

# Compliance and Reporting in Human Subjects Research and the Human Subjects System (HSS) Troubleshooting

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National Institutes of Health  
Office of Extramural Research

# Compliance and Reporting in Human Subjects Research

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# 45 CFR 46 Subpart A: The Common Rule and Subparts B, C, and D

- Harmonizes protection of human subjects among different U.S. Federal departments and agencies
- Outlines regulations for:
  - IRB review and approval
  - Informed consent
  - Federalwide assurance
- Subpart B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
- Subpart C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
- Subpart D – Additional Protections for Children Involved as Subjects in Research



# Determining if a Proposed Activity is Non-Exempt Human Subjects Research



IS THE ACTIVITY **RESEARCH**?



DOES THE RESEARCH ACTIVITY INVOLVE **HUMAN SUBJECTS**?



IS THE HUMAN SUBJECTS RESEARCH **EXEMPT**?



# 1. Is the Activity Research

Research is a **systematic investigation**, including research development, testing, and evaluation, designed to **develop or contribute to generalizable knowledge**

45 CFR 46.102(I)



# Deeper Dive: Is the Activity Research?

Is the activity a systematic investigation?

- Are there plans using a methodical approach?
  - Is there a hypothesis? A research question? Plans to systematically collect and analyze data?

Is the activity designed to develop or contribute to generalizable knowledge?

- Will the activity add information and contribute to generalizable knowledge?
- Note- plans to share results with the larger community does not determine if the evaluation is designed to develop or contribute to generalizable knowledge.



## 2. Does the Research Activity Involve Human Subjects

**Human subject** are a living individual about whom an investigator conducting research

Obtains information or biospecimens through **intervention or interaction** with the individual, and uses, studies, or analyzes the information or biospecimens; or

Obtains, uses, studies, analyzes, or generates **identifiable private information or identifiable biospecimens**

45 CFR 46.102(e)(1)



# Are Human Subjects Involved in the Research?

Identify who is the subject

- A human subject is the person that the information is about or from whom the specimen was taken

Is there an interaction or intervention?  
*OR* Does the investigator have

- Identifiable, private information about the subject or
- Identifiable biospecimens?



### 3. Is the Human Subjects Research Activity Exempt?

Research activities that meet the conditions for an exemption category are exempt from the typical requirements of the Common Rule (i.e., IRB review and approval according to the regulations)

Institutions generally designate experienced individuals (IRB member or in the IRB office) to make exemption determinations

*NOTE:* If the proposed human subjects research activity is exempt under one or more categories, **STOP**. The activity is *not* nonexempt human subjects research.

45 CFR 46.104



# Exempt Categories of Research

**Exemption 1:** Normal educational practices in established or commonly accepted settings\*

**Exemption 2:** Interactions involving educational tests, surveys, interviews, or observations of public behavior

**Exemption 3:** Benign behavioral interventions in adults if information is sensitive and identifiable\*

**Exemption 4:** Secondary research use of identifiable, private information or identifiable biospecimens

**Exemption 5:** research or demonstration projects designed to study, evaluate, improve, or examine an NIH public benefit or service program\*

**Exemption 6:** taste and food quality\*

**Exemption 7:** Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research

**Exemption 8:** Secondary research using identifiable private information or identifiable biospecimens

*\*Exempt categories that may include an NIH-defined clinical trial*

See [Common Rule Exempt Research](#) and [NIH OER Definition of Human Subjects Research](#) websites



# Non-Exempt Human Subjects Research

When the answer to the first two questions is yes, and the answer to the third question is no, the activity *is* non-exempt human subjects research and requires IRB review and approval.

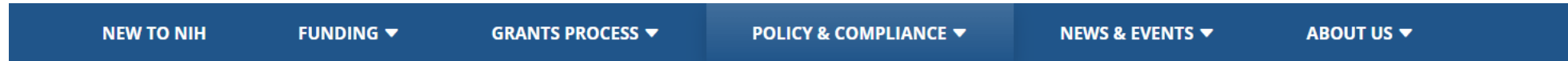
1. Is the activity research?
2. Does the research activity involve human subjects?
3. Is the human subjects research exempt?

## References and Resources:

- [OHRP Human Subject Regulations Decision Charts](#)
- [NIH Human Subjects Research Infographic](#)
- [NIH Decision Tool: Am I Doing Human Subjects Research?](#)



# Decision Tool: Am I Doing Human Subjects Research



[Home](#) > [Policy & Compliance](#) > [Policy Topics](#) > [Human Subjects Research](#) > Decision Tool: Am I Doing Human Subjects Research?

