# 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)

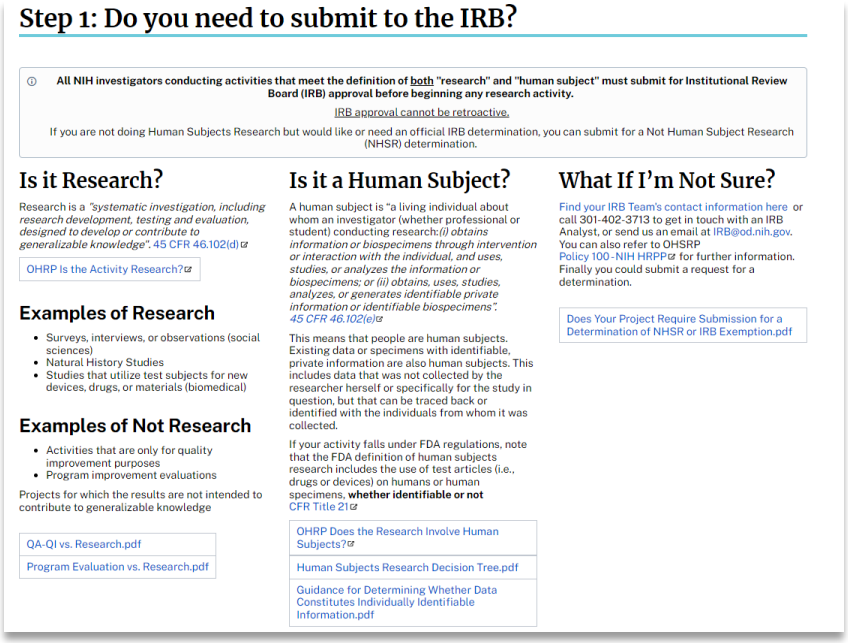


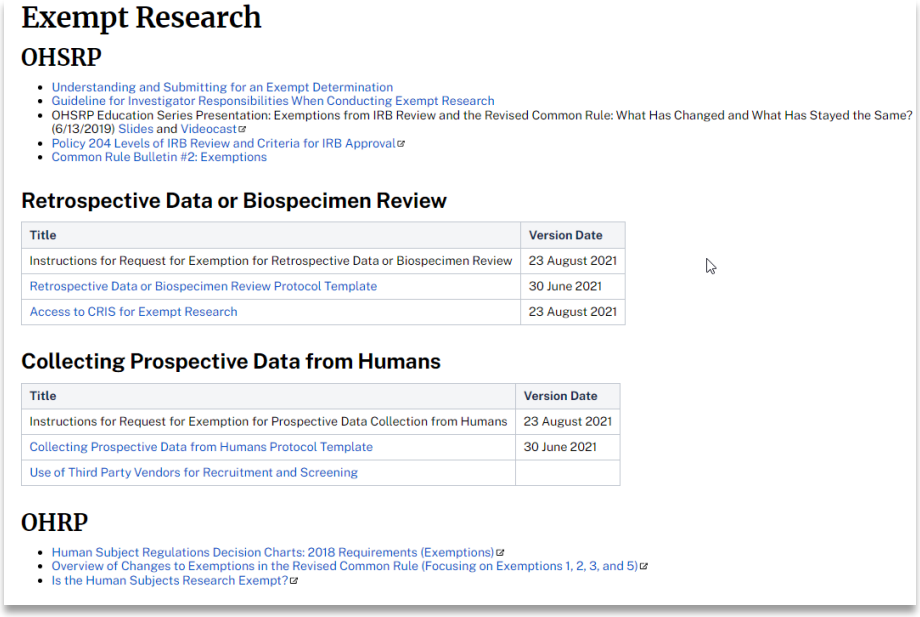

*fig 1*

2. *Not Human Subjects Research*
   URL: NHSR Research (nih.gov)


*fig 2*

3. *Exempt Research*

   URL: [Exempt Research (nih.gov)]



# 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 | |

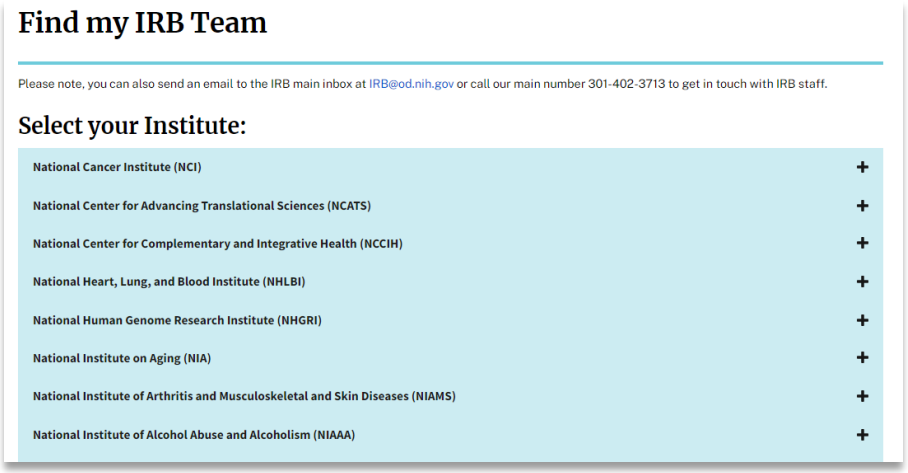
## OHRP

- 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 NHSR 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.