NIH FORMS-E
Human Subjects and Clinical Trials Information Worksheet
FOR INTERNAL USE ONLY

This worksheet was created by a University of Michigan Research Administration Advisory Council (RAAC) Communications subcommittee working group, as a result of the implementation of the National Institutes of Health (NIH) SF424 (R&R) Application Packages – Version E, commonly referred to as "FORMS-E." The worksheet is consistent with the sequence and wording of the excerpted sections of FORMS-E contained herein, as of the "Last Updated" date in the document footer. Specifically, ***this worksheet focuses only on those sections of FORMS-E related to human subjects and clinical trials****. It does not relate to other sections of the NIH SF424 (R&R) application package or guidance.*

Information in this document is only relevant to the University of Michigan (U-M). It should not be construed as having applicability anywhere outside the U-M. The worksheet serves to guide U-M personnel (specifically, investigators and research administrators) through the changes arising in FORMS-E, as they relate to our institution.

FORMS-E must be used for all NIH submissions with ***due dates on or after January 25, 2018****. See NIH - How to Apply - Application Guide for information related to NIH forms and applications. Additional information about the FORMS-E implementation at the University of Michigan may be found on the Office of Research and Sponsored Projects (ORSP) NIH Changes website.*

The RAAC Communications subcommittee is comprised of volunteer membership. Although we will do our best to ensure this worksheet is up-to-date with the latest versions of NIH forms and instructions, we advise you e-mail the RAAC Communications subcommittee at RAAC.Comm@umich.edu to obtain the most current information about this worksheet.

Consult the table below for a list of recent changes to this worksheet. ***For the most recent version of the worksheet, please visit the ORSP Website****.*

VERSION HISTORY

Document Version	Date	Document Revisions
v.1	12/21/2017	(Original document)
v.2	1/16/2018	• Added guidance to Study Record header information (p. 4). • Added additional outcome measures (p. 12) and guidance on question 4.3 (p. 7). • Added "Reset Question" buttons.
v.3	1/24/2018	• Corrected guidance on attachment 3.5 (p. 5), indicating it is required for clinical trials and optional for human subjects.
v.4	2/23/2018	• Added version history table and link to document on ORSP website.
v.5	4/6/2018	• Updated page references. • Added "Unknown or Not Reported" Racial Category to Cumulative enrollment table (p. 10).
v.6	5/7/2018	• Updated wording on question 4.5.
v.7	6/15/2018	• Clarified instructions on questions 2.5, 2.6, 2.7, 2.8, 3.4, and 4.2.d.

INSTRUCTIONS / REMINDERS:

- Always consult the Funding Opportunity Announcement (FOA) related to the application submission. The FOA may contain submission-specific information and requirements that are not addressed here.
- If your study qualifies as a clinical trial *(p. 4)*, make sure you are responding to an FOA that allows for clinical trial submissions.
- If your study qualifies as a clinical trial *(p. 4)*, make sure you understand all of the requirements that accompany designation as a clinical trial. For more information, see the ORSP Clinical Trials website.
- Create a new copy of this worksheet for each proposal submission.
- To make this worksheet concise, some of the text fields are smaller than what their character limits will allow. When transferring information from the worksheet to the SF424 (R&R) application package, be sure to check all text fields in the worksheet, as they may not print completely.
- When transferring information from this worksheet to the SF424 (R&R) application forms, be sure to review the SF424 (R&R) forms and clarify any questions with the Principal Investigator of the study.
- Answers appearing in checkboxes on this worksheet may actually appear as either checkboxes or drop-down menus in the SF424 (R&R) forms.
- This worksheet does not address system validations within the actual SF424 (R&R) forms. Be advised that system validations within the SF424 (R&R) sections referenced in this worksheet may be dependent upon other SF424 (R&R) sections not contained in this worksheet. Consult eResearch Proposal Management support for more information, including how to contact the ITS Help Desk.
- Use or adoption of this worksheet is entirely optional and voluntary. Please provide any feedback related to this worksheet to RAAC.Comm@umich.edu.

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RESEARCH & RELATED Other Project Information

*1. **Are Human Subjects Involved?**

☐ Yes	☐ No	Reset Question

If YES	If NO
• answer question 1.a. **and** • upload a Study Record *(see below and p. 4)* for each study.	• skip to PHS Human Subjects and Clinical Trials Information question below.

*1.a. **If *YES* to Human Subjects** *(question 1 above)*

Is the Project Exempt from Federal regulations?

