



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

This worksheet was originally 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,” and has subsequently been revised to accommodate the implementation of NIH SF424 (R&R) FORMS-F.

*The worksheet is consistent with the sequence and wording of the excerpted sections of FORMS-F contained herein, as of the “Last Updated” date in the document footer. Specifically, **this worksheet focuses only on those sections of FORMS-F 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 both FORMS-E and FORMS-F, as they relate to our institution.

*FORMS-F must be used for all NIH submissions with **due dates on or after May 25, 2020**. See [NIH - How to Apply - Application Guide](#) for information related to NIH forms and applications.*

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

<u>Document Version</u>	<u>Date</u>	<u>Document Revisions</u>
v.1	3/10/2020	(Original document – replaces NIH FORMS-E worksheet)
	4/14/2020	Minor formatting changes
v.2	7/15/2020	Add "Inclusion of Individuals Across the Lifespan" to document checklist



NIH FORMS-F
Human Subjects and Clinical Trials Information
Worksheet
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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.



NIH FORMS-F
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Worksheet
FOR INTERNAL USE ONLY

RESEARCH & RELATED Other Project Information

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

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	-----------------------------

If YES	If NO
<ul style="list-style-type: none"> • answer <u>question 1.a.</u> and • upload a <u>Study Record</u> (see <i>below and p. 4</i>) for each study. 	<ul style="list-style-type: none"> • skip to <u>PHS Human Subjects and Clinical Trials Information question</u> below.

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

Is the Project Exempt from Federal regulations?

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	-----------------------------

If yes, check the appropriate exemption number.

1 2 3 4 5 6 7 8

If no, is the IRB review Pending?

Yes No

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

Use of Human Specimens and/or Data

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

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	-----------------------------

If YES	If NO
<ul style="list-style-type: none"> • <u>provide an explanation of why the application does not involve human subjects</u> (attachment) 	<p><u>STOP</u> The rest of this worksheet is not required.</p>

Study Record – add a study record for each proposed study involving human subjects (see p. 4)

Delayed Onset Study(ies)

Study Title _____
(Up to 600 characters)

Anticipated Clinical Trial? Yes No

Justification (attachment)



NIH FORMS-F

Human Subjects and Clinical Trials Information

Worksheet

FOR INTERNAL USE ONLY

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?**

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	-----------------------------

If YES	If NO
<ul style="list-style-type: none"> check the appropriate <u>exemption number</u> below. 	<ul style="list-style-type: none"> skip to <u>question 1.4</u> below.

1.3. Exemption Number 1 2 3 4 5 6 7 8

***1.4. Clinical Trial 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.

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

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.)



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

Section 2 – Study Population Characteristics **NOTE: This section is required unless you selected only Exemption 4 and no other exemptions on the “1.3 Exemption Number” question.**

2.1 Conditions or Focus of Study _____
(Up to 20 conditions at 255 characters each.)

2.2 Eligibility Criteria _____

2.3 Age Limits

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

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

2.3.a Inclusion of Individuals Across the Lifespan *(attachment)*

2.4 Inclusion of Women and Minorities *(attachment)*

2.5 Recruitment and Retention Plan *(attachment)*

2.6 Recruitment Status

- (check one)*
- | | |
|--|---|
| <input type="checkbox"/> Not yet recruiting | <input type="checkbox"/> Completed |
| <input type="checkbox"/> Recruiting | <input type="checkbox"/> Suspended |
| <input type="checkbox"/> Enrolling by invitation | <input type="checkbox"/> Terminated (Halted Prematurely) |
| <input type="checkbox"/> Active, not recruiting | <input type="checkbox"/> Withdrawn (No Participants Enrolled) |

2.7 Study Timeline *(attachment)*

2.8 Enrollment of First Participant

Date _____ *(check one)* Anticipated Actual

2.9 Inclusion Enrollment Report(s) *(attachment(s)) (see sample, p. 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?

<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
------------------------------	-----------------------------	------------------------------

(“N/A” is only a valid option if you answered “Yes” to question 1.2 above or you are a training grant applicant.)

If YES	If NO
• a <u>single IRB plan</u> will be required with the Just-in-Time submission prior to award.	• skip to <u>question 3.3</u> 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 be appointed for this study? Yes No
(Answer is required for clinical trial; answer is optional for human subjects.)

3.5 Overall Structure of the Study Team *(attachment) (Optional – refer to your specific FOA)*



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

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 Study Design:

4.1.a. Detailed Description _____
(Up to 32,000 characters; typically needs only 5,000 characters)

4.1.b. Primary Purpose

- (check one)
- | | |
|--|---|
| <input type="checkbox"/> Treatment | <input type="checkbox"/> Screening |
| <input type="checkbox"/> Prevention | <input type="checkbox"/> Health Services Research |
| <input type="checkbox"/> Diagnostics | <input type="checkbox"/> Basic Science |
| <input type="checkbox"/> Supportive Care | <input type="checkbox"/> Device Feasibility |
| <input type="checkbox"/> Other _____ | |

4.1.c. Interventions
(up to 20 Interventions allowed.)

