Human Subjects Research

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NIEHS

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Topics

- Basic Definitions
- Human Subjects Study Record and Inclusion Enrollment Reports
- Monitoring Human Subjects Inclusion
- ASSIST and the Human Subjects System
- Case Studies
- Resources

Basic Definitions

Definition of Human Subject (HS) 45 CFR 46 102(f)

Human subject: a living individual about whom an investigator conducting research

1. Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens

What Does Exempt Research Mean?

- Exempt research is no more than minimal risk and falls within any of the 8 categories identified under the Revised Common Rule.
- Doesn't require full or continuing IRB review
- Exemption determinations should be made by someone other than the PI – preferably IRB
- Exemption ≠ no Study Records/Inclusion Enrollment Reports (IERs) required – All Exemptions require Study Records/IERs EXCEPT #4

Clinical Trial

A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Basic Experimental Studies Involving Humans (BESH) use an intervention to understand fundamental aspects of a phenomena without specific application towards processes or products in mind. These studies are subject to NIH stewardship policies including Good Clinical Practice Training and the NIH Policy on Dissemination of NIH-Funded Clinical Trial Information. See here for more information.

Human Subject Study Record and Inclusion Enrollment Reports

Study Record

- Created as part of new Human Subjects System
- Consolidates most human subjects information into one location.
- Includes four questions that determine whether a study is a clinical trial.

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

RESEARCH & RELATED Other Project Information

OMB Number: 4040-0001
Expiration Date: 12/31/2022

1. Are Human Subjects Involved? ☐ Yes ☐ No

1.a. If YES to Human Subjects

Is the Project Exempt from Federal regulations? ☐ Yes ☐ No

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

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

IRB Approval Date: _____

Human Subject Assurance Number: _____

2. Are Vertebrate Animals Used? ☐ Yes ☐ No

2.a. If YES to Vertebrate Animals

Is the IACUC review Pending? ☐ Yes ☐ No

IACUC Approval Date: _____

Animal Welfare Assurance Number: _____

3. Is proprietary/privileged information included in the application? ☐ Yes ☐ No

4.a. Does this Project Have an Actual or Potential Impact - positive or negative - on the environment? ☐ Yes ☐ No

4.b. If yes, please explain: _____

4.c. If this project has an actual or potential impact on the environment, has an exemption been authorized or an environmental assessment (EA) or environmental impact statement (EIS) been performed? ☐ Yes ☐ No

4.d. If yes, please explain: _____

5. Is the research performance site designated, or eligible to be designated, as a historic place? ☐ Yes ☐ No

5.a. If yes, please explain: _____

6. Does this project involve activities outside of the United States or partnerships with international collaborators? ☐ Yes ☐ No

6.a. If yes, identify countries: _____

6.b. Optional Explanation: _____

7. Project Summary/Abstract		Add Attachment	Delete Attachment	View Attachment
8. Project Narrative		Add Attachment	Delete Attachment	View Attachment
9. Bibliography & References Cited		Add Attachment	Delete Attachment	View Attachment
10. Facilities & Other Resources		Add Attachment	Delete Attachment	View Attachment
11. Equipment		Add Attachment	Delete Attachment	View Attachment
12. Other Attachments	Add Attachments	Delete Attachments	View Attachments	☐

PHS Human Subjects and Clinical Trials Information

View Burden Statement

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

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

If No to Human Subjects

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 Study' as appropriate. Delayed onset studies are those for which there is no well-defined plan for human subject involvement at the time of submission, per agency policies on Delayed Onset Studies. For delayed onset studies, you will provide the study name and a justification for omission of human subjects study information.

Other Requested Information

Add Attachment | Delete Attachment | View Attachment

Click here to extract the Human Subject Study Record Attachment

Study Record(s)

Attach human subject study records using unique filenames.

x 1) Please attach Human Subject Study 1 | Add Attachment | Delete Attachment | View Attachment

Add New Study

Delayed Onset Study(ies)

	Study Title	Anticipated Clinical Trial?	Justification
x		☐	Add Attachment | Delete Attachment | View Attachment

Add New Delayed Onset Study

Justification should include :

1) Not collected for your research – Identify source of materials;
2) No investigator has ID or access to key code

All exempt studies must include the study record except Exemption 4

If required by FOA

Delayed Onset versus Delayed Start

- Delayed Onset
  - A human study is planned but cannot be described
    - Example: Plan a human study based on mechanistic research to be conducted in mice in first two years of the grant; needs the mechanistic data before study can be developed
- Delayed Start
  - A human study is planned and can be described but it will begin later in the project period
    - Example: PI plans a study using sensors to collect biological and exposure data in 200 children, 100 living in rural versus 100 in living in urban environments; needs to develop the sensor first
  - Requires full HS Study Record/IERs

Delayed Onset

On the PHS Human Subjects and Clinical Trials Information Form

- Check Delayed Onset Box
- Include One Study with Study Title
- Include Delayed Onset Justification Attachment

