

PROTECT Tip Sheet for IRB RESEARCHERS

NHSR & Exempt Submissions in PROTECT

Overview:

This guide is intended for Researchers and Study Team members and other NIH staff who need to submit to the IRB applications for activity that might be **Not Human Subjects Research** or **Exempt**. It will cover where on our Office of Human Subjects Research (OHSRP) website to find resources on these types of activities, as well as how to submit these applications in PROTECT.

OHSRP Website Resources:

Determining how to submit **Not Human Subjects Research** or **Exempt** applications:

1. *Do you need to submit to the IRB?*

URL: [Step 1 \(nih.gov\)](#)

The screenshot shows a webpage with the following content:

- Step 1: Do you need to submit to the IRB?**
- All NIH investigators conducting activities that meet the definition of both "research" and "human subject" must submit for Institutional Review Board (IRB) approval before beginning any research activity.**
- IRB approval cannot be retroactive.**
- If you are not doing Human Subjects Research but would like or need an official IRB determination, you can submit for a Not Human Subject Research (NHSR) determination.
- Is it Research?**
Research is a "systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge". 45 CFR 46.102(d) [↗](#)
[OHRP Is the Activity Research? \[↗\]\(#\)](#)
- Is it a Human Subject?**
A human subject is "a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens". 45 CFR 46.102(e) [↗](#)
This means that people are human subjects. Existing data or specimens with identifiable, private information are also human subjects. This includes data that was not collected by the researcher herself or specifically for the study in question, but that can be traced back or identified with the individuals from whom it was collected.
If your activity falls under FDA regulations, note that the FDA definition of human subjects research includes the use of test articles (i.e., drugs or devices) on humans or human specimens, **whether identifiable or not** CFR Title 21 [↗](#)
- What If I'm Not Sure?**
[Find your IRB Team's contact information here](#) or call 301-402-3713 to get in touch with an IRB Analyst, or send us an email at IRB@od.nih.gov. You can also refer to OHSRP Policy 100-NIH HRRPP [↗](#) for further information. Finally you could submit a request for a determination.
[Does Your Project Require Submission for a Determination of NHSR or IRB Exemption.pdf](#)
- Examples of Research**
 - Surveys, interviews, or observations (social sciences)
 - Natural History Studies
 - Studies that utilize test subjects for new devices, drugs, or materials (biomedical)
- Examples of Not Research**
 - Activities that are only for quality improvement purposes
 - Program improvement evaluationsProjects for which the results are not intended to contribute to generalizable knowledge
- [QA-QI vs. Research.pdf](#)
- [Program Evaluation vs. Research.pdf](#)
- [OHRP Does the Research Involve Human Subjects? \[↗\]\(#\)](#)
- [Human Subjects Research Decision Tree.pdf](#)
- [Guidance for Determining Whether Data Constitutes Individually Identifiable Information.pdf](#)

fig 1

2. *Not Human Subjects Research*

URL: [NHSR Research \(nih.gov\)](#)

The screenshot shows a webpage with the following content:

- Not Human Subjects Research (NHSR)**
- Not Human Subjects Research Application**
 - [Not Human Subjects Research Application \(05/24/23\)](#)
- OHSRP Instructions and Guidelines**
 - [Policy Memo - Change re: Requirement for NHSR Determinations \(01/15/19\)](#)
 - [Does Your Project Require Submission for a Determination of NHSR or IRB Exemption? \(06/30/21\)](#)
 - [Human Subjects Research Decision Tree Final \(01/17/19\)](#)
 - [Guidance for Determining Whether Data Constitutes Individually Identifiable Information Under 45 CFR 46 \(07/30/19\)](#)
 - [OHSRP Education Series Presentation: When IRB Approval is Necessary and How to Complete the New Investigator Attestation for Tech Transfer Agreements \(03/18/19\) Slides and Videocast \[↗\]\(#\)](#)
- OHRP Guidance**
 - [Engagement of Institutions in Human Subjects Research \[↗\]\(#\) \(10/16/08\)](#)
 - [Coded Private Information or Biospecimens Used in Research, Guidance \(01/19/18\)](#)
 - [What is Human Subjects Research? \[↗\]\(#\) \(06/28/21\)](#)
- Not Research (NR)**
- OHSRP Guidelines**
 - [OHSRP NLM Presentation: Determining Whether Your Project Meets the Definition of Research \(04/13/23\) Slides](#)
 - [Program Evaluation vs. Research: Do I Need to Submit for an Exemption or IRB Approval? \(08/23/21\)](#)
 - [QA/QI vs. Research: Do I Need to Submit for an Exemption or IRB Approval? \(08/23/21\)](#)

