RED
Research Education Development

Symposium for Research Administrators

University of Wisconsin-Madison
September 26th, 2018

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Navigating the new NIH E-forms and decoding the new Human Subjects Section

September 26, 2018

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Department of Medicine
Office of Research Services

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1. Use the correct FOA number for your grant

Program Announcements
Typical and Atypical Patterns of Language and Literacy in Dual Language Learners (**R01-Clinical Trial Optional**)
(PA-18-316)

Typical and Atypical Patterns of Language and Literacy in Dual Language Learners (**R21-Clinical Trial Optional**)
(PA-18-328)

Investigator-Initiated Clinical Trials Targeting Diseases within the Mission of NIDDK (**R01-Clinical Trial Required**)
(PA-18-330)

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Testing Interventions for Health-Enhancing Physical Activity (**R01 - Clinical Trial Optional)**
(PAR-18-324)

Simulation Modeling and Systems Science to Address Health Disparities
(R01-Clinical Trial Not Allowed)
(PAR-18-331)

Clinic Testing Therapeutic/Indication Pairing Strategies **(U01 Clinical Trial Required)**
(PAR-18-332)

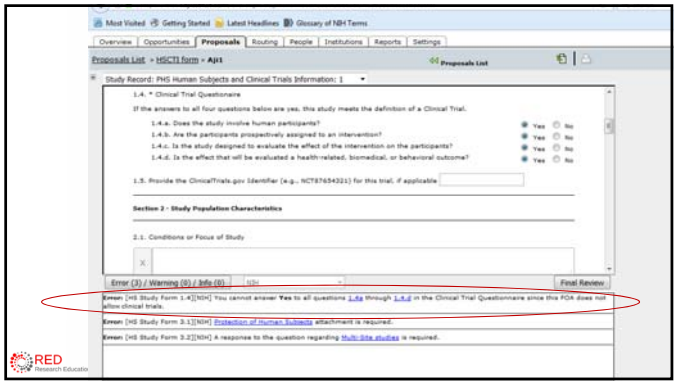
NHLBI Program Project Applications **(P01 - Clinical Trials Optional)**
(PAR-18-405)
National Heart, Lung, and Blood Institute

Parent Announcements

R01	NIH Research Project Grant (Parent R01 Clinical Trial Not Allowed)	PA-18-484	NIH	12/06/2017	01/05/2018	01/08/2021
R01	NIH Research Project Grant (Parent R01 Clinical Trial Required)	PA-18-345	NIH	11/03/2017	01/05/2018	01/08/2021
R21	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Not Allowed)	PA-18-489	NIH	12/06/2017	01/16/2018	01/08/2021
R21	NIH Exploratory/Developmental Research Grant Program (Parent R21 Clinical Trial Required)	PA-18-344	NIH	11/03/2017	01/16/2018	01/08/2021

2. Cayuse is set to keep you from submitting to the wrong FOA.

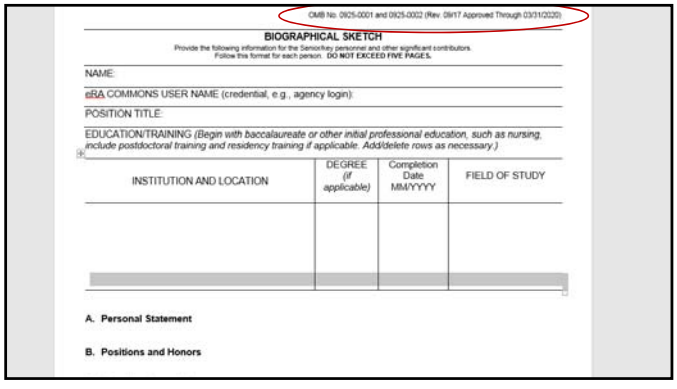
Once you answer the questions on the form Cayuse will create ERRORS if you answered wrong to the FOA that was uploaded!