- Once study finalized, and before the project begins:
  - Submit study description, including the study record information, to your Program Officer (PO) for review and approval. Once approved:
    - Convert delayed onset to full Study Record in HSS
    - Complete Sections 1 - 3 of the HSCT study record (including IERs)
      - If Clinical Trial, also complete section 4
  - Submit completed Study Record through Signing Official
  - Submit IRB approval to GMS through Signing Official

Human Subjects Study Record – Section 1

Study Record: PHS Human Subjects and Clinical Trials Information

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

* 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

Automatically checked Yes, if Yes for HS in R&R Other Project Info

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

Not required at time of submission unless enrollment has started

ClinicalTrials.gov NCT Number

- ClinicalTrials.gov registration
  - within 21 days of enrollment of first participant for ALL CTs
  - Exception: BESH trials have until September 24, 2021
- For NIH defined clinical trial, must include dissemination plan in (Section 4.7)
  - Do not restate policy; Identify how you will comply with rules:
    - ✓Register in clinicaltrials.gov
    - ✓Report results in clinicaltrials.gov
    - ✓Post copy of one consent form

Human Subjects Study Record – Section 2

Section 2 - Study Population Characteristics

2.1. Conditions or Focus of Study

Add New Condition

2.2. Eligibility Criteria

2.3. Age Limits **Minimum Age** **Maximum Age**

2.3.a. Inclusion of Individuals Across the Lifespan Add Attachment | Delete Attachment | View Attachment

2.4. Inclusion of Women and Minorities Add Attachment | Delete Attachment | View Attachment

2.5. Recruitment and Retention Plan Add Attachment | Delete Attachment | View Attachment

2.6. Recruitment Status

2.7. Study Timeline Add Attachment | Delete Attachment | View Attachment

2.8. Enrollment of First Participant

2.9. Inclusion Enrollment Report(s)

Add Inclusion Enrollment Report

Human Subjects Study Record – Section 3

Section 3 - Protection and Monitoring Plans

3.1. Protection of Human Subjects | Add Attachment | Delete Attachment | View Attachment

3.2. Is this a multi-site study that will use the same protocol to conduct non-exempt human subjects research at more than one domestic site?

☐ Yes ☐ No ☐ N/A

If yes, describe the single IRB plan | Add Attachment | Delete Attachment | View Attachment

3.3. Data and Safety Monitoring Plan | Add Attachment | Delete Attachment | View Attachment

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

☐ Yes ☐ No

3.5. Overall Structure of the Study Team | Add Attachment | Delete Attachment | View Attachment

Using the Human Subjects and Clinical Trial (HSCT) Form

Form Section	If answered "No" to <u>any</u> questions in Clinical Trial Questionnaire	If answered "Yes" to <u>all</u> questions in Clinical Trial Questionnaire
Section 1 Basic Information	Required	Required
Section 2 Study Population Characteristics	Required; some fields optional if exemption 4	Required
Section 3 Protection and Monitoring Plans	Some fields required; some fields optional	Required
Section 4 Protocol Synopsis	Not permitted	Required
Section 5 Other Clinical Trial-related Attachments	Not permitted	Required *only* if specified in FOA

Inclusion Enrollment Reports (IERs)

IERs are part of the process used by staff to monitor inclusion. Data may be collected using any culturally appropriate terms for the study population – must be able to report using NIH categories

- Gender
- Ethnicity/Race
  - Identify Ethnicity first
  - Identify Race
- Age (Inclusion Across the Lifespan)
  - Child – under age 18
  - Adult – age 18-65
  - Older Adult – age 65 and over

For receipt dates beginning January 25, 2019, all applications with human subjects need to address inclusion across the lifespan

Planned versus Cumulative

- New Enrollment (or Re-enrolling to collect new data) (Existing attribute = No)
  - Planned included in the application
    - Planned should never change*
  - Cumulative – how many total enrolled, submitted with RPPR
    - Cumulative should never decrease
- Existing dataset/resource = Yes
  - Cumulative – if have demographic information for all data/samples to be used during study
  - Planned - if data/samples aren't in hand
    - Cumulative added in RPPR as obtain the data/samples

*If budget cuts necessitate a change to planned, revise pre-award; document in PI comments
*If change in study that requires changes to planned, talk to PO; preference is to document change in comments – not revise the original planned numbers
*Revisions may be made for honest mistakes; document in PI comments

Foreign versus Domestic

- If a study includes both foreign and domestic participants, MUST report on separate IERs; use attribute to identify country
- If a study includes participants from more than one country, prefer separate IER for each and use the attribute to identify the country* in each IER.

*This allows us to identify what studies/# subjects are involved in a specific country

Monitoring Inclusion

Why do we monitor inclusion of human subjects?

- Required by Congress
- NIH Policy
  - Fiscal Accountability
    - Assuring NIH funds are being spent appropriately in accordance with research plan; Is PI on track to complete study in the time planned and within budget?
  - Ethical Responsibility
    - If enrollment ≥ 10% over planned, required to obtain justification for “over-enrollment”
    - Has PI enrolled from underrepresented populations as planned?
      - Lupus – occurs 6x more in women than men; black women affected 2x more than white. If PI is only recruiting white women, PO needs to contact the PI for a remediation plan. Money isn’t a factor in recruitment.