fig 2

3. Exempt Research

URL: [Exempt Research \(nih.gov\)](https://www.fda.gov/oc/ohsrp/exempt-research)

Exempt Research
OHSRP

- [Understanding and Submitting for an Exempt Determination](#)
- [Guideline for Investigator Responsibilities When Conducting Exempt Research](#)
- [OHSRP Education Series Presentation: Exemptions from IRB Review and the Revised Common Rule: What Has Changed and What Has Stayed the Same? \(6/13/2019\) Slides and Videocast](#)
- [Policy 204 Levels of IRB Review and Criteria for IRB Approval](#)
- [Common Rule Bulletin #2: Exemptions](#)

Retrospective Data or Biospecimen Review

Title	Version Date
Instructions for Request for Exemption for Retrospective Data or Biospecimen Review	23 August 2021
Retrospective Data or Biospecimen Review Protocol Template	30 June 2021
Access to CRIS for Exempt Research	23 August 2021

Collecting Prospective Data from Humans

Title	Version Date
Instructions for Request for Exemption for Prospective Data Collection from Humans	23 August 2021
Collecting Prospective Data from Humans Protocol Template	30 June 2021
Use of Third Party Vendors for Recruitment and Screening	

OHRP

- [Human Subject Regulations Decision Charts: 2018 Requirements \(Exemptions\)](#)
- [Overview of Changes to Exemptions in the Revised Common Rule \(Focusing on Exemptions 1, 2, 3, and 5\)](#)
- [Is the Human Subjects Research Exempt?](#)

fig 3

4. What if I'm Not Sure?

[Find your IRB Team's contact information here \(fig 4\)](#) or call 301-402-3713 to get in touch with an IRB Analyst, or send us an email at IRB@od.nih.gov. You can also refer to OHSRP [Policy 100 - NIH HRPP](#) for further information. Finally, you could submit a request for a determination.

Find my IRB Team

Please note, you can also send an email to the IRB main inbox at IRB@od.nih.gov or call our main number 301-402-3713 to get in touch with IRB staff.

Select your Institute:

- National Cancer Institute (NCI) +
- National Center for Advancing Translational Sciences (NCATS) +
- National Center for Complementary and Integrative Health (NCCIH) +
- National Heart, Lung, and Blood Institute (NHLBI) +
- National Human Genome Research Institute (NHGRI) +
- National Institute on Aging (NIA) +
- National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) +
- National Institute of Alcohol Abuse and Alcoholism (NIAAA) +

fig 4

INTRODUCING 2 NEW PROTECT GUIDES: 

★ **NIH Guide for Submission for NHR and Not Research**
COMING SOON / Will be posted on the OHSRP Website

★ **NIH Guide for Submission for Exemptions**
COMING SOON / Will be posted on the OHSRP Website

Questions / Help

For system-related questions about these submissions in the PROTECT system:

Please [submit a ticket](#) and our IT trainers will assist you.

For process/regulatory questions about your submission:

Contact the IRB Team: [Find my IRB Team \(nih.gov\)](#).

NOTE: You can also send an email to the IRB main inbox at IRB@od.nih.gov or call our main number 301-402-3713 to get in touch with IRB staff.