## Policy & Compliance

[← Back to Human Subjects Research](#)

Definition of Human Subjects Research

Decision Tool: Am I Doing Human Subjects Research?

Human Subjects Research Infographic (PDF)

Exempt Human Subjects Research Infographic (PDF)

Research Involving Private Information or Biospecimens Flowchart (PDF)

Public Health Surveillance Exclusions

## Decision Tool: Am I Doing Human Subjects Research?

The Office of Extramural Research (OER) has developed a quick decision tool that should assist you with determining if your research involves human subjects, may be considered exempt from Federal regulations, or is not considered human subjects research. This tool should not be used as the sole determination of exemption.



### Tip

This tool uses the 2018 Revised Common Rule requirements. For more information, please visit [OHRP's page](#)

### Question 1

#### Please check which best describes your research

- For the purpose of this study, at some point there will be an intervention or interaction with subjects for the collection of biospecimens or data (including health or clinical data, surveys, focus groups or observation of behavior). Or identifiable private information or identifiable biospecimens will be obtained, used, studied, analyzed, or generated for the purpose of this study.
- The study will involve only secondary research using data or biospecimens not collected specifically for this study.
- This study will involve only materials/specimens or data from deceased individuals.

<https://grants.nih.gov/policy-and-compliance/policy-topics/human-subjects/hs-decision>



**Institutions engaged  
in NIH conducted or  
supported non-  
exempt human  
subject research  
must**

- Provide **written assurance** that it will comply with the regulatory requirements
  - OHRP-approved Federalwide Assurance (FWA)  
*and*
- Certify to NIH that research was reviewed and approved by an **IRB** and that the research will be subject to continuing review by an IRB

45 CFR 46.103



# Engagement in Human Subjects Research



**In general, institutions are considered engaged in an NIH conducted or supported non-exempt human subjects research project when:**



**The institution's employees or agents obtain, for research purposes:**

data about the human subjects through intervention or interaction;

or

identifiable private information about the subjects  
Informed consent



# Multi-site Study Consideration

In general, Prime recipients of an NIH award (e.g., grant, contract, cooperative agreement) for non-exempt human subjects research are ***considered engaged in the research*** project, even when all activities involving human subjects are carried out by employees or agents of another institution.



All engaged sites must have:

FWA (can be covered under recipient's FWA)

- [Extending a FWA to Cover Collaborating Investigators](#)

IRB Approval

U.S. sites to rely on one IRB under [45 CFR 46.114](#)

- [OHRP Institutional Review Board \(IRB\) Authorization Agreement](#)



# Required Education Protection of Human Subjects

**All key personnel** must have education on the protection of human research participants:

- Individuals responsible for design and conduct of the research
- Also applies to key personnel at performance sites

One-time training

- Also applies to investigators who conduct exempt human subjects research

See NIH Guide Notices

- [NOT-OD-00-039](#) and
- [NOT-OD-11-061](#)



# Just-in-Time Requirements-Human Subjects

## Verify required information received

- Federal-wide Assurance Number (FWA)
- Certification of IRB approval (or exemption)
- Human subjects education for key personnel

## Initiate policy requests (*rare*)

- Exemption 5 (HSS)
- sIRB exception request (email)
- Public Health Surveillance Exclusion (HSS)



# NIH GPS Certification of IRB Approval



Recipients must provide a certification to NIH that all nonexempt research involving human subjects has been reviewed and approved by an appropriate IRB. The date of final IRB approval is the date that all protocols in the proposed research application received IRB review and approval.



NIH requires the date of final IRB approval; Conditional IRB approval is not sufficient.

See the NIH Grants Policy Statement (GPS) 4.1.15.2



## NIH Single IRB Policy

- Multi-site domestic studies where each site will conduct the same protocol involving non-exempt human subjects research must use a single Institutional Review Board
- See Guide Notice [NOT-OD-16-094](#)

## Common Rule Cooperative Research

- Any institution located in the United States that is *engaged* in cooperative research must rely upon approval by a single IRB for that portion of the research that is conducted in the United States
- See HHS Regulations at [45 CFR 46.114\(a\)](#)

Resource: NIH website, [Single IRB for Multi-Site or Cooperative Research](#)



Institutional Review Board (IRB): committee charged with reviewing human subjects research to ***ensure*** that the ***rights*** and ***welfare*** of research participants ***are protected***.