Monitoring Plans

- Goal is to set up plan so PO can see the status of study progress
  - All subjects need to be counted.
  - If there is a subproject that will pull out a subset of people for a unique aim, that is generally pulled out separately.

How to set up IERs for NIEHS

- New Study (Enrolling Participants)
  - If single population, example all adults – one IER
  - If adults and children – separate IERs for each generation/population
    - Studies that include children/parents/grandparents (3 IERs – one for each generation)
    - Studies that include children/parent/teachers (3 IERs – one for each group)
- Existing data
  - Generally report a dataset as one group
  - If desired by Program Officer, populations can be split out
  - If using multiple datasets, include each dataset in its own IER

How to Avoid Requests for Clarification/Revision

- Attributes should be consistent with recruitment status
- If enrolling subjects, existing attribute is No
- To avoid confusion, match tenses to recruitment status
- Numbers should be same between verbiage and IERs
- In IERs, include only people who will be enrolled, or whose data will be included, in the study.
- If change planned, document in PI comments
- Subjects are reported enrolled once – not every follow-up visit
- Enter actual enrollment in the existing IER instead of a new one.
- For delayed onset studies, convert to a full study record

Common Errors

- Missing Data
- Conflicting data
  - Existing - Yes, but study is enrolling
  - Existing – No, but only cumulative report is completed
- Inappropriately combining data
  - Including existing and enrolling in same IER
  - Including domestic and foreign participants in same IER
- Not all subjects were reported on the planned or cumulative IERs
  - Study enrolls parent/child pairs, but only mothers included
  - Study includes children, but mothers data will be used in analyses
- Age range doesn't include all subjects in the study – include minimum and maximum
  - Study includes children and adults (minimum 3 - maximum 65)

Pilot or Other Center Projects - Prior Approval Required (Proposed Process)

For projects that are designated human subjects research, before work can begin submit the following information to the Core Center Program Officer, for approval:

1. Description of the Project including the investigators on the study
2. Human Subjects and Clinical Trials Study Record(s) including the Planned/Cumulative Inclusion Enrollment Reports (IERs) (for all studies except Exemption 4)
3. Certification of IRB review and approval

Changes

- With the new Forms F, an IER title field has been added
  - IER titles should be different from the study title
  - If there are multiple IERs on a study, each title will need to be different
    - Suggestions
      - Keep titles short
      - Create a base title – add the population or unique feature to the base title
        - Effect of phthalates on children – mothers
        - Effect of phthalates on children– child;
        - Effects of phthalates on children – MRI child subset

ASSIST and the NIH Human Subjects System

ASSIST - What is it?

ASSIST is the tool through which data is entered into the NIH Human Subjects System

Who Uses ASSIST?

- Principal Investigator (PI)
  - Create or edit study records
  - Delete IERs (can only be done by PI or delegate)
  - If designated by their organization, submit study records
- Signing Official (SO)
  - Submit study records
  - In some institutions, SO may create or edit study records
- NIH Staff
  - To change responses to the exemptions and/or the Clinical Trial questionnaire
  - To determine status of the study record(s) when PI can't edit

