study Record information

Section 1 – Basic Information **REQUIRED for all proposals involving human subjects** *Page 104-107 of Application Guide*
1.1 Study Title (each study title must be unique)
1.2 Is this Study Exempt from Federal Regulations? (auto populated from answers provided in the Other Project Information form)
1.3 Exemption Number. Please make sure to verify exemption numbers and IRB approval requirements here (auto populated from answers provided in the Other Project Information form)
1.4 Clinical Trial Questionnaire 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 being evaluated a health-related biomedical or behavioral outcome?*

CT	**If YES to ALL questions above**, this proposal is considered a clinical trial per NIH definition and the application needs to include all information and documents identified with CT below.
HS	**If NO to ANY of the questions above**, this proposal is NOT a clinical trial per NIH definition and the application needs to include only all information and documents identified with HS below.

Required for	**Section 2 – Study Population Characteristics** *Page 107-117 of Application Guide*
CT HS	2.1 Conditions or Focus of Study - At least 1 entry is required
CT HS	2.2 Eligibility Criteria
CT HS	2.3 Age Limits
CT HS	2.3a Inclusion of Individuals Across the Lifespan
CT HS	2.4 Inclusion of Women and Minorities
CT HS	2.5 Recruitment and Retention Plan (REQUIRED except for Exemption 4)
CT HS	2.6. Recruitment Status
CT	2.7 Study Timeline (OPTIONAL for Exemption 4 and non-CT)
CT HS	2.8. Enrollment of First Participant (NOT REQUIRED for Exemption 4)
CT HS	2.9 Inclusion Enrollment Report(s) (NOT REQUIRED for Exemption 4): - Planned Enrollment Report (i.e.,projected), and/or - Cumulative Enrollment Report (i.e.,actual from existing dataset)

Required for	**Section 3 – Protection and Monitoring Plans** *Page 117-124 of Application Guide*
CT HS	3.1 Protection of Human Subjects
CT HS	3.2 Is this a multi-site study that will use the same protocol to conduct nonexempt human subjects research at more than one domestic site? Single IRB Plan Attachment For NIH Applicants, the single IRB plan is no longer required. See additional information in the content section below. For AHRQ applicants, if this is a research project that involves more than one institution and that will be conducted in the United States, Applicants are expected to use a single Institutional Review Board (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research, and

	include a single IRB plan as instructed below, unless review by a sIRB would be prohibited by a federal, tribal, or state law, regulation, or policy.
CT	3.3 Data and Safety Monitoring Plan (OPTIONAL for non-CT)
CT	3.4 Will a Data and Safety Monitoring Board be appointed for this study? (OPTIONAL for non-CT)
CT	3.5 Overall Structure of the Study Team (OPTIONAL for non-CT)

Required for	**Section 4 – Protocol Synopsis – DO NOT COMPLETE IF NOT CT** *Page 124-130 of Application Guide*
CT	4.1 Study Design
CT	4.2 Outcome Measures
CT	4.3 Statistical Design and Power
	4.4 Subject Participation Duration
CT	4.5 Will the study use an FDA-regulated intervention?
	4.6 Is this an applicable clinical trial under FDAAA?
CT	4.7 Dissemination Plan

Required only per RFA	**5. Other Clinical Trial-related Attachments** *Page 130-131 of Application Guide*
CT	COMPLTE ONLY if clinical trial and ONLY if specifically requested in the RFA