## Initial IRB review

- Convened review
- Expedited review
- Limited review

## Amendments

- Expedited review
- Convened review

## Continuing review

Periodic review (annually or more frequently) of ongoing research, including study progress and if risks and benefits have changed. Evaluates if research still satisfies criteria for approval.

*Not required* for research eligible for expedited or limited IRB review, or for research where all interventions are complete and only accessing follow-up data or performing data analyses..

# Continuing Review Requirements

No NIH requirement for annual review if not required by Common Rule unless otherwise specified in Notice of Funding Opportunity

- Examples: Studies eligible for expedited review, studies that have completed interventions

NOTE: Institutions/IRBs may have additional requirements

See the HHS regulations at 45 CFR 46.109(e)



# Informed Consent Requirements

## – Include Key Information

Concise and focused presentation of key information needed by a “reasonable person” to decide on participation

- 9 basic elements & 9 additional elements
- Obtain written informed consent from participant or legally authorized representative, unless consent waived or documentation of consent waived



# Certificates of Confidentiality (CoC) Policy

**Prohibits** disclosure of names or information, documents, or biospecimens containing identifiable, sensitive information

- To persons not connected to the research
- In any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding (unless with participants' consent)
- For any other purpose, with some exceptions

Deemed issued to all NIH-funded research that collects or uses identifiable, sensitive information as of December 13, 2016

Copies of research protected

Covered information protected in perpetuity

See Guide Notice [NOT-OD-17-109](#)



# NIH Inclusion Policies

- Women and members of racial and ethnic minority groups must be included in all NIH-funded clinical research studies unless there is a compelling rationale for exclusion
- Additional reporting and analysis requirements for NIH-defined phase 3 clinical trials
- Individuals of **all ages** must be included in NIH human subjects research unless there are scientific or ethical reasons not to do so



Policy Notices: [NOT-OD-18-014](#) and  
Policy Notice: [NOT-OD-18-116](#)



# Subaward/Pilot Project Requirements

- **All applicable NIH policies and regulations apply to subawards and pilot projects (e.g., for research involving human subjects, regulations at 45 CFR 46 and NIH Certificate of Confidentiality Policy may apply)**

Obtain IRB approval before involving participants in nonexempt human subjects research activities.

- Note: Single IRB requirements may apply

Prior NIH IC approval may be needed, if research activity was not described in grant application.

- Note: prior approval requests must be submitted at least 30 days before proposed activity occurs

Recipient institution will submit progress reports that include relevant information on pilot projects, subawardee activities



# Post Award Human Subject Activities



## Submit reportable events to the IRB, NIH, and others

Unanticipated problems involving risks to subjects or others

Serious or continuing noncompliance with 45 CFR 46 or the requirements or determinations of the IRB

Suspension or termination of IRB approval



## Reporting adverse events



## Research Performance Progress Reports (RPPR)

Annual, Final, and Interim



## Request prior NIH approval for changes to human subject research activities



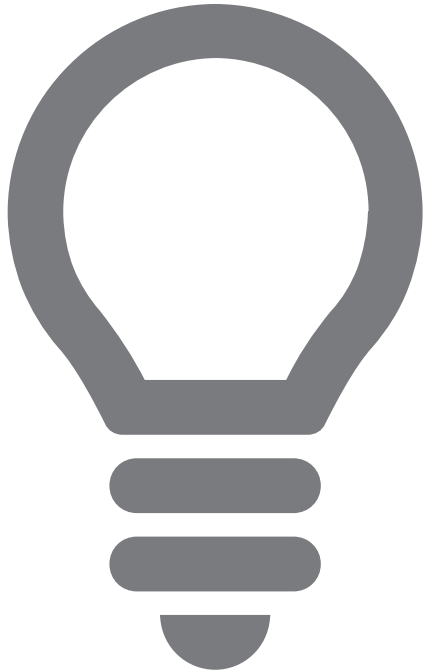
# Prior Approval for Changes in Human Subjects



## Situations That May Require Prior Approval:

- Results in an overall increase in risk level for subjects
  - Human subjects added to project with no human subjects
  - Exempt to non-exempt human subjects research
  - “No Clinical Trial” to “Includes a Clinical Trial”
  - Adding a performance site to a single-site study
- See [NOT-OD-15-128](#) and [NOT-OD-15-129](#) (delayed onset), both published on July 30, 2015

# Resources: Human Subjects Protections



See flyer with QR code, Human Subjects,  
Clinical Trials and Inclusion Resources  
One-Pager