Accessing the Human Subjects System

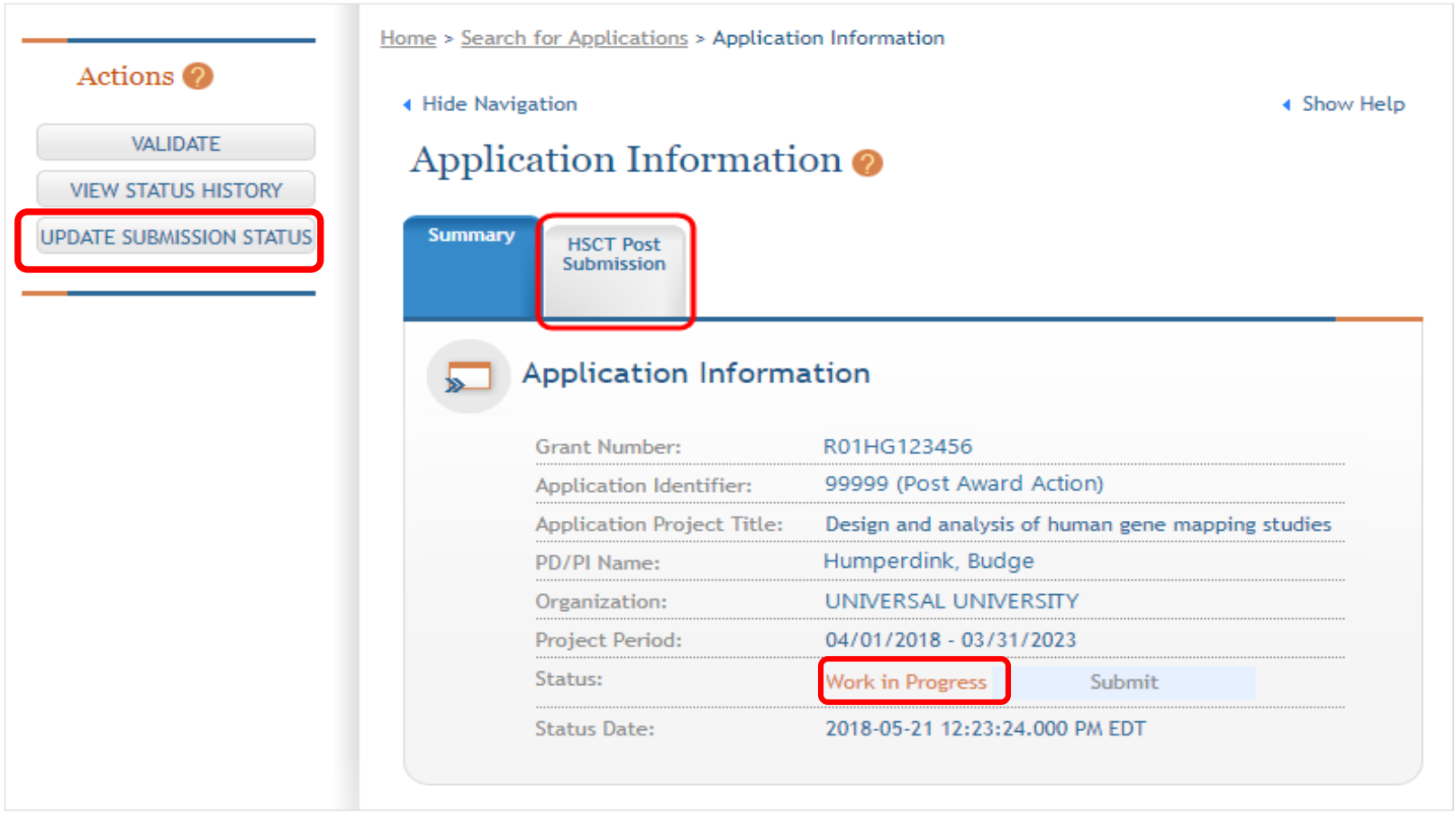
- SO: Status tab > General Search screen > Specific Award >Action column > Human Subjects Link*

- PI: Status tab > Status — PI Search screen > Status Result — List of Applications/Awards screen > Specific Award >Action column > Human Subjects Link*

- Both: RPPR tab > Manage RPPR > Specific Grant > RPPR Menu screen > Edit button > Inclusion Section (G.4.b) > Human Subjects Link*

*Clicking on Human Subjects Link takes you to ASSIST

HSCT Post Submission



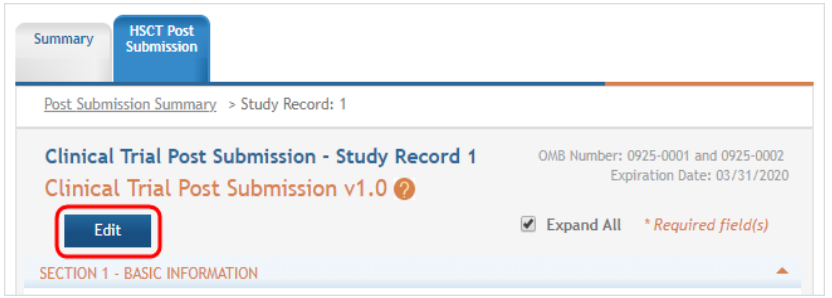
The Status must be in **Work in Progress** to EDIT. Use **Update Submission Status** in the Actions panel to change to Work in Progress. **Then** click on HSCT Post Submission tab to bring up the list of study records associated with the grant.

Editing Existing Studies

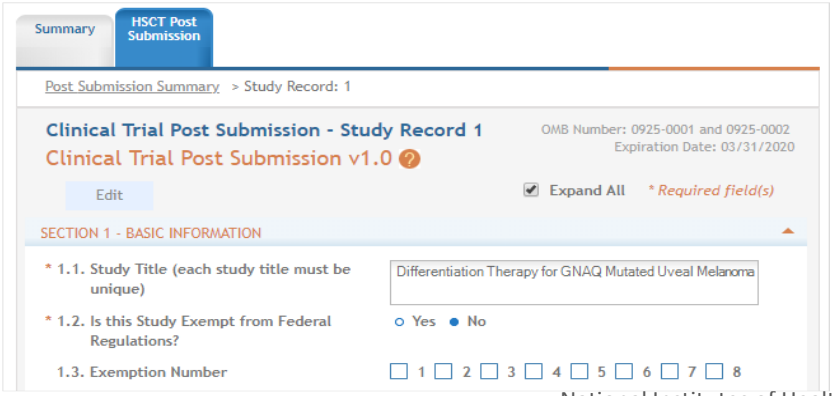
Clicking on HSCT Post Submission brings up a list of existing studies on that grant.