3. New forms expiration date

For any type of a form page be sure to get the latest version:

OMB Expiration date to 3/31/2020


OMB No. 0925-0001 and 0925-0002 (Rev. 09/17 Approved Through 03/31/2020)

BIOGRAPHICAL SKETCH

Provide the following information for the Senior/key personnel and other significant contributors.
Follow this format for each person. **DO NOT EXCEED FIVE PAGES.**

NAME:

eRA COMMONS USER NAME (credential, e.g., agency login):

POSITION TITLE:

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, include postdoctoral training and residency training if applicable. Add/delete rows as necessary.)*

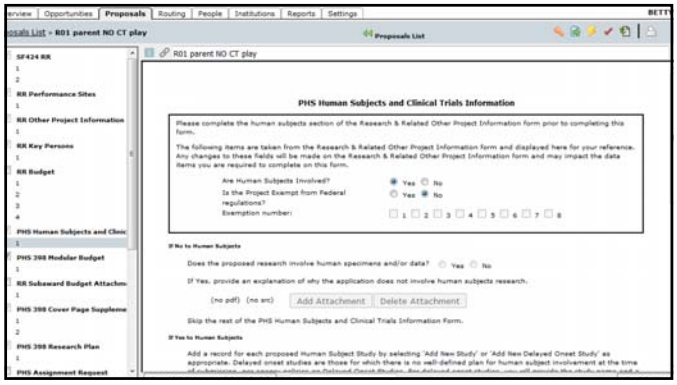
INSTITUTION AND LOCATION	DEGREE *(if applicable)*	Completion Date MM/YYYY	FIELD OF STUDY

A. Personal Statement

B. Positions and Honors

4. Human Subjects Information was removed from the Research Plan page

**Now on it's own form



4 types of projects:

1. For No Human Subjects or animals OR animals, only just answer the HS/CT opening page.
2. Human Subjects with Exemption 4, answer Section 1 and upload 3.1 Protection of Human Subjects
3. Human subjects research (aka: Clinical Research), complete Sections 1, 2 and 3.
4. For a Clinical Trial, complete Sections 1-4.

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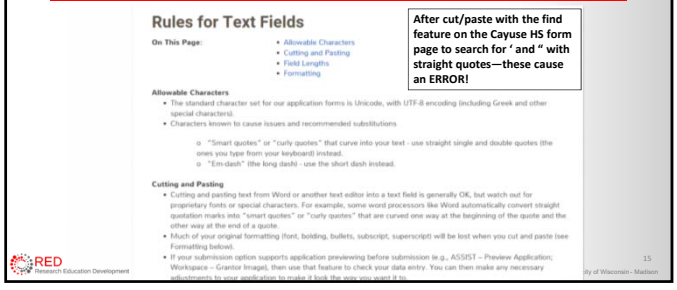
Before you begin adding text into the Sections…….KNOWN PROBLEM !



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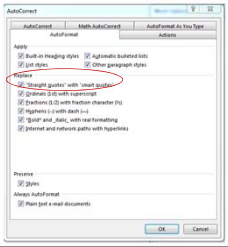
Word can be set to not use smart quotes by going here:

File ➡ Options ➡ Proofing ➡ Auto Correct Options… ➡ AutoFormat ➡ Check Replace "straight quotes" with "smart quotes"



Cannot add a Study Record if you answer No to Human Subjects question on R&R Other Project Information form.

HS = Human Subjects
CT = Clinical Trials

Study Record: PHS Human Subjects and Clinical Trials Information

OMB Number: 0925-0001
Expiration Date: 03/31/2020

* Always required field

600 is not correct—Limited to 30 characters! If you need to change the title it can only be done on this page.

Section 1 - Basic Information

1.1. * Study Title (each study title must be unique)
Required and system enforced. Up to 600 characters. Study title must be unique within the application. First 150 characters of title will show in application bookmark.

1.2. * Is this Study Exempt from Federal Regulations? Yes No ← Answer required and system enforced.

1.3. Exemption Number 1 2 3 4 5 6 7 8 ← If Study Exempt is Yes, must provide exemption number.

1.4. * Clinical Trial Questionnaire ← Answers to questionnaire required and system enforced.

If the answers to all four questions below are yes, this study meets the definition of a Clinical Trial.

1.4.a. Does the study involve human participants? Yes No
1.4.b. Are the participants prospectively assigned to an intervention? Yes No
1.4.c. Is the study designed to evaluate the effect of the intervention on the participants? Yes No
1.4.d. Is the effect that will be evaluated a health-related biomedical or behavioral outcome? Yes No

If four questions are all Yes AND FOA allows clinical trials, then study will be flagged as a Clinical Trial (CT) study.*

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable
Optional, provide NCT# if available. Newly proposed studies do not need

Section 1.2: Is this study exempt from federal regulations?