*and*

Human Subjects Research websites

# Human Subjects System (HSS) Troubleshooting

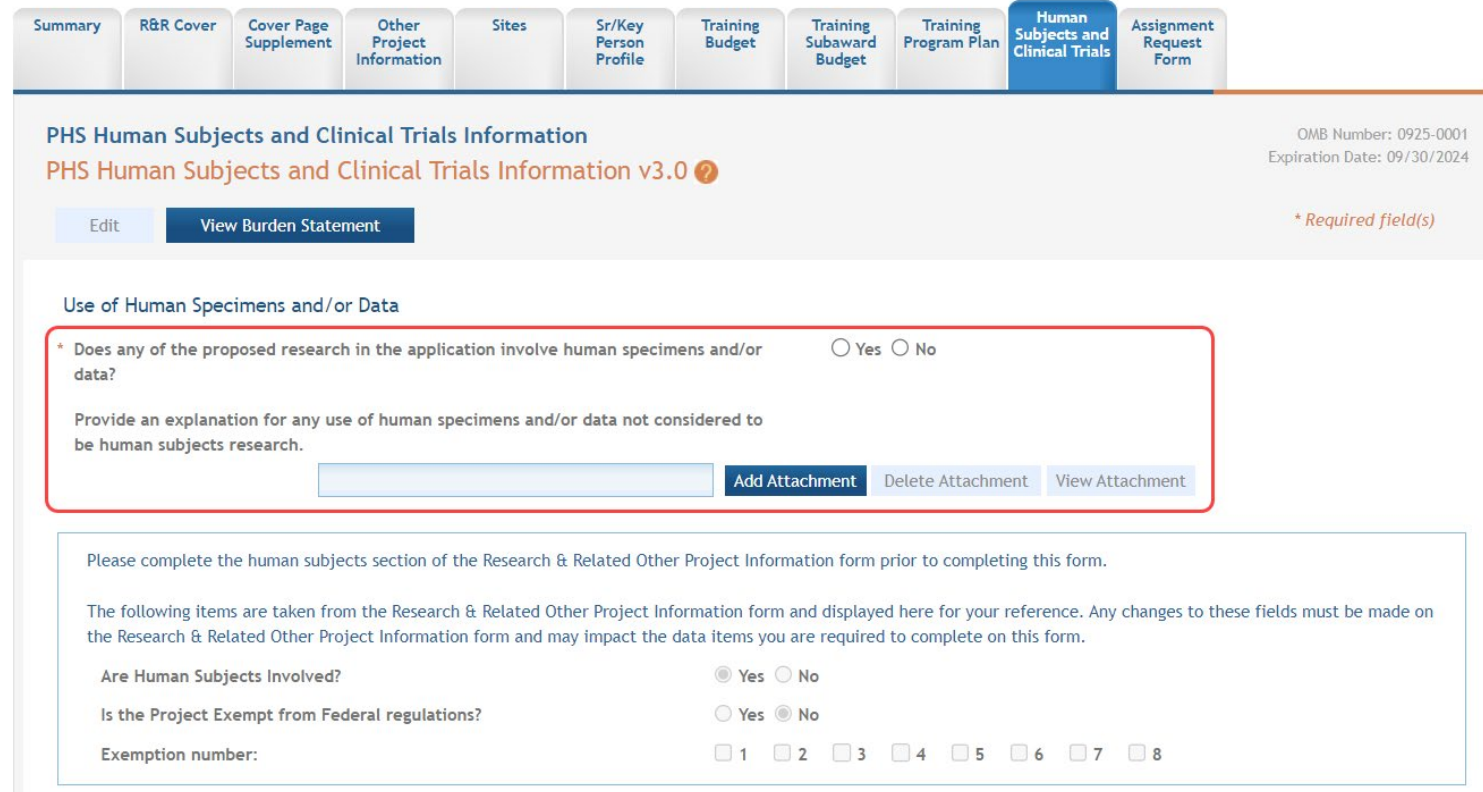
Dawn Corbett, MPH  
NIH Inclusion Policy Officer  
Office of Extramural Research  
National Institutes of Health



National Institutes of Health  
*Office of Extramural Research*


- Application Submission System & Interface for Submission Tracking (ASSIST)
  - Online system to prepare grant applications and forms
- Human Subjects System (HSS)
  - Uses ASSIST interface to allow NIH grant recipients and contract vendors to submit and update study data on human subjects

## Application Information



The screenshot displays the 'Application Information' page with a navigation bar containing tabs for Summary, R&R Cover, Cover Page Supplement, Other Project Information, Sites, Sr/Key Person Profile, Training Budget, Training Subaward Budget, Training Program Plan, Human Subjects and Clinical Trials (selected), and Assignment Request Form. The main content area is titled 'PHS Human Subjects and Clinical Trials Information' and 'PHS Human Subjects and Clinical Trials Information v3.0'. It includes an 'Edit' button and a 'View Burden Statement' button. A red box highlights a required question: '\* Does any of the proposed research in the application involve human specimens and/or data?' with radio buttons for 'Yes' and 'No'. Below this is a text area for an explanation and an 'Add Attachment' button. At the bottom, there are instructions and a list of exemption numbers (1-8) with radio buttons.