- (check one)
- | | |
|---|--|
| Intervention Type: | |
| <input type="checkbox"/> Drug (including placebo) | <input type="checkbox"/> Genetic (including gene transfer, stem cell, and recombinant DNA) |
| <input type="checkbox"/> Device (including sham) | |
| <input type="checkbox"/> Biological/Vaccine | <input type="checkbox"/> Dietary Supplement (e.g., vitamins, minerals) |
| <input type="checkbox"/> Procedure/Surgery | <input type="checkbox"/> Combination Product |
| <input type="checkbox"/> Radiation | <input type="checkbox"/> Diagnostic Test |
| <input type="checkbox"/> Behavioral (e.g., Psychotherapy, Lifestyle Counseling) | <input type="checkbox"/> Other _____ |

Name _____
(Up to 200 characters.)

Description _____
(Up to 1,000 characters.)

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

4.1.d. Study Phase *(If behavioral or device study, select “Other” and provide explanation.)*

- (check one)
- | | |
|---|------------------------------------|
| <input type="checkbox"/> Early Phase 1 (or Phase 0) | <input type="checkbox"/> Phase 2/3 |
| <input type="checkbox"/> Phase 1 | <input type="checkbox"/> Phase 3 |
| <input type="checkbox"/> Phase 1/2 | <input type="checkbox"/> Phase 4 |
| <input type="checkbox"/> Phase 2 | <input type="checkbox"/> N/A |

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

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

4.1.e. Intervention Model

- (check one)
- | | |
|---------------------------------------|--------------------------------------|
| <input type="checkbox"/> Single Group | <input type="checkbox"/> Factorial |
| <input type="checkbox"/> Parallel | <input type="checkbox"/> Sequential |
| <input type="checkbox"/> Cross-Over | <input type="checkbox"/> Other _____ |

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



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

Section 4 – Protocol Synopsis (cont.)

4.1.f. Masking

<input type="checkbox"/> Yes	<input type="checkbox"/> No
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If YES	If NO
<ul style="list-style-type: none"> • check all that apply below. 	<ul style="list-style-type: none"> • skip to <u>question 4.1.g</u> below.

- (check all that apply)
- | | |
|--|--|
| <input type="checkbox"/> Participant | <input type="checkbox"/> Investigator |
| <input type="checkbox"/> Care Provider | <input type="checkbox"/> Outcomes Assessor |

4.1.g. Allocation

- (check one) N/A Non-randomized Randomized

4.2. Outcome Measures

(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)

4.3. Statistical Design and Power *(attachment)*

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

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

<input type="checkbox"/> Yes	<input type="checkbox"/> No
------------------------------	-----------------------------

4.5.a.

If YES	If NO
<ul style="list-style-type: none"> • describe the availability of Investigational Product (IP) and Investigational New Drug (IND)/ Investigational New Drug Exemption (IDE) status <i>(attachment)</i> 	<ul style="list-style-type: none"> • skip to <u>question 4.6</u> below.

4.6. Is this an applicable clinical trial under FDAAA? Yes No

4.7. Dissemination Plan *(attachment)*



NIH FORMS-F

Human Subjects and Clinical Trials Information

Worksheet

FOR INTERNAL USE ONLY

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**.

REQUIREMENTS:

If you answered:	To question:	Then attach or complete:
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RESEARCH & RELATED Other Project Information

Yes	1	<ul style="list-style-type: none"> Attach a Study Record (p. 4) for each study
-----	---	---

PHS Human Subjects and Clinical Trials Information

Yes	<i>Human Specimens and/or Data</i>	<ul style="list-style-type: none"> Attach an explanation of why the application does not involve human subjects (p. 3)
-----	------------------------------------	---

Yes	<i>Delayed Onset Study(ies)</i>	<ul style="list-style-type: none"> 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	<i>1.4.a. through 1.4.d.</i>	<ul style="list-style-type: none"> Complete Section 2 (p. 4) Complete Section 3 (p. 5) Complete Section 4 (p. 6) Complete Section 5 (p. 8), if required by FOA
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No to any	<i>1.4.a. through 1.4.d.</i>	<ul style="list-style-type: none"> Complete Section 2 (p. 4) Complete Section 3 (p. 5)
------------------	------------------------------	--

Yes	3.2	<ul style="list-style-type: none"> Attach Single IRB Plan (p. 5)
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Yes	4.6	<ul style="list-style-type: none"> Attach Description (p. 7)
-----	-----	---

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

Section	Question	Description	Page
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PHS Human Subjects and Clinical Trials Information