Exemptions:

(1) Research conducted in established or commonly accepted **educational settings, involving normal educational practices**, such as (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

(2) Research involving the use of **educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior**, unless:

(3) Research involving the use of **educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt.**

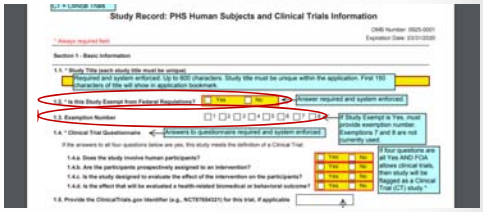
(4) Research involving **the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.**

(5) Research and **demonstration projects** which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:

(i) Public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

(6) Research involving **Taste and food quality evaluation and consumer acceptance studies**, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Section 1.3: If exempt, which exemption?



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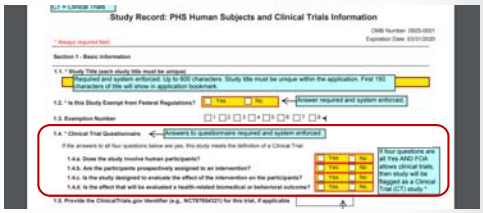
Section 1.4: Clinical Trial Questionnaire



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Section 1.4: Clinical Trial?

The 4 questions determine if the project is a clinical trial:

1) Does this study involve **human subjects**?
2) Are the participants assigned prospectively 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**?

✓YES to <u>all four</u> = Clinical Trial

If yes, must fill out Sections 1-4

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Case studies:

Clinical Trial?

Case Study #1:

The study involves the recruitment of research participants who are randomized to receive one of two approved drugs. It's designed to compare the effects of the drugs on the blood level of a protein.

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?

Case Study #2:

The study involves the recruitment of patients with disease X who are receiving one of three standard therapies as part of their clinical care. It's designed to assess the relative effectiveness of the 3 therapies by monitoring survival rates using medical records over a few years.

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?

Case Study #3:

The study involves the recruitment of research participants with disease X vs healthy controls and comparing these participants on a range of health processes and outcomes including genomics, biomarkers, lab measures, etc. to explore differences that may be relevant to the development of disease x.

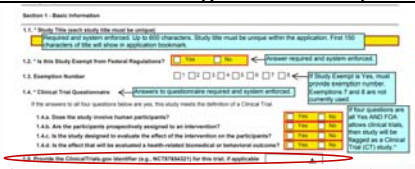
1. Does the study involve human participants?
2. Are the participants prospectively assigned to an intervention?
3. Is the study designed to evaluate the effect of the intervention on the participants?
4. Is the effect being evaluated a health-related biomedical or behavioral outcome?

Case Study #4:

The study involves the recruitment of physicians who will be randomly assigned to use a new app or an existing app, which cues directed interviewing techniques. The study is designed to determine whether the new app is better than the existing app at assisting physicians in identifying families in need of social service support. The number of community service referrals will be measured.

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?

Section 1.5. ClinicalTrials.gov identifier (NCT#)

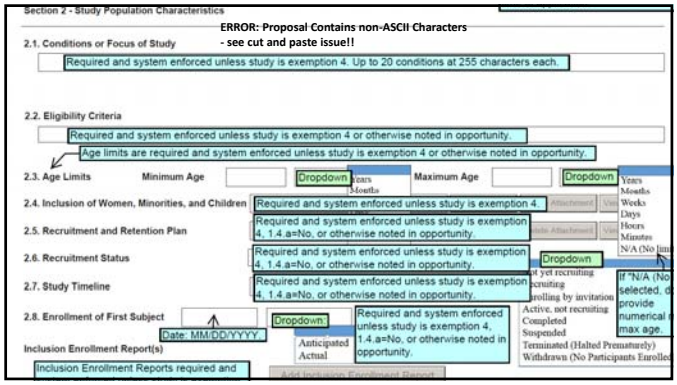


Critically important- If it is a clinical trial, it will need to be registered to **ClinicalTrials.gov** (CT.gov) and study results must be reported within 1 year of last subject off study.