Summary R&R Cover Cover Page Supplement Other Project Information Sites Sr/Key Person Profile Training Budget Training Subaward Budget Training Program Plan **Human Subjects and Clinical Trials** Assignment Request Form

PHS Human Subjects and Clinical Trials Information  
PHS Human Subjects and Clinical Trials Information v3.0 

OMB Number: 0925-0001  
Expiration Date: 09/30/2024

\* Required field(s)

Edit View Burden Statement

Use of Human Specimens and/or Data

\* Does any of the proposed research in the application involve human specimens and/or data?  Yes  No

Provide an explanation for any use of human specimens and/or data not considered to be human subjects research.

Add Attachment Delete Attachment View Attachment

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.

The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?  Yes  No

Is the Project Exempt from Federal regulations?  Yes  No

Exemption number:  1  2  3  4  5  6  7  8

# Who Uses HSS/ASSIST?

	Principal Investigator	Signing Official (SO)
View study records	X	X
Receive notifications		X
Edit fields	X	X
Initiate study record submission	X	X
Submit study record	X (if delegated by SO)	X





# What Information is Entered in HSS/ASSIST?

1. Basic Information
2. Study Population Characteristics
3. Protection and Monitoring Plans
4. Protocol Synopsis (**CT only**)
5. Other Clinical Trial-related Attachments (**CT only**)
6. Clinical Trial Milestones (**post-submission CT only**)

**PHS Human Subjects and Clinical Trials Information**  
OMB Number: 0925-0001  
Expiration Date: 03/01/2020

Please complete the human subjects section of the Research & Related Other Project Information form prior to completing this form.  
The following items are taken from the Research & Related Other Project Information form and displayed here for your reference. Any changes to these fields must be made on the Research & Related Other Project Information form and may impact the data items you are required to complete on this form.

Are Human Subjects Involved?  Yes  No  
Is the Project Exempt from Federal regulations?  Yes  No  
Exemption number:  1  2  3  4  5  6  7  8

**If No to Human Subjects**  
Does the proposed research involve human specimens and/or data?  Yes  No  
If Yes, provide an explanation of why the application does not involve human subjects research.  
Skip the rest of the PHS Human Subjects and Clinical Trials Information Form.

**If Yes to Human Subjects**  
Add a record for each proposed Human Subject Study by selecting 'Add New Study' or 'Add New Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects research.

**Other Requested Information**  
Click here to extract the Human Subject Study Record Attachments

**Study Record(s)**  
Attach human subject study records using unique filenames.

**Delayed Onset Study(ies)**

Study Title	Anticipated Clinical Trial?	Justification
	<input type="checkbox"/>	

**Study Record: PHS Human Subjects and Clinical Trials Information**  
OMB Number: 0925-0001  
Expiration Date: 09/30/2024

\* Always required field

**Section 1 - Basic Information**

1.1. \* Study Title (each study title must be unique)

1.2. \* Is this Study Exempt from Federal Regulations?  Yes  No

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

1.4. \* Clinical Trial Questionnaire  
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

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87664321) for this trial, if applicable

See the [Application Guide](#) for detailed instructions



# Section 1: Basic Information

For trials, select "Yes" to all 4 questions

Answer drives validations for:

- NOFOs to which the application may be submitted
  - ✓ Clinical Trial Required
  - ✓ Clinical Trial Not Allowed
  - ✓ Clinical Trial Optional
- Required/accessible sections of the form:
  - NCT
  - Data and Safety Monitoring Plan
  - Sections 4, 5, & 6

PHS Human Subjects and Clinical Trials Information - Study Record 1  
PHS Human Subjects and Clinical Trials Information v2.0 ?

OMB Number: 0925-0001  
Expiration Date: 02/28/2023

Edit  Expand All \* Required field(s)

**SECTION 1 - BASIC INFORMATION**

\* 1.1. Study Title (each study title must be unique)

\* 1.2. Is this Study Exempt from Federal Regulations?  Yes  No

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

\* 1.4. Clinical Trial Questionnaire  
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

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable  
Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.