<input type="checkbox"/>	N/A	<i>Human Specimens and/or Data</i>	Explanation of why the application does not involve human subjects	3
<input type="checkbox"/>	N/A	<i>Study Record(s)</i>	Study Record: PHS Human Subjects and Clinical Trials Information for each study	3
<input type="checkbox"/>	N/A	<i>Delayed Onset Study(ies)</i>	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

<input type="checkbox"/>	2	2.3.a	Inclusion of Individuals Across the Lifespan	5
<input type="checkbox"/>	2	2.4	Inclusion of Women, Minorities, and Children	5
<input type="checkbox"/>	2	2.5	Recruitment and Retention Plan	5
<input type="checkbox"/>	2	2.7	Study Timeline	5
<input type="checkbox"/>	2	N/A	Inclusion Enrollment Report(s)	5, 9
<input type="checkbox"/>	3	3.1	Protection of Human Subjects	5
<input type="checkbox"/>	3	3.2	Single IRB Plan	5
<input type="checkbox"/>	3	3.3	Data and Safety Monitoring Plan	5
<input type="checkbox"/>	3	3.5	Overall Structure of the Study Team Statistical	5
<input type="checkbox"/>	4	4.4	Design and Power	7
<input type="checkbox"/>	4	4.6	FDA-regulated Intervention	7
<input type="checkbox"/>	4	4.7	Dissemination Plan	7
<input type="checkbox"/>	5	see FOA	See FOA for details	8



NIH FORMS-F
Human Subjects and Clinical Trials Information
Worksheet
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Inclusion Enrollment Report (*Sample*)

- *1. **Inclusion Enrollment Report Title** _____
- *2. **Using Existing Dataset or Resource** Yes No
- 3. **Enrollment Location Type** Domestic Foreign
- 4. **Enrollment Country(ies)** _____
- 5. **Enrollment Locations** (*optional*) _____
(Indicate the type of enrollment location – e.g., hospital, university, or research center), not the name of the enrollment location.)
- 6. **Comments** _____
(Up to 500 characters.)

Planned

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



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

Inclusion Enrollment Report (Sample) (cont.)

Cumulative (Actual)

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

Report ___ of ___



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

Additional Interventions *(if needed)*

4.1.c. Interventions (cont.)

- (check one)*
- Intervention Type:**
- | | |
|---|--|
| <input type="checkbox"/> Drug (including placebo) | <input type="checkbox"/> Genetic (including gene transfer, stem cell, and recombinant DNA) |
| <input type="checkbox"/> Device (including sham) | <input type="checkbox"/> Dietary Supplement (e.g., vitamins, minerals) |
| <input type="checkbox"/> Biological/Vaccine | <input type="checkbox"/> Combination Product |
| <input type="checkbox"/> Procedure/Surgery | <input type="checkbox"/> Diagnostic Test |
| <input type="checkbox"/> Radiation | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Behavioral (e.g., Psychotherapy, Lifestyle Counseling) | |

Name _____
(Up to 200 characters.)

Description _____
(Up to 1,000 characters.)

4.1.c. Interventions (cont.)

- (check one)*
- Intervention Type:**
- | | |
|---|--|
| <input type="checkbox"/> Drug (including placebo) | <input type="checkbox"/> Genetic (including gene transfer, stem cell, and recombinant DNA) |
| <input type="checkbox"/> Device (including sham) | <input type="checkbox"/> Dietary Supplement (e.g., vitamins, minerals) |
| <input type="checkbox"/> Biological/Vaccine | <input type="checkbox"/> Combination Product |
| <input type="checkbox"/> Procedure/Surgery | <input type="checkbox"/> Diagnostic Test |
| <input type="checkbox"/> Radiation | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Behavioral (e.g., Psychotherapy, Lifestyle Counseling) | |

Name _____
(Up to 200 characters.)

Description _____
(Up to 1,000 characters.)

4.1.c. Interventions (cont.)

- (check one)*
- Intervention Type:**
- | | |
|---|--|
| <input type="checkbox"/> Drug (including placebo) | <input type="checkbox"/> Genetic (including gene transfer, stem cell, and recombinant DNA) |
| <input type="checkbox"/> Device (including sham) | <input type="checkbox"/> Dietary Supplement (e.g., vitamins, minerals) |
| <input type="checkbox"/> Biological/Vaccine | <input type="checkbox"/> Combination Product |
| <input type="checkbox"/> Procedure/Surgery | <input type="checkbox"/> Diagnostic Test |
| <input type="checkbox"/> Radiation | <input type="checkbox"/> Other _____ |
| <input type="checkbox"/> Behavioral (e.g., Psychotherapy, Lifestyle Counseling) | |

Name _____
(Up to 200 characters.)

Description _____
(Up to 1,000 characters.)



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

Additional Outcome Measures *(if needed)*

4.2. Outcome Measures

(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.)

4.2. Outcome Measures

(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.)

4.2. Outcome Measures

(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.)