When you submit your grant, you probably won't have registered it to CT.gov yet, but don't forget that it must be registered!

- SMPH will not sign off in ICTR OnCore if it is a clinical trial with SOC billing to Medicare.
- Trial must be registered to CT.gov prior to first subject enrolled to meet both FDA and ICMJE requirements.
- Note: Many of these newly added data element fields in the NIH E-Form Clinical Trial Questionnaire come directly from the CT.gov protocol registration system. https://prsinfo.clinicaltrials.gov/definitions.html

It's all about accountability and transparency!!



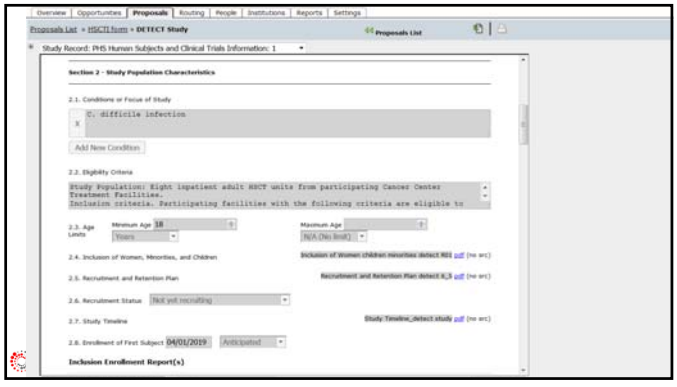
Section 2: Study Population Characteristics

2.1 Conditions of Focus of Study: Identify the name(s) of the disease(s) that you are studying, or the focus of the study.

2.2 Eligibility Criteria: Using bullets or dashes, provide a list of the inclusion and exclusion criteria directly from the grant/protocol.

2.3 Age limits: minimum and maximum age of potential participants for the trial as indicated in the grant/protocol

2.4 Inclusion of Women, Minorities, and Children- attach pdf



Section 2.5. Recruitment and Retention

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

Examples:

Recruitment- "Participants will be primary care patients from XYZ clinic. Pre-screening will identify those grossly eligible patients that have had disease x in the last year, btw the ages of 20-57, and currently use an inhaled steroid. A primary care physician will approach the patient to see if they are interested and, if so, a research staff member will go through the consent with them. No study procedures will be conducted until after informed consent is received."

Retention- "Building rapport and trust with enrolled subjects is the primary retention mechanism used in this research project. Subjects are called for reminders to study visits and occasional check-ins from the research coordinators (noted in protocol). In addition, as a way to offset travel costs, we are able to offer our subjects $25 for each study visit, which contributes to the high rate of subjects who come in for follow-up visits."

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Section 2.6. Recruitment Status

Required unless you indicated Exemption 4 and/or if you selected "no" to 1.4.a. "Does the study involve human participants."

Drop-down options:

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated (Halted prematurely)
- Withdrawn (No participants enrolled)

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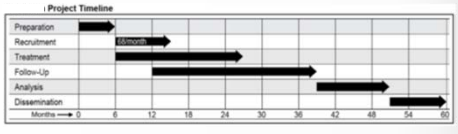
Section 2.7. Study Timeline

Provide a description or diagram describing the study timeline. The description should be general (i.e one year after notice of award) and should not include specific dates.



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Section 2.8. Enrollment of first subject

- Requires MM/DD/YYYY and a drop down menu of:
  - Anticipated
  - Actual

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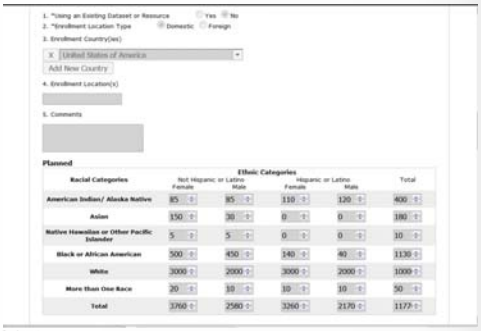
Inclusion Enrollment Report


1. *Using an Existing Dataset or Resource Yes No
2. *Enrollment Location Type Domestic Foreign
3. Enrollment Country(ies)
United States of America
Add New Country
4. Enrollment Location(s)
5. Comments