# Section 2: Study Population Characteristics

2.1. Conditions or Focus of Study

Condition 1 Action Delete

[Add New Condition](#)

2.2. Eligibility Criteria

Eligibility Criteria

Characters Remaining: 14980

2.3. Age Limits

Minimum Age  N/A (No limit)  Maximum Age  N/A (No limit)

2.4. Inclusion of Women, Minorities, and Children

[InclOfChildren\\_\(5\).pdf](#) Replace Attachment Delete Attachment View Attachment

2.5. Recruitment and Retention Plan

[RecruitmentRetention\\_\(5\).pdf](#) Replace Attachment Delete Attachment View Attachment

2.6. Recruitment Status

2.7. Study Timeline

[StudyTimeline\\_\(5\).pdf](#) Replace Attachment Delete Attachment View Attachment

**Inclusion Enrollment Report(s)**

[Add New Inclusion Enrollment Report](#)

Entry #	Enrollment Location Type	Enrollment Location	Action
278370	Domestic		<span>Edit</span> <span>View</span>

Inclusion Enrollment Report 2 v1.0 ? OMB Number: 0925-0770 Expiration Date: 09/30/2024

[Edit](#)

\* 1. Inclusion Enrollment Report Title

Characters Remaining: 590

\* 2. Using an Existing Dataset or Resource  Yes  No

\* 3. Enrollment Location Type  Domestic  Foreign

4. Enrollment Country(ies)

5. Enrollment Location(s)

Characters Remaining: 255

6. Comments

Characters Remaining: 500

Planned

Racial Categories	Ethnic Categories				Total
	Not Hispanic or Latino		Hispanic or Latino		
	Female	Male	Female	Male	
American Indian/Alaska Native	<input type="text" value="3"/>	<input type="text" value="3"/>	<input type="text" value="2"/>	<input type="text" value="2"/>	10
Asian	<input type="text" value="20"/>	<input type="text" value="20"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	42
Native Hawaiian or Other Pacific Islander	<input type="text" value="5"/>	<input type="text" value="5"/>	<input type="text" value="1"/>	<input type="text" value="1"/>	12
Black or African American	<input type="text" value="20"/>	<input type="text" value="20"/>	<input type="text" value="10"/>	<input type="text" value="10"/>	60
White	<input type="text" value="20"/>	<input type="text" value="20"/>	<input type="text" value="20"/>	<input type="text" value="20"/>	80
More than One Race	<input type="text" value="10"/>	<input type="text" value="10"/>	<input type="text" value="10"/>	<input type="text" value="10"/>	40
<b>Total</b>	<b>78</b>	<b>78</b>	<b>44</b>	<b>44</b>	<b>244</b>



# Section 3: Protection and Monitoring Plans

## SECTION 3 - PROTECTION AND MONITORING PLANS

All HS

3.1. Protection of Human Subjects

Add Attachment

Delete Attachment

View Attachment

All 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

Single IRB plan attachment

Add Attachment

Delete Attachment

View Attachment

Not required

CT only

3.3. Data and Safety Monitoring Plan

Add Attachment

Delete Attachment

View Attachment

CT only

3.4. Will a Data and Safety Monitoring Board be appointed for this study?

Yes  No

Optional

3.5. Overall Structure of the Study Team

Add Attachment

Delete Attachment

View Attachment



# Section 4: Protocol Synopsis

## SECTION 4 - PROTOCOL SYNOPSIS

### 4.1. Study Design

CT.gov

4.1.a. Detailed Description

Enter up to 32000 Characters

Characters Remaining: 32000

CT.gov

4.1.b. Primary Purpose

Dropdown menu

### 4.1.c. Interventions

CT.gov

Intervention Type	Name	Description	Action
Nothing found to display			

Add New Intervention

CT.gov

4.1.d. Study Phase

Dropdown menu

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

CT.gov

4.1.e. Intervention Model

Dropdown menu

This field does not map to Clinicaltrials.gov

CT.gov

4.1.f. Masking

Yes  No

Participant  Care Provider  Investigator  Outcomes Assessor

CT.gov

4.1.g. Allocation

Dropdown menu

CT.gov Maps to ClinicalTrials.gov



## For all study types

### Section 2

- Inclusion enrollment
- Recruitment status

### If applicable:

- Convert delayed onset study
- Additional information requested by NIH program officer

## For clinical trials

### Section 1

- NCT (Clinicaltrials.gov ID)

### Section 6

- Clinical trial milestones
  - Enrollment of First Participant Date
  - Study Completion Date
  - 25% Enrollment Date, etc.