- Click on View for study you want to edit

- Then, Click on Edit button

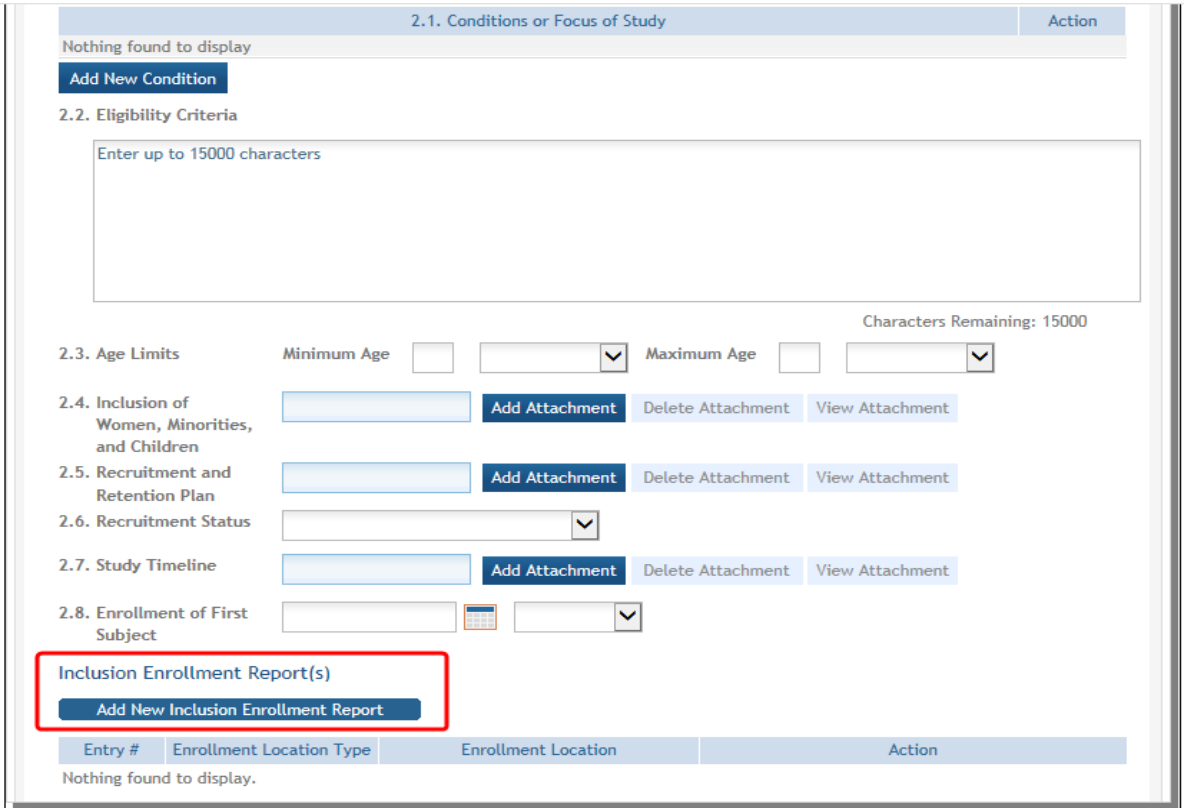


- Study Record Opened and Editable



Add Inclusion Enrollment Record

- If you need to add a new population to the existing study, Add a New IER Button is available in Section 2.9 (up to 20 IERs may be added per study)



Where to Add Study Records

For Core Centers, study records should be added only on:

- Community Engagement Core (CEC)
- Pilot Projects
- Facility Cores with specific set-aside funds for Center-initiated studies (must describe in the application to be able to enter studies on this record)

ALL other Human Subject inclusion is reported on the grant that funds the study, NOT in the Facility Cores

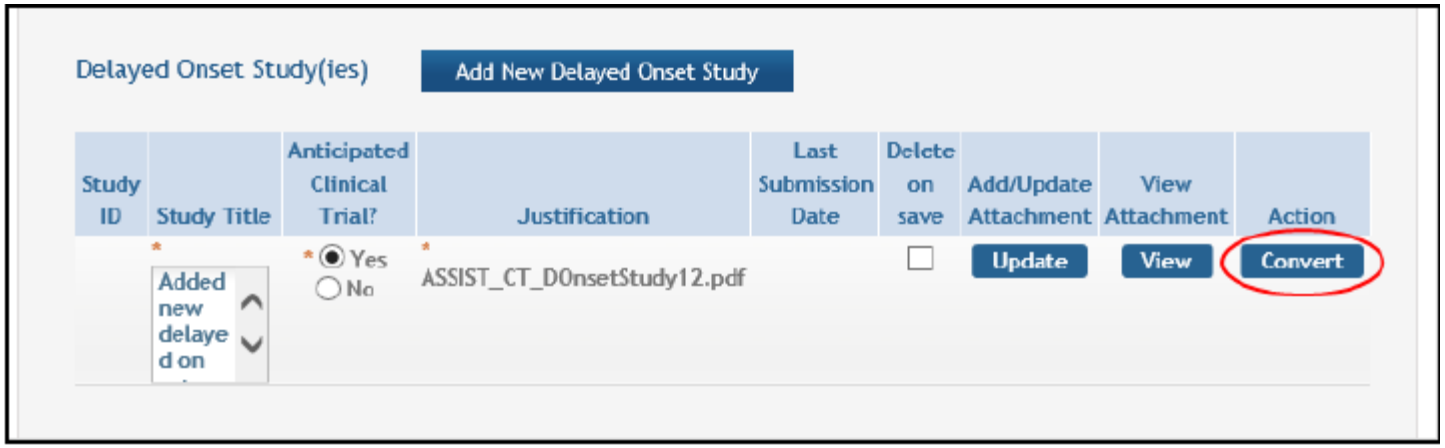
When entering study records, add directly onto the subproject NOT under main grant.