☐ Yes	☐ No	Reset Question

If *yes*, check the appropriate exemption number.
☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 Reset Question

If *no*, is the IRB review Pending?
☐ Yes ☐ No Reset Question

IRB Approval Date *(optional)* _____

Human Subjects Assurance Number FWA 00004969
(This is the University of Michigan's Human Subjects Assurance Number.)

PHS Human Subjects and Clinical Trials Information

If *NO* to Human Subjects *(question 1, **RESEARCH AND RELATED Other Project Information**, above)*

Does the proposed research involve human specimens and/or data?

☐ Yes	☐ No	Reset Question

If YES	If NO
• provide an explanation of why the application does not involve human subjects *(attachment)*	**STOP** **The rest of this worksheet is not required.**

Study Record *(see p. 4)*

Delayed Onset Study(ies)

Study Title _____
(Up to 600 characters)

Anticipated Clinical Trial? ☐ Yes ☐ No Reset Question

Justification *(attachment)*

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Study Record: PHS Human Subjects and Clinical Trials Information

NOTE: If the proposal has multiple studies, create a new study record with a unique title for each study.

Section 1 – Basic Information

***1.1.** **Study Title** _____

(Up to 600 characters. Study Title must be unique within the application.)

***1.2.** **Is this study exempt from Federal Regulations?**

☐ Yes	☐ No	Reset Question

If YES	If NO
• check the appropriate exemption number below.	• skip to question 1.4 below.

1.3. **Exemption number** ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 Reset Question

***1.4.** **Clinical Trial Questionnaire** Reset Questionnaire

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

After responding to the Clinical Trial Questionnaire, refer to the table below to determine the required application sections.

Form Section	If you answered "Yes" to **all** the questions *(see Clinical Trial Questionnaire)*	If you answered "No" to **any** of the questions *(see Clinical Trial Questionnaire)*
Section 2 – Study Population Characteristics	**Required**	**Required**
Section 3 – Protection and Monitoring Plans	**Required**	**Required**
Section 4 – Protocol Synopsis	**Required**	**Do not complete**
Section 5 – Other Clinical Trial-related Attachments	***Required if specified in the FOA***	**Do not complete**

1.5 **Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable.**

_____

(Newly proposed studies do not need to be entered in ClinicalTrials.gov at the time of application.)

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Section 2 – Study Population Characteristics

2.1 Conditions or Focus of Study _____
(Up to 20 conditions at 255 characters each. Not required if study is exemption 4.)

2.2 Eligibility Criteria _____
(Not required if study is exemption 4.)

2.3 Age Limits *(Not required if study is exemption 4.)*

Minimum age _____ *(enter number)* Reset Question
(check one) ☐ Years ☐ Months ☐ Weeks ☐ Days ☐ Hours ☐ Minutes ☐ N/A (no limit)

Maximum age _____ *(enter number)* Reset Question
(check one) ☐ Years ☐ Months ☐ Weeks ☐ Days ☐ Hours ☐ Minutes ☐ N/A (no limit)

2.4 Inclusion of Women, Minorities, and Children *(attachment)* *(Not required if study is exemption 4.)*

2.5 Recruitment and Retention Plan *(attachment)* *(Not required if study is exemption 4 or if the answer to question 1.4.a is "No.")*

2.6 Recruitment Status *(Not required if study is exemption 4 or if the answer to question 1.4.a is "No.")*

(check one)

☐ Not yet recruiting
☐ Recruiting
☐ Enrolling by invitation
☐ Active, not recruiting
☐ Completed
☐ Suspended
☐ Terminated (Halted Prematurely
☐ Withdrawn (No Participants Enrolled)

Reset Question

2.7 Study Timeline *(attachment)* *(Not required if study is exemption 4 or if the answer to question 1.4.a is "No.")*

2.8 Enrollment of First Subject *(Not required if study is exemption 4 or if the answer to question 1.4.a is "No.")*

Date _____ *(check one)* ☐ Anticipated ☐ Actual Reset Question

Inclusion Enrollment Report(s) *(attachment(s))* *(Not required if study is exemption 4.)* *(See sample on 9)*

Section 3 – Protection and Monitoring Plans

3.1 Protection of Human Subjects *(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

("N/A" is only a valid option for fellowship and career development applications or if exemption 4.)

Reset Question

If YES	If NO
• describe the single IRB plan *(attachment)*	• skip to question 3.3 below.

3.3 Data and Safety Monitoring Plan *(attachment)* *(Required for clinical trial; optional for human subjects.)*

3.4 Will a Data Safety and Monitoring Board by appointed for this study? ☐ Yes ☐ No
(Answer is required for clinical trial; answer is optional for human subjects.)