Planned

Racial Categories	Ethnic Categories: Not Hispanic or Latino Female	Not Hispanic or Latino Male	Hispanic or Latino Female	Hispanic or Latino Male	Total
American Indian/ Alaska Native	85	85	110	120	400
Asian	150	30	0	0	180
Native Hawaiian or Other Pacific Islander	5	5	0	0	10
Black or African American	500	450	140	40	1130
White	3000	2000	3000	2000	1000
More than One Race	20	10	10	10	50
Total	3760	2580	3260	2170	1177

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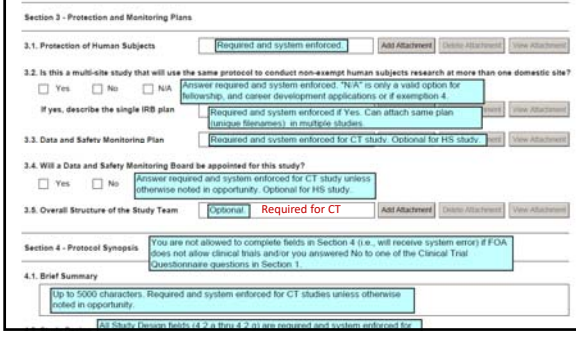
Section 3- Protection and Monitoring Plans


Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects — Required and system enforced. — Add Attachment | Delete Attachment | View Attachment

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?
Yes No N/A — Answer required and system enforced. "N/A" is only a valid option for fellowship, and career development applications or if exemption 4.

If yes, describe the single IRB plan — Required and system enforced if Yes. Can attach same plan (unique filenames) in multiple studies.

3.3. Data and Safety Monitoring Plan — Required and system enforced for CT study. Optional for HS study.

3.4. Will a Data and Safety Monitoring Board be appointed for this study?
Yes No — Answer required and system enforced for CT study unless otherwise noted in opportunity. Optional for HS study.

3.5. Overall Structure of the Study Team — Optional — Required for CT — Add Attachment | Delete Attachment | View Attachment

Section 4 - Protocol Synopsis — You are not allowed to complete fields in Section 4 (i.e., will receive system error) if FOA does not allow clinical trials and/or you answered No to one of the Clinical Trial Questionnaire questions in Section 1.

4.1. Brief Summary
Up to 5000 characters. Required and system enforced for CT studies unless otherwise noted in opportunity.

All Study Design fields (4.2.a thru 4.2.g) are required and system enforced for

Section 3.1: Protection of Human Subjects (PHS)

For studies that involve Non-Exempt Human Subjects Research: NIH requires a PHS attachment that is commensurate with the risks of the study, size and complexity

This section requires 4 sections, following the headings and specified order below:

1. Risks to Human Subjects
   a. Human Subjects Involvement, Characteristics, Design
   b. Study Procedures, materials, and Potential Risks
2. Adequacy of Protection Against Risks
   a. Informed Consent and Assent
   b. Protections Against Risk
   c. Vulnerable Subjects, if relevant
3. Potential Benefits of the Proposed Research to Research Participants and Others
4. Importance of the knowledge to be gained

For specifics on completing section: go to, https://grants.nih.gov/grants/how-to-apply-application-guide/forms-e/general/g.500-phs-human-subjects-and-clinical-trials-information.htm#PHS

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Section 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?

No- not a multi-site trial

N/A- indicated exempt in 1.2, training or fellowship applicant

Yes- This is a multi-site trial within the US and you are expected to use a single IRB (sIRB) to conduct the ethical review required by HHS regulations for the Protections of Human Subjects Research

If YES, you will need to describe the sIRB plan, which should include the following elements:

- Describe how you will comply with the NIH Policy on the Use of sIRB for Multi-Site Research.
- Provide the name of the 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.
- Briefly 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.