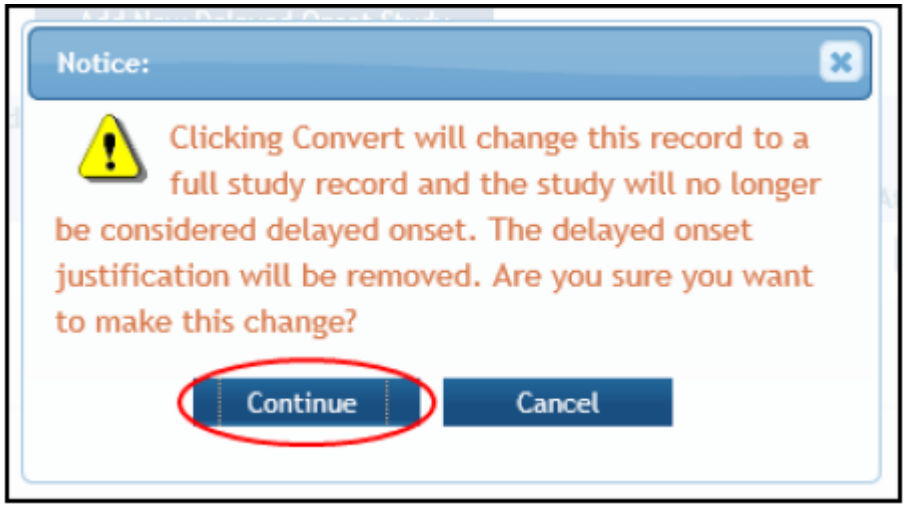
Where to Correctly Add Study Records

View Options: Hide All Subprojects | Show Subprojects with IDRs Only

Project Details	Flag	IDR#	IDR IC ID	IDR Status	Planned Last Update Date/ID	Actuals Last Update Date/ID	Actions
2P30ES005605-27 **PI Name:** Thorne, Peter S **Project Title:** Environmental Health Sciences Research Center	No Inclusion Data Records						
2P30ES005605-27/Admin-Core-001 **PI Name:** Thorne, Peter S **Subproject Project Title:** Administrative Core	No Inclusion Data Records						
2P30ES005605-27/Core-001 **PI Name:** COMELLAS, ALEJANDRO Pierre **Subproject Project Title:** Integrative Health Sciences Facility Core	No Inclusion Data Records						
2P30ES005605-27/Core-002 **PI Name:** O'SHAUGHNESSY, PATRICK T **Subproject Project Title:** Environmental Modeling and Exposure Assessmen...More	No Inclusion Data Records						
2P30ES005605-27/Core-003 **PI Name:** Thorne, Peter S **Subproject Project Title:** Pulmonary Toxicology Facility Core	No Inclusion Data Records						
2P30ES005605-27/Core-004 **PI Name:** Parker, Edith A **Subproject Project Title:** Community Outreach and Engagement Core	No Inclusion Data Records						
2P30ES005605-27/Pilot-Proj-Program--001 **PI Name:** Peters, Thomas Michael **Subproject Project Title:** Pilot Grant Program	P	1098716		Accepted - Not Rolled Forward		05/07/2016 Peters, Thomas Michael	View
	Study Title: Implications of and Association Between Radiographic Evidence of Interstitial (...more)						
	P	1098715		Accepted - Not Rolled Forward		05/07/2016 Peters, Thomas Michael	View
	Study Title: Microvascular and Endothelial Cell Responses to Inhaled Endotoxin in Humans: (...more)						