Reset Question

3.5 Overall Structure of the Study Team *(attachment)* *(Required for clinical trial; optional for human subjects.)*

Section 4 – Protocol Synopsis

***Refer to the *Clinical Trial Questionnaire on p. 4.* If you answered "No" to any of the questions, this section is not required.**

4.1 Brief Summary _____
(Up to 5,000 characters)

4.2 Study Design:

4.2.a. Narrative Study Description _____
(Up to 32,000 characters)

4.2.b. Primary Purpose Reset Question

(check one)

- ☐ Treatment
- ☐ Prevention
- ☐ Diagnostics
- ☐ Supportive Care
- ☐ Screening
- ☐ Health Services Research
- ☐ Basic Science
- ☐ Device Feasibility

4.2.c. Interventions Reset Question
(up to 20 Interventions allowed.)

Intervention Type:

(check one)

- ☐ 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
- ☐ Other _____

Name _____
(Up to 200 characters.)

Description _____
(Up to 1,000 characters.)

(Additional intervention entries available on p. 11, if needed)

4.2.d. Study Phase (*If behavioral or device study, select "Other" and provide explanation.*) Reset Question

(check one)

- ☐ Early Phase 1 (or Phase 0)
- ☐ Phase 1
- ☐ Phase 1/2
- ☐ Phase 2
- ☐ Phase 2/3
- ☐ Phase 3
- ☐ Phase 4
- ☐ Other _____

(If selecting "Other", response is limited to 255 characters.)

Is this an NIH-defined Phase III clinical trial? ☐ Yes ☐ No Reset Question

4.2.e. Intervention Model Reset Question

(check one)

- ☐ Single Group
- ☐ Parallel
- ☐ Cross-Over
- ☐ Factorial
- ☐ Sequential
- ☐ Other _____

(If selecting "Other", response is limited to 255 characters.)

Section 4 – Protocol Synopsis (cont.)

4.2.f. Masking

☐ Yes	☐ No	Reset Question

If YES	If NO
• check all that apply below.	• skip to question 4.2.g below.

(check all that apply) ☐ Participant ☐ Investigator ☐ Care Provider ☐ Outcomes Assessor

4.2.g. Allocation

(check one) ☐ N/A ☐ Non-randomized ☐ Randomized Reset Question

4.3. Outcome Measures Reset Question

(At least one Outcome Measure required, unless noted in the opportunity. Up to 50 Outcome Measures allowed.)

Name _____
(Up to 255 characters.)

Type
(check one) ☐ Primary ☐ Secondary ☐ Other

Time Frame _____
(Up to 255 characters.)

Brief Description _____
(Up to 999 characters.)

(Additional outcome measure entries available on p. 12, if needed)

4.4. Statistical Design and Power *(attachment)*

4.5. Subject Participation Duration _____
(Up to 255 characters.)

4.6. Will the study use an FDA-regulated intervention?

☐ Yes	☐ No	Reset Question

4.6.a.

If YES	If NO
• describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational New Drug Exemption (IDE) status *(attachment)*	• skip to question 4.7 below.

4.7. Dissemination Plan *(attachment)*

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Section 5 – Other Clinical Trial Attachments (attachments, if required by FOA)

*Refer to the Clinical Trial Questionnaire on p. 4. If you answered "No" to any of the questions, this section is not required.

If you answered:	To question:	Then attach or complete:
RESEARCH & RELATED Other Project Information		
Yes	*1*	• Attach a Study Record *(p. 4)* for each study
PHS Human Subjects and Clinical Trials Information		
Yes	*Human Specimens and/or Data*	• Attach an explanation of why the application does not involve human subjects *(p. 3)*
Yes	*Delayed Onset Study(ies)*	• Complete Delayed Onset Study questions *(see p. 3)* • Attach Justification *(see p. 3)*
Study Record: PHS Human Subjects and Clinical Trials Information		
Yes to **all**	*1.4.a. through 1.4.d.*	• Complete Section 2 *(p. 5)* • Complete Section 3 *(p. 5)* • Complete Section 4 *(p. 6)* • Complete Section 5 *(p. 7)*, if required by FOA
No to **any**	*1.4.a. through 1.4.d.*	• Complete Section 2 *(p. 5)* • Complete Section 3 *(p. 5)*
Yes	*3.2*	• Attach Single IRB Plan *(p. 5)*
Yes	*4.6*	• Attach Description *(p. 7)*

ATTACHMENT CHECKLIST: *(Not all of the attachments listed below may be required. Consult the table above.)*