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Section 3.3: Data and Safety Monitoring Plan (DSMP)

A DSMP is required for all clinical trials (optional for all other human subjects research- although if there are significant risks to participants, it may be appropriate to include a DSMP)

NIH requires a DSMP that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

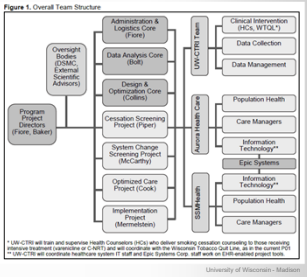
- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs) including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems, will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH, and the FDA, if applicable.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
  - While the PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PI to also be responsible for carrying out the DSMP.
  - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
  - Data Monitoring Committee (DMC) – an small group of independent experts to monitor data and safety.
  - Data and Safety Monitoring Board (DSMB)- a formal independent board of experts including investigators and biostatisticians. 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, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

Section 3.4: Will a Data and Safety Monitoring Board (DSMB) be appointed for this study?

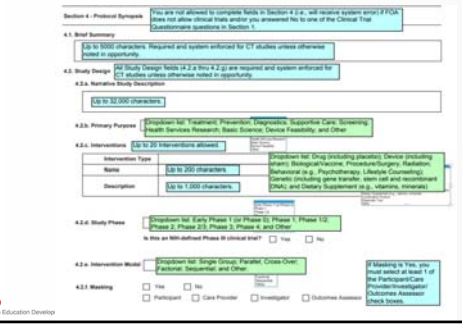
- Answer required if your project is a Clinical Trial
  - Yes or No
  - DSMB: NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all **Phase III clinical trials**.

Section 3.5: Overall structure of the Study Team

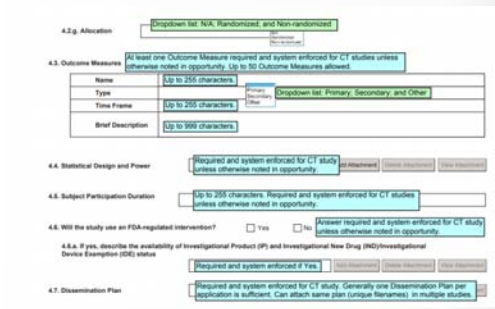
- The "Overall Structure of the Study Team" pdf attachment is required if you answered "Yes" to all the questions in the "Clinical Trial Questionnaire."
  - This question is optional for all other human subjects research.
- Provide a brief overview of the organizational structure of the study team, particularly the administrative sites, data coordinating sites, enrollment/participating sites, and any separate laboratory or testing centers.
  - Note: Do not include study team members' individual professional experiences (i.e., biosketch information).



Section 4: For Clinical Trials only



Section 4: For Clinical Trials only



Section 4: Protocol Synopsis

Section 4.1: Brief Summary-

- The NIH instructs to enter here a brief description of the **objectives** of the protocol, including the primary and secondary endpoints.
  - Limited to 5,000 characters

Section 4.2: Study Design

Section 4.2.a: Narrative Study Design

Enter a narrative description of the protocol.

- Studies differ considerably in the methods used to assign participants and deliver interventions. 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.
- For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage https://researchmethodsresources.nih.gov/

The narrative description is limited to 32,000 characters.

Section 4.2: Study Design

Section 4.2.b: Primary Purpose

Enter or select from the dropdown menu a single "Primary Purpose" that best describes the clinical trial. Choose from the following options:

- Treatment
- Prevention
- Diagnostics
- Supportive Care
- Screening
- Health Services Research
- Basic Science
- Device Feasibility
- Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

Section 4.2: Study Design

Section 4.2.c: Interventions

Complete the "Interventions" fields for each intervention to be used in your proposed protocol. You can add up to 20 interventions.

Intervention Type: Enter or select from the dropdown menu the intervention type the clinical trial will administer during the proposed award. Choose from the following options:

- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell, and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Combination Product
- Diagnostic Test

Name: Enter the name of the intervention. The name must be unique within each study record. The name is limited to 200 characters.
Description: Enter a description of the intervention. The description is limited to 1,000 characters.

Section 4.2: Study Design

Section 4.2.d: Study Phase

Enter or select from the dropdown menu a "Study Phase" that best describes the clinical trial. If your study involves a device, choose "Other."

Choose from the following options:

- Early Phase 1 (or Phase 0)
- Phase 1
- Phase 1/2
- Phase 2
- Phase 2/3
- Phase 3
- Phase 4
- Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

Is this an NIH-defined Phase III clinical trial? Yes/No

Select "Yes" or "No" to indicate whether the study includes an NIH-defined Phase III clinical trial.