Convert Delayed Onset Study to Full Study Record

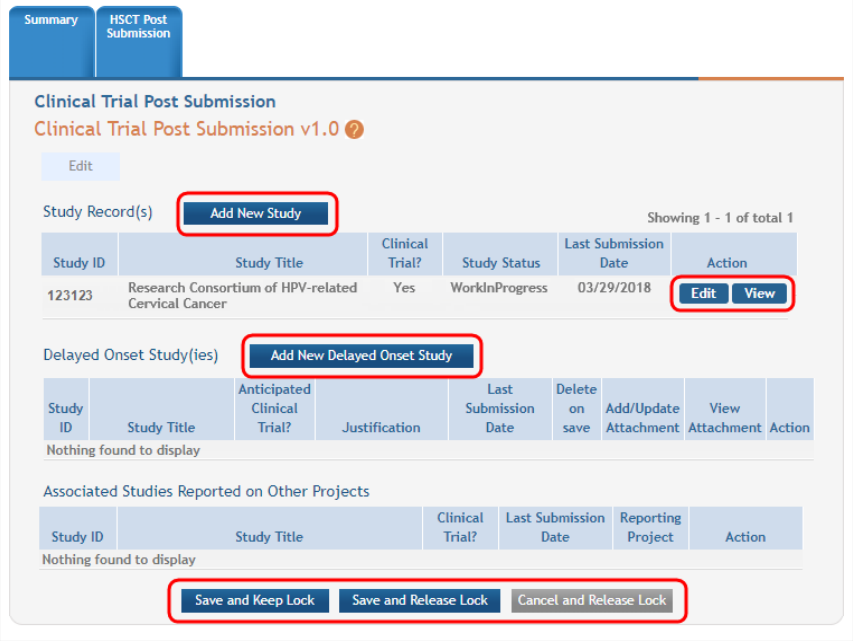




Add a New Study

- Click on Post HSCT, then click EDIT

- Opens options to Add New Study



Keep versus Release Lock

- Save and Keep Lock
  - Retains “Work in Progress” Status – saves work, application cannot be submitted
- Save and Release Lock
  - Are able to change status to “Ready for Submission” so application can be submitted to NIH

Validation of Study Record Data

- On the Actions Panel of the Summary Screen the first button is Validate.
- You can click on Validate prior to changing the Status to Ready for Submission OR
- Setting the record to “Ready for Submission” automatically validates the record.
- Errors prevent the change to Ready for Submission.
- Go back and fix any errors found
- Then either validate again or change the status to re-validate
- The Status will not change to Ready for Submission until the study records pass validation

Note: Validation only occurs if revision is needed – application process doesn’t validate HSS information (incentive to do it right in application)

HSS – Things to remember

- System operates on Statuses
- If you cannot make changes, check the Status
  - EDIT button is not available - make sure Status is set to “Work in Progress”
- Do not change to “Ready for Submission” until all edits are completed
- SO doesn’t know record is waiting for submission, and cannot Submit records unless Status is set to “Ready for Submission”
- Changes do not become permanent, and staff cannot see them in the HSS, until SO Submits them to NIH
- RPPR and HSS data must be approved by SO separately - submit HSS data first
- Institution may set a policy to allow SO to delegate the Submission task to PI
  - Still must set status to “Ready for Submission” before can Submit

Case Studies

Case Study 1 - ASSIST

- Dr. Green needs to revise her study and its associated inclusion record. She has successfully accessed ASSIST, but when she clicks on the HSCT Post Submission tab, she can't edit.

1. What does she need to do?
   - Go back to the summary page and change the status to 'Work in Progress'

2. She has managed to successfully make the changes, but can't submit the record. What does she need to do?
   - Change the status to 'Ready for Submission'

Case Study 2 - ASSIST

Dr. Brown submitted an application to be funded. Due to cuts to budget, aims and time, she must make major revisions to the study to reduce data to be collected and the number of subjects to be enrolled.

What does she need to do?

1. Access ASSIST through the status tab of her NIH Commons account.
2. Revise study record to match the work that will be done.
3. Revise planned enrollment.
4. Submit the revised record through her signing official by changing the status to 'Ready for Submission'

Case Study 1 - Monitoring

Dr. George is re-enrolling 500 children from a large pregnancy cohort of Mothers (age 21-45) to examine neurodevelopment in the children at ages 3-7.

- All children undergo cognitive and behavioral assessments
- Study analyses include past and current Child assessments and Mothers prenatal exposure data.
- Sub-study of fMRI in 20% of children

- Do you need more than one study record?
- Who needs to be included in the study? Is data existing or not?
  - Children? Enrolling or Existing?
  - Mothers? Enrolling or Existing
  - Separate IER for children undergoing fMRI?
  - Recruiting Status?
  - What is the age range? Minimum? Maximum?

Case Study 1 – Monitoring (with answers)

Dr. George is re-enrolling 500 children from a large pregnancy cohort of Mothers (age 21-45) to examine neurodevelopment in the children at ages 3-7.

- All children undergo cognitive and behavioral assessments
- Study analyses include past and current Child assessments and Mothers prenatal exposure data.
- Sub-study of fMRI in 20% of children

- Do you need more than one study record? No
- Who needs to be included in the study? Is data existing or not?
  - Children? Yes Enrolling or Existing? Enrolling (Planned)
  - Mothers? Yes Enrolling or Existing Existing (Cumulative)
  - Separate IER for children undergoing fMRI? Yes
- Recruiting Status? Enrolling
- What is the age range? Minimum - 3 Maximum - 45

Case Study 2 – Delayed Start versus Delayed Onset

Dr. Aster submits an application to support a project on the effects of walking versus running on lung function on green versus orange ozone days in 100 Native American adults ages 18-40. Before he can start the project, the PI needs to develop a simple, inexpensive personal sampler to measure and track the level of air particulates, duration of exercise, distance traveled, and lung function.

Is this delayed onset or delayed start?

Delayed start.

What if a sampler exists, but the PI plans to work with community organizers to develop a survey to determine community needs before the study is developed.

Delayed onset.

Case Study 3 – Human Subjects

Dr. Hare plans to analyze de-identified Medicare data for all states to look at rates of hospitalization for asthma in older adults ages 65-89 between 1990 and 2015. Data includes gender, race, ethnicity, state, age, hospitalization for asthma. PI entered a study record with cumulative enrollment.

