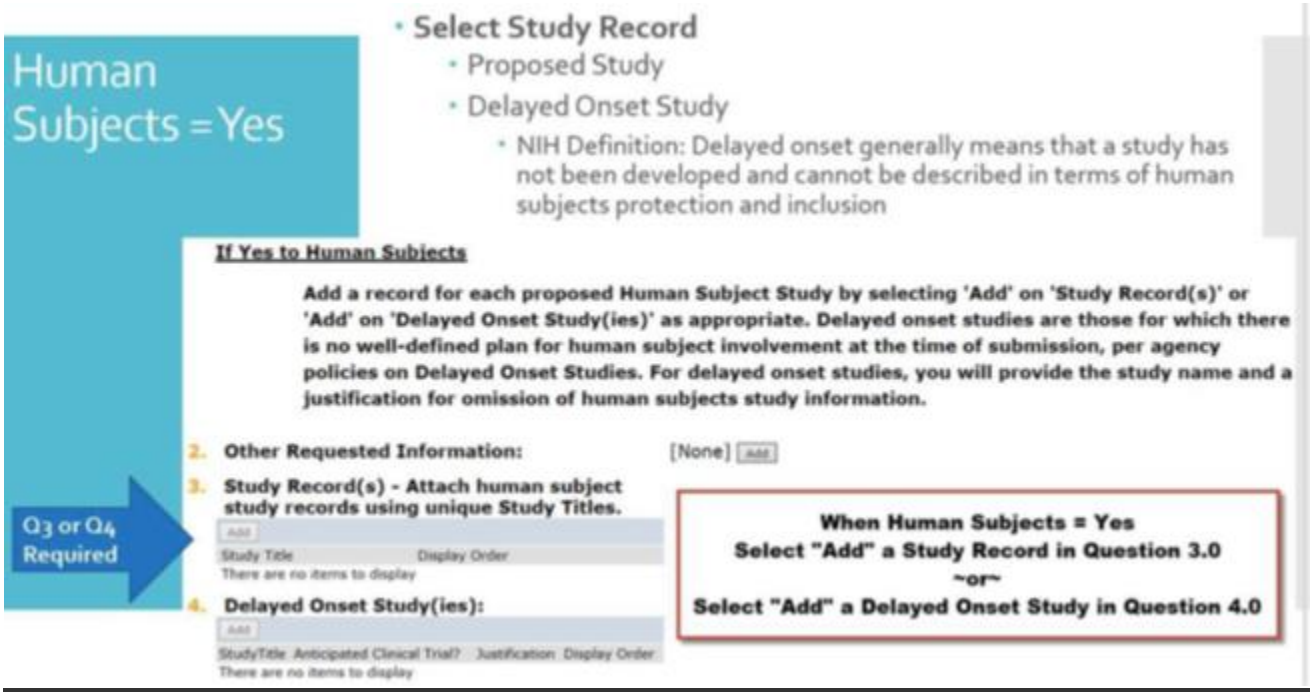
BROWN
Division of Biology
and Medicine

Human Subjects & Clinical Trials Information– Forms E
(HUMAN SUBJECTS SUPPLEMENTAl INFORMATION FORM)

Effective for applications due on or after January 25, 2018, the required new NIH Forms-E packet includes a new Human Subjects and Clinical Trials Information form. This new form is intended to aid investigators in determining whether the proposed project involves non-exempt human subjects research; to confirm whether the proposed project meets the NIH definition of a “clinical trial”; and to consolidate and extend the HS/CT information formerly scattered throughout the application.

If “yes” to Human subjects you will need to create a study record



□ Study Record *(add a study record for each proposed study involving human subjects)*

□ Inclusion of Women, Minorities, and Children

□ Recruitment and Retention Plan

□ Study Timeline

□ Inclusion Enrollment Report(s)

□ Protection of Human Subjects

□ Data and Safety Monitoring Plan *(required if study meets the definition of a Clinical Trial)*

□ Overall Structure of the Study Team

□ Statistical Design and Power

□ Dissemination Plan

NOTE: There are NO PAGE LIMITS for any attachment in the PHS Human Subjects and Clinical Trials Information form.