Section 4.2: Study Design

Section 4.2.e: Intervention Model

Enter or select from the dropdown menu a single "Intervention Model" that best describes the clinical trial. If you select "Other," provide a description in the space provided. Choose from the following options:

- Single Group
- Parallel
- Cross-Over
- Factorial
- Sequential
- Other (If you select "Other," provide a description in the space provided. Your response is limited to 255 characters.)

Section 4.2: Study Design

Section 4.2.f: Masking (Blinding)

Select "Yes" or "No" to indicate whether the protocol uses masking.

If you answered "Yes" to the "Masking" question, select one or more types of masking that best describes the protocol. Choose from the following options:

- Participant
- Care Provider
- Investigator
- Outcomes Assessor

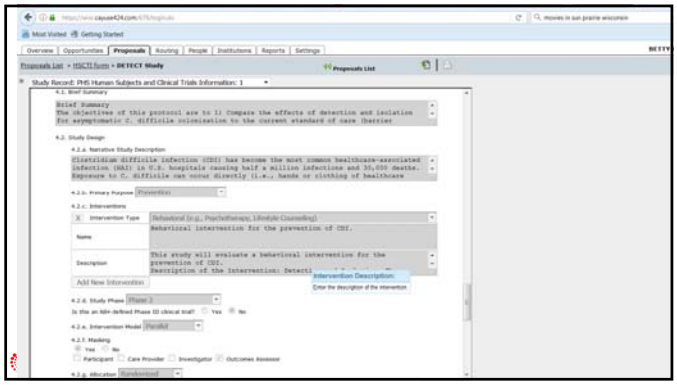
Section 4.2: Study Design

Section 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.

Choose from the following options:

- Randomized
- Non-randomized
- N/A- select if allocation is not applicable to your clinical trial (e.g., for a single-arm trial).



Section 4.3: Outcome Measures

Complete the "Outcome Measures" fields for each primary, secondary, and other important measures to be collected during your proposed clinical trial.

You may have more than one primary outcome measure, and you can add up to 50 outcome measures. TIP: For each secondary and other outcome measure you list, you will have to report out in Clinical Trials.gov when you do reporting.

For each outcome measure, you will need to list:

Name: Enter the name of the individual outcome measure. The outcome measure must be unique within each study record.

Type: Enter or select from the dropdown menu the type of the outcome measure. Choose from the following options:

- **Primary** - select this option for the outcome measures specified in your protocol that are of greatest importance to your study
- **Secondary** - select this option for outcome measures specified in your protocol that are of lesser importance to your study than your primary outcomes
- **Other** - select this option for additional key outcome measures used to evaluate the intervention.

Time Frame: Indicate when a measure will be collected for analysis (e.g., baseline, post-treatment).

Brief Description: Describe the metric used to characterize the outcome measure if the metric is not already included in the outcome measure name. Your description is limited to 999 characters.

Section 4.4: Statistical Design and Power

Content:

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. For trials that randomize groups or deliver interventions to groups, special methods are required; additional information is available at the Research Methods Resources webpage https://researchmethodsresources.nih.gov/ .

Section 4.5: Subject Participation Duration

- Enter the time (e.g., in months) it will take for each individual participant to complete all study visits.

  e.g. 24 months

- If the participation duration is unknown or not applicable, write "unknown" or "not applicable."
- The subject participation duration is a text field limited to 255 characters.

Section 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 (see the definition of "FDA Regulated Intervention"

- If yes, describe the availability of study agents and support for the acquisition and administration of the study agent(s).
- Indicate the IND/IDE status of the study agent, if applicable, and whether the investigators have had any interactions with the FDA.
- If the study agent currently has an IND/IDE number, provide that information.
- Note: The awarding component may request consultation with the FDA and the IND/IDE sponsor about the proposed clinical trial after peer review and prior to award.

Section 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. The plan must contain sufficient information to assure the following:
  - The applicant will ensure that clinical trial(s) 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;
  - Informed consent documents for the clinical trial(s) will include a specific statement relating to posting of clinical trial information at ClinicalTrials.gov; and
  - The recipient institution has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with policy requirements.

Handout provided:

- Outline to all grant components
- Outline to new Human Subjects section