Is study record needed?

Why/Why not?

Dr. Hare has decided to combine Medicare data with air pollution levels so also requests the street address.

Is study record needed?

Why/Why not?

Case Study 3 – Human Subjects (with answers)

Dr. Hare plans to analyze de-identified Medicare data for all states to look at rates of hospitalization for asthma in older adults ages 65-89 between 1990 and 2015. Data includes gender, race, ethnicity, state, age, hospitalization for asthma. PI entered a study record with cumulative enrollment.

Is study record needed? No

Why/Why not? Publicly available dataset without identifiers, no re-identification using available information. Not HS.

Dr. Hare has decided to combine Medicare data with air pollution levels so also requests the street address.

Is study record needed? Yes

Why/Why not? Data is now identifiable.

Any Questions?

Contact

Martha I. Barnes, MS

barnes@niehs.nih.gov

984-287-3235

Submitted Question

Q. I am a project manager and prepare the annual reports for submission, however, I do not have access to the system so I always modify the prior year report and then forward each section to my PI to complete. Is there a way I could have admin access to do the reports, then forward to the PI and the grant manger for edits?

A. Yes. The PI can delegate authority to allow the program manager to make changes to the reports in the system.

Resources

- NIH Human Subjects Website - https://grants.nih.gov/policy/humansubjects.htm
- Human Subjects System Help - https://era.nih.gov/erahelp/HSS_External/#about_hss_external.htm%3FTocPath%3DThe%2520Human%2520Subjects%2520System%2520(HSS)%7C_____0
- Exempt Human Subjects Research Graphic: https://grants.nih.gov/sites/default/files/exemption_infographic_v7_508c-4-4-19.pdf
- De-identification under HIPPA: https://privacyruleandresearch.nih.gov/pr_08.asp
- Certificates of Confidentiality https://humansubjects.nih.gov/coc/index
- Single IRB Policy https://osp.od.nih.gov/clinical-research/irb-review/
- Inclusion Across the Lifespan: https://grants.nih.gov/grants/funding/lifespan/lifespan.htm
- Annotated Forms Set for NIH Grant Applications: https://grants.nih.gov/grants/ElectronicReceipt/files/Annotated_Forms_General_FORMS-F.pdf

Exemption Codes 45 CFR 46 104(d)

- **Exemption 1** – research is conducted in an educational setting involving normal educational practices
- **Exemption 2** – research uses cognitive, diagnostic, aptitude or achievement tests; interviews; or observations of public behavior, unless subjects are identifiable and disclosure could place them at risk. If subjects are identifiable*, limited IRB review is required.
- **Exemption 3** – research using benign behavioral interventions in adults. If subjects are identifiable, limited IRB review is required. NEW

* Studies with children cannot be exempt if identifying information is collected

Inclusion Enrollment Records Required

Exemption 4

Secondary research for which consent is not required

- Research involving the collection or study of existing data, documents, records or pathological or diagnostic specimens:
  - if the identifying information is publicly available; or
  - the information is recorded so subjects identity cannot readily be ascertained directly or through a key, the PI won't re-contact, and PI won't re-identify; or
  - the data are already protected under HIPAA* and data is used for "health care operations" or "research" or for "public health activities and purposes"
  - the data were collected by, or on behalf of, the government for non-research purposes and is already protected by another federal privacy rule.

*identifiers may be retained; project should undergo Limited IRB Review

Inclusion Enrollment Records are NOT Required for Exemption 4

Exempt Human Subjects Research

8 Exemptions

1 **Meets the definition of human subjects research.**

Exempt studies involve human subjects research: research involving a living individual about whom data or biospecimens are obtained/used/studied/analyzed through interaction/intervention, or identifiable, private information is used/studied/analyzed/generated

2 **Meets the criteria of one of the following exemptions:**

Exemption 1: conducted in an educational setting using normal educational practices*

*Cannot include any other procedures, such as collection of clinical data or biospecimens

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

*Limited IRB review may be required.

Exemption 3: benign behavioral interventions in adults*

*Limited IRB review may be required.

Exemption 4: involves the collection/study of data or specimens if publicly available, or recorded such that subjects cannot be identified*

*May be identifiable in limited cases. See §46.104(d)(4)(iii) and (iv)

Exemption 5: public service program research or demonstration projects

Exemption 6: taste and food quality evaluations

Exemption 7: storage of identifiable information or biospecimens for secondary research use. *Broad consent* and *limited IRB review* are required.

Exemption 8: secondary research use of identifiable information or biospecimens. *Broad consent* and *limited IRB review* are required.

For more information see the NIH OER Human Subjects Research website.
Send questions/comments to OER-HS@nih.gov.

Consider

NIH Requirements:

- HS education
- Inclusion tracking for all except 4.

45 CFR 46 Requirements:

- Limited IRB review for 7 & 8, and some study designs under 2 & 3.
- Broad consent for 7 & 8.

Cannot involve **prisoners**, unless includes a broader population that happens to include prisoners.

Cannot involve **children** in:

- Exemption 2 if investigators participate in the activity being observed or includes identifiable info, OR
- Exemption 3.