Study Record

Add a study record for *each* proposed study involving human subjects. A blank Study Record can be found here.

SECTION 1 – BASIC INFORMATION

1.1 Study Title: This field is required. The Study Title can have a maximum of 600 characters. Enter a brief title that describes the study the participants will be involved in. If there is more than one study (i.e., you are including more than one study record and/or delayed onset study in your application), each one must have a unique study title. Full instructions page R-96.

1.2 Is this Study Exempt from Federal Regulations?: An answer is required. For more information, see the NIH's Exempt Human Subjects Research Infographic.

1.3 Exemption Number: The Exemption Number field is required if you selected "Yes" to the "Is this Study Exempt from Federal Regulations?" question. If applicable, select the appropriate exemption number(s) for this particular study. Full instructions page R-97.

1.4 Clinical Trial Questionnaire: The Clinical Trial Questionnaire is required. Full instructions pages R-97 and R-98.

1.5 Provide the ClinicalTrials.gov Identifier for this trial, if applicable: If a clinical trial has already been entered into ClinicalTrials.gov, enter the ClinicalTrials.gov identifier (e.g., NCT87654321) for this trial. Full instructions page R-99.

SECTION 2 – STUDY POPULATION CHARACTERISTICS

2.1 Conditions or Focus of Study: At least one entry is required, and up to 20 entries are allowed. Each entry is limited to 255 characters. Identify the name(s) of the disease(s) or condition(s) you are studying, or the focus of the study. If available, use appropriate descriptors from NLM's Medical Subject Headings (MeSH) so the application can be categorized. Include an entry for each condition.

2.2 Eligibility Criteria: List the study's inclusion and exclusion criteria (text entry is limited to 15,000 characters). Full instructions page R-99.

2.3 Age Limits: Enter the numerical value for the minimum/maximum age a potential participant can be to be eligible for the study. Full instructions pages R-99 and R-100.

2.4 Inclusion of Women, Minorities, and Children

Start each section with the appropriate section heading – "Inclusion of Women and Minorities" and "Inclusion of Children." Also include any additional information requested in the FOA. Full instructions pages R-100 – R102.

2.5 Recruitment and Retention Plan

The Recruitment and Retention Plan attachment is required unless either or both of the following apply to you: You selected only Exemption 4 and no other exemptions on question 1.3; you selected "No" to "Does the study involve human participants?" Otherwise, 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.

2.6 Recruitment Status: The Recruitment Status question is required unless either or both of the following apply to you: You selected only Exemption 4 and no other exemptions on question 1.3; you selected "No" to "Does the study involve human participants?" Otherwise, from the dropdown menu select a single

Recruitment Status that best describes the proposed study, based upon the status of the individual sites. Full instructions pages R-102 and R-103.

2.7 Study Timeline
The Study Timeline attachment is required unless either or both of the following apply to you: You selected only Exemption 4 and no other exemptions on question 1.3; you selected "No" to "Does the study involve human participants?" Otherwise, 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.

2.8 Enrollment of First Subject: The Enrollment of First Subject question is required unless either or both of the following apply to you: You selected only Exemption 4 and no other exemptions on question 1.3; you selected "No" to "Does the study involve human participants?" Otherwise, enter the date (MM/DD/YYYY) of the enrollment of the first subject into the study. From the dropdown menu, select whether this date is anticipated or actual.

Inclusion Enrollment Report(s)
Each proposed study, unless it falls under Exemption 4, must contain at least one Inclusion Enrollment Report (IER). However, more than one IER per study is allowed. You must enter planned enrollment counts if your proposed study will not use an existing dataset or resource. You must enter cumulative enrollment counts if your proposed study will use an existing dataset or resource. Full instructions pages R-104 – R-108.

