THE OHIO STATE UNIVERSITY
COLLEGE OF NURSING

NIH FORMS-E

Human Subjects and Clinical Trials Information Worksheet

FOR INTERNAL USE ONLY

This worksheet was created 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 Ohio State University College of Nurisng (OSU-C0N). It should not be construed as having applicability anywhere outside the OSU-CoN. The worksheet serves to guide 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 may be found on the Office of Research and Sponsored Projects (ORSP) NIH Changes website.*

The OSU-CoN Research Coordinator Working Group is dedicated to assisting faculty in managing NIH application submission with transparency and seamlessness. The Working Group will do our best to ensure this worksheet is up-to-date with the latest versions of NIH forms and instructions.

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. 3)*, make sure you are responding to an FOA that allows for clinical trial submissions.
- If your study qualifies as a clinical trial *(p. 3)*, 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 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.
- Use or adoption of this worksheet is entirely optional and voluntary. Please provide any feedback related to this worksheet to CON_ResearchCoordinators@OSU.edu.

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RESEARCH & RELATED Other Project Information

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

☐ Yes	☐ No

If YES	If NO
• answer question 1.a. **and** • complete a Study Record *(see below and p. 3)* 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

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 FWA00006378
(This is The Ohio State University'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

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. 3)*

Delayed Onset Study(ies)

Study Title _____
(Up to 600 characters)

Anticipated Clinical Trial? ☐ Yes ☐ No

Justification *(attachment)*

Study Record: PHS Human Subjects and Clinical Trials Information

Section 1 – Basic Information

CT HS *1.1. **Study Title** _____
(Up to 600 characters. Study Title must be unique within the application.)

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

☐ Yes	☐ No

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

CT HS 1.3. **Exemption number** ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8

CT HS *1.4. **Clinical Trial Questionnaire**

CT HS 1.4.a.	**Does the study involve human participants?**	☐ Yes	☐ No
CT HS 1.4.b.	**Are the participants prospectively assigned to an intervention?**	☐ Yes	☐ No
CT HS 1.4.c.	**Is the study designed to evaluate the effect of the intervention on the participants?**	☐ Yes	☐ No
CT HS 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

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

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

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

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)

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

CT HS **2.5** **Recruitment and Retention Plan** *(attachment)* *(Not required if study is exemption 4.)*

CT HS **2.6** **Recruitment Status** *(Not required if study is exemption 4.)*

(check one)

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

CT HS **2.7** **Study Timeline** *(attachment)* *(Not required if study is exemption 4.)*

CT HS **2.8** **Enrollment of First Subject** *(Not required if study is exemption 4.)*
Date _____ *(check one)* ☐ Anticipated ☐ Actual

Inclusion Enrollment Report(s) *(attachment(s))* *(see sample, p. 8)*

Section 3 – Protection and Monitoring Plans

CT HS **3.1** **Protection of Human Subjects** *(attachment)*

CT HS **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.)

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

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

CT **3.4** **Will a Data Safety and Monitoring Board by appointed for this study?** ☐ Yes ☐ No
(Required for phase III clinical trial; optional for human subjects.)

CT **3.5** **Overall Structure of the Study Team** *(attachment)* *(optional)*

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Section 4 – Protocol Synopsis

***Refer to the *Clinical Trial Questionnaire on p. 3.* If you answered "No" to any of the questions, this section is not required.**

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

CT **4.2 Study Design:**

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

CT **4.2.b. Primary Purpose**

(check one)

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

CT **4.2.c. Interventions**
(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. 10, if needed)

CT **4.2.d. Study Phase**

(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

CT **4.2.e. Intervention Model**

(check one)

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

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

Section 4 – Protocol Synopsis (cont.)

CT **4.2.f. Masking**

☐ Yes	☐ No

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

CT **4.2.g. Allocation**

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

CT **4.3. 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.)

CT **4.4. Statistical Design and Power** *(attachment)*

CT **4.5. Study Participation Duration** _____
(Up to 255 characters.)

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

☐ Yes	☐ No

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.

CT **4.7. Dissemination Plan** *(attachment)*

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

***Refer to the *Clinical Trial Questionnaire on p. 3.* If you answered "No" to any of the questions, this section is not required.**

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REQUIREMENTS:

If you answered:	To question:	Then attach or complete:
RESEARCH & RELATED Other Project Information		
Yes	*1*	• Complete a Study Record *(p. 3)* 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. 2)*
Yes	*Delayed Onset Study(ies)*	• Complete Delayed Onset Study questions *(see p. 2)* • Attach Justification *(see p. 2)*
Study Record: PHS Human Subjects and Clinical Trials Information		
Yes to **all**	*1.4.a. through 1.4.d.*	• Complete Section 2 *(p. 4)* • Complete Section 3 *(p. 4)* • Complete Section 4 *(p. 5)* • Complete Section 5 *(p. 6)*, if required by FOA
No to **any**	*1.4.a. through 1.4.d.*	• Complete Section 2 *(p. 4)* • Complete Section 3 *(p. 4)*
Yes	*3.2*	• Attach Single IRB Plan *(p. 4)*
Yes	*4.6*	• Attach Description *(p. 6)*

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	2
☐	*N/A*	*Study Record(s)*	Study Record: PHS Human Subjects and Clinical Trials Information for each study	2
☐	*N/A*	*Delayed Onset Study(ies)*	Justification explaining why human subjects study information is not available at the time of application	2
Study Record: PHS Human Subjects and Clinical Trials Information				
☐	2	*2.4*	Inclusion of Women, Minorities, and Children	4
☐	2	*2.5*	Recruitment and Retention Plan	4
☐	2	*2.7*	Study Timeline	4
☐	2	*N/A*	Inclusion Enrollment Report(s)	4, 8
☐	3	*3.1*	Protection of Human Subjects	4
☐	3	*3.2*	Single IRB Plan	4
☐	3	*3.3*	Data and Safety Monitoring Plan	4
☐	3	*3.5*	Overall Structure of the Study Team	4
☐	4	*4.4*	Statistical Design and Power	6
☐	4	*4.6*	FDA-regulated Intervention	6
☐	4	*4.7*	Dissemination Plan	6
☐	5	*see FOA*	See FOA for details	6

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Inclusion Enrollment Report

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

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

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
Total	0	0	0	0	0	0	0	0	0	0

Report ___ of ___

Additional Interventions *(if needed)*

4.2.c. Interventions (cont.)

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.)

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.)

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.)