# Editing a study record

Home > Search for Applications > Application Information

Actions ?

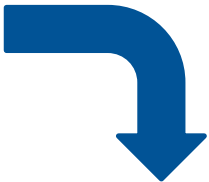
VALIDATE  
VIEW STATUS HISTORY  
UPDATE SUBMISSION STATUS

Application Information ?

Summary HSCCT Post Submission

Application Information

Grant Number: R01HG123456  
Application Identifier: 99999 (Post Award Action)  
Application Project Title: Design and analysis of human gene mapping studies  
PD/PI Name:  
Organization:  
Project Period:  
Status:  
Status Date:



Summary HSCCT Post Submission

Post Submission Summary > Study Record: 1

Clinical Trial Post Submission - Study Record 1 OMB Number: 0925-0001 and 0925-0002  
Clinical Trial Post Submission v1.0 ? Expiration Date: 03/31/2020

Edit Expand All \* Required field(s)

SECTION 1 - BASIC INFORMATION

Summary HSCCT Post Submission

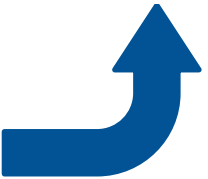
Clinical Trial Post Submission  
Clinical Trial Post Submission v1.0 ?

Edit

Study Record(s)

Showing 1 - 1 of total 1

Study ID	Study Title	Clinical Trial?	Study Status	Last Submission Date	Action
123456	Differentiation Therapy for GNAQ Mutated Uveal Melanoma	Yes	ReceivedByAgency	02/14/2019	View Export XML



See also *How Do I Edit Studies?* in the [HSS Online Help](#)



# Inclusion Enrollment Report

	A	B	C	D	E
1	Race	Ethnicity	Sex	Age	Age Unit
2	Asian	Not Hispanic or Latino	Male	23	Years
3	White	Hispanic or Latino	Female	6	Months
4	Unknown	Unknown	Unknown	15	Days
5	More than one race	Not Hispanic or Latino	Male	30	Years
6	American Indian	Not Hispanic or Latino	Male	10	Years
7	Black	Not Hispanic or Latino	Female	15	Years
8	Hawaiian	Not Hispanic or Latino	Male		Unknown
9	Unknown	Unknown	Female		Ninety Plus

**Need Help ?**

Participant level data file (CSV):



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	0	0	0	0	1	0	0	0	0	1
Asian	131	189	0	0	0	0	0	0	0	320
Native Hawaiian or Other Pacific Islander	32	36	0	0	0	0	0	0	0	68
Black or African American	103	92	3	0	0	0	0	0	0	198
White	24	23	0	7	1	0	0	0	0	55
More than One Race	21	12	0	5	4	0	0	0	0	42
Unknown or Not Reported	5	3	0	1	1	0	0	0	0	10
<b>Total</b>	<b>316</b>	<b>355</b>	<b>3</b>	<b>13</b>	<b>7</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>694</b>

Age Enrollment Report

Age Categories	0-1	2-5	6-12	13-17	18-25	26-45	46-64	65-75	76+	Unknown/Not Reported	Total
Total	54	53	41	20	191	102	119	95	7	12	694

Note: Less than 5 participants will not appear in any Age Enrollment Report category except within the Total.



Once an NCT is entered, the Populate button can be used to update HSS fields that map to ClinicalTrials.gov

**SECTION 1 - BASIC INFORMATION**

\* 1.1. Study Title (each study title must be unique)

\* 1.2. Is this Study Exempt from Federal Regulations?  Yes  No

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

\* 1.4. Clinical Trial Questionnaire  
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

1.5. Provide the ClinicalTrials.gov Identifier (e.g., NCT87654321) for this trial, if applicable  
Click the Populate button to retrieve data from ClinicalTrials.gov registration once Identifier is entered.

←

# Populated Fields


<b>HSS Fields</b>	<b>Clinicaltrials.gov Fields</b>
Study Title	Brief Title
Conditions or Focus of Study	Primary Disease or Condition Being Studied in the Trial, or the Focus of the Study
Eligibility Criteria	Eligibility Criteria
Age Limits	Age Limits
Recruitment Status	Overall Recruitment Status
Narrative Study Description	Detailed Description
Primary Purpose	Primary Purpose
Study Phase	Study Phase
Interventions	Interventions, including Intervention Type and Intervention Name(s)
Intervention Model	Interventional Study Model
Masking	Masking
Allocation	Allocation
Outcome Measures	Primary Outcome Measure Information
Study Primary Completion Date	Primary Completion Date
Study Final Completion Date	Study Completion Date
Enrollment of the first participant	Study Start Date
Reporting of results in ClinicalTrials.gov	Results First Submitted