SECTION 3 – PROTECTION AND MONITORING PLANS

3.1 Protection of Human Subjects
The Protection of Human Subjects attachment is required. Full instructions Pages R-109 – R-111.

3.2 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?: Select "Yes", "No", or "N/A". If "Yes", describe the single IRB plan. Full instructions pages R-111 and R-113.

3.3 Data and Safety Monitoring Plan
A Data and Safety Monitoring Plan attachment is required if you answered "Yes" to all the questions in the Clinical Trial Questionnaire. The attachment is optional for all other human subjects research. Full instructions pages R-113 and R-114.

3.4 Will a Data and Safety Monitoring Board be appointed for this study?: The Data Safety and Monitoring Board question is required if you answered "Yes" to all the questions in the Clinical Trial Questionnaire. This question is optional for all other human subjects research.

3.5 Overall Structure of the Study Team
The Overall Structure of the Study Team attachment is required if you answered "Yes" to all the questions in the Clinical Trial Questionnaire. This question is optional for all other human subjects research. Provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.

SECTION 4- PROTOCOL SYNOPSIS *(only complete this section if proposing a Clinical Trial)*

4.1 Brief Summary: Enter a brief description of objectives of the protocol, including the primary and secondary endpoints. The Brief Summary is limited to 5,000 characters.

4.2.a Narrative Study Description: Enter a narrative description of the protocol. Describe your plans for assignment of participants and delivery of interventions. You will also need to show that your methods for sample size and data analysis are appropriate given those plans. Full instructions page R-115.

4.2.b Primary Purpose: Enter or select from the dropdown menu a single Primary Purpose that best describes the clinical trial. Full instructions page R-115.

4.2.c Interventions: Complete the Interventions fields for each intervention to be used in your proposed protocol. Full instructions page R-116.

4.2.d Study Phase: Enter or select from the dropdown menu a Study Phase that best describes the clinical trial. Select "Yes" or "No" to indicate whether the study includes an NIH-defined Phase III clinical trial. Full instructions page R-116.

4.2.e Intervention Model: Enter or select from the dropdown menu a single Intervention Model that best describes the clinical trial. Full instructions page R-117.

4.2.f Masking: Select "Yes" or "No" to indicate whether the protocol uses masking. Note that masking is also referred to as "blinding". If you answered "Yes" to the Masking question, select one or more types of masking that best describes the protocol. Full instructions page R-117.

4.2.g Allocation: Enter or select from the dropdown menu a single Allocation that best describes how subjects will be assigned in your protocol. Full instructions page R-117.

4.3 Outcomes Measures: Complete the Outcome Measures fields for each primary, secondary, and other important measures to be collected during your proposed clinical trial. Full instructions pages R-117 and R-118.

4.4 Statistical Design and Power

Specify the number of subjects you expect to enroll, the expected effect size, the power, and the statistical methods you will use with respect to each outcome measure you listed in 4.3 Outcome Measures. You will need to show that your methods for sample size and data analysis are appropriate given your plans for assignment of participants and delivery of interventions. Full instructions page R-118.

4.5 Subject Participation Duration

Enter the time (e.g., in months) it will take for each individual participant to complete all study visits. If the participation duration is unknown or not applicable, write "unknown" or "not applicable".

4.6 Will the study use an FDA-regulated intervention?: Select "Yes" or "No" to indicate whether the study will use an FDA-regulated intervention. If "Yes", describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/Investigational Device Exemption (IDE) status. Full instructions pages R-118 and R-119.

4.7 Dissemination Plan

Explain briefly your plan for the dissemination of NIH-funded clinical trial information and address how the expectations of the policy will be met. Full instructions page R-119.

SECTION 5 – OTHER CLINICAL TRIAL-RELATED ATTACHMENTS

Provide additional trial-related information only if your FOA specifically requests it. Include only attachments requested in the FOA, and use requested file names.

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