	Section	Question	Description	Page
PHS Human Subjects and Clinical Trials Information				
☐	*N/A*	*Human Specimens and/or Data*	Explanation of why the application does not involve human subjects	3
☐	*N/A*	*Study Record(s)*	Study Record: PHS Human Subjects and Clinical Trials Information for each study	3
☐	*N/A*	*Delayed Onset Study(ies)*	Justification explaining why human subjects study information is not available at the time of application	3
Study Record: PHS Human Subjects and Clinical Trials Information				
☐	2	*2.4*	Inclusion of Women, Minorities, and Children	5
☐	2	*2.5*	Recruitment and Retention Plan	5
☐	2	*2.7*	Study Timeline	5
☐	2	*N/A*	Inclusion Enrollment Report(s)	5, 9
☐	3	*3.1*	Protection of Human Subjects	5
☐	3	*3.2*	Single IRB Plan	5
☐	3	*3.3*	Data and Safety Monitoring Plan	5
☐	3	*3.5*	Overall Structure of the Study Team	5
☐	4	*4.4*	Statistical Design and Power	7
☐	4	*4.6*	FDA-regulated Intervention	7
☐	4	*4.7*	Dissemination Plan	7
☐	5	*see FOA*	See FOA for details	7

Inclusion Enrollment Report *(Sample)*

***1. Using Existing Dataset or Resource** ☐ Yes ☐ No **Reset Question**

***2. Enrollment Location Type** ☐ Domestic ☐ Foreign **Reset Question**

3. Enrollment Country(ies) _____

4. Enrollment Locations *(optional)* _____
(Indicate the type of enrollment location – e.g., hospital, university, or research center), not the name of the enrollment location.)

5. Comments _____
(Up to 500 characters.)

Planned

Racial Categories	**Ethnic Categories**				
	Not Hispanic or Latino		Hispanic or Latino		**Total**
	Female	**Male**	**Female**	**Male**	
American Indian/ Alaska Native					0
Asian					0
Native Hawaiian or Other Pacific Islander					0
Black or African American					0
White					0
More than One Race					0
Total	0	0	0	0	0

Inclusion Enrollment Report *(Sample) (cont.)*

Cumulative (Actual)

Racial Categories	Ethnic Categories									
	Not Hispanic or Latino			Hispanic or Latino			Unknown/Not Reported Ethnicity			Total
	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	Female	Male	Unknown/ Not Reported	
American Indian/ Alaska Native										0
Asian										0
Native Hawaiian or Other Pacific Islander										0
Black or African American										0
White										0
More than One Race										0
Unknown or Not Reported										0
Total	0	0	0	0	0	0	0	0	0	0

Report ___ of ___

Additional Interventions *(if needed)*

4.2.c. Interventions (cont.) Reset Question

Intervention Type:

(check one)

- ☐ 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
- ☐ Other ____________________

Name ________________________________
(Up to 200 characters.)

Description ________________________________
(Up to 1,000 characters.)

4.2.c. Interventions (cont.) Reset Question

Intervention Type:

(check one)

- ☐ 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
- ☐ Other ____________________

Name ________________________________
(Up to 200 characters.)

Description ________________________________
(Up to 1,000 characters.)

4.2.c. Interventions (cont.) Reset Question

Intervention Type:

(check one)

- ☐ 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
- ☐ Other ____________________

Name ________________________________
(Up to 200 characters.)

Description ________________________________
(Up to 1,000 characters.)

Additional Outcome Measures *(if needed)*

4.3. Outcome Measures **Reset Question**

(At least one Outcome Measure required, unless noted in the opportunity. Up to 50 Outcome Measures allowed.)

Name ______________________________

(Up to 255 characters.)

Type

(check one) ☐ Primary ☐ Secondary ☐ Other

Time Frame ______________________________

(Up to 255 characters.)

Brief Description ______________________________

(Up to 999 characters.)

4.3. Outcome Measures **Reset Question**

(At least one Outcome Measure required, unless noted in the opportunity. Up to 50 Outcome Measures allowed.)

Name ______________________________

(Up to 255 characters.)

Type

(check one) ☐ Primary ☐ Secondary ☐ Other

Time Frame ______________________________

(Up to 255 characters.)

Brief Description ______________________________

(Up to 999 characters.)

4.3. Outcome Measures **Reset Question**

(At least one Outcome Measure required, unless noted in the opportunity. Up to 50 Outcome Measures allowed.)

Name ______________________________

(Up to 255 characters.)

Type

(check one) ☐ Primary ☐ Secondary ☐ Other

Time Frame ______________________________

(Up to 255 characters.)

Brief Description ______________________________

(Up to 999 characters.)