# Section 6: Update Clinical Trial Milestones


Summary **HST Post Submission**


SECTION 6 - Clinical Trial Milestone Plan


6.1. Study Primary Completion Date    Anticipated  Actual


6.2. Study Final Completion Date    Anticipated  Actual


6.3. Enrollment and randomization


Enrollment of the first participant (Study Start Date)    Anticipated  Actual


25% of planned enrollment recruited by    Anticipated  Actual

50% of planned enrollment recruited by    Anticipated  Actual

75% of planned enrollment recruited by    Anticipated  Actual

100% of planned enrollment recruited by    Anticipated  Actual

6.4. Completion of primary endpoint data analyses    Anticipated  Actual

6.5. Reporting of results in ClinicalTrials.gov    Anticipated  Actual

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

- Update dates to “actual” when milestones are met
- Enrollment of First Participant and Study Primary Completion date are locked once set to “actual”
  - Can still be refreshed directly from Clinicaltrials.gov if registered
  - NIH program officer must contact [inclusion@mail.nih.gov](mailto:inclusion@mail.nih.gov) for assistance when needed



# HSS/ASSIST and Clinicaltrials.gov Match Checks

<b>Clinicaltrials.gov Fields</b>	<b>HSS Fields</b>	<b>HSCT Form Section</b>
Age Limits	Age Limits	Section 2
Overall Recruitment Status	Recruitment Status	Section 2
Primary Purpose	Primary Purpose	Section 4
Study Phase	Study Phase	Section 4
Masking	Masking	Section 4
Allocation	Allocation	Section 4
Primary Completion Date	Study Primary Completion Date	Section 6
Study Completion Date	Study Final Completion Date	Section 6
Study Start Date	Enrollment of the First Participant	Section 6
Results First Submitted	Reporting of Results in ClinicalTrials.gov	Section 6

TIP: It's typically easiest to have separate study record for trial and non-trial activities  
(e.g. 1 Clinicaltrials.gov record = 1 HSS/ASSIST Study Record)



# Common HSS warnings and errors

Warning or error	Have you...?
No participant-level data and falls under Inclusion Across the Lifespan Policy	... <b>submitted</b> individual-level inclusion data?
Enrollment of 1st participant is more than 21 days ago and <b>no NCT has been provided</b>	... <b>registered</b> in Clinicaltrials.gov?
Primary completion date is more than 12 months ago and <b>no results have been provided</b>	... <b>reported results</b> in Clinicaltrials.gov?
<b>Information does not match</b> the information in Clinicaltrials.gov	...refreshed data from Clinicaltrials.gov using the " <b>Populate</b> " feature?

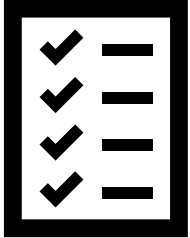
TIP: Update Clinicaltrials.gov first, then use the "Populate" feature to refresh the data in HSS/ASSIST



## Human Subjects System (HSS) Quick Guide for Warnings and Errors

This guide describes some of the warnings and errors commonly encountered by users in the Human Subjects System, or HSS. The guide provides instructions on how to resolve the warnings and errors, and general tips on getting information updated and submitted.





Before submitting:

- Resolve all warnings and errors
  - “Validate” feature can be used to check prior to submission
  - Read the warnings and errors in the RPPR Module and in HSS: they often mention what the problem is
- Make sure you have submitted updated cumulative individual-level participant data if you have enrolled participants
- Change status from *Work in Progress* to *Ready for Submission*

**Warnings and errors remain for NIH staff and may delay award!**

Submit HSS data **prior to** submitting RPPR



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ASSIST Login

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## eRA Training - Human Subjects System (HSS)

### Video Tutorials



- [Overview video of the Human Subjects System \(See transcript\)](#) -- 7:30 minutes; April 30, 2018
- [How to Export Study Records \(See transcript\)](#) -- 5:53 minutes; March 4, 2019

### Resources



- [HSS: Quick Guide for Warnings and Errors](#) -- PDF; May 10, 2023
- [Participant-level Data Template](#) -- CSV; February 7, 2025
- [Tip Sheet: Using the Participant-level Data Template](#) -- PDF; January 20, 2022
- [Infographic of the HSS process \(for principal investigators and signing officials\)](#) -- PowerPoint; May 21, 2018

