Division of General Internal Medicine
Duke Department of Medicine

# Guide to Submitting Exempt and Non-Exempt IRBs Through GIM

## Where and how do I submit a Duke Health IRB?

The IRB system is called iRIS at https://iris.duke.edu/.

For iRIS training, FAQs and step by step information on navigating and submitting an IRB in iRIS, go to https://medschool.duke.edu/research/clinical-and-translational-research/duke-office-clinical-research/clinical-research-resources-and-applications/docr-imedris-support-page.

## What are the GIM requirements for IRB submissions?

Before submitting an IRB through GIM:

- Contact Tara Strigo (tara.strigo@duke.edu), Director or Research Programs in GIM, to alert her of your planned submission.
  - **Do not submit your IRB until speaking with Tara.**
  - Tara will assist with completing/reviewing your IRB and other regulatory requirements so it will not be returned due to missing or incorrect information.
- Include GIM as a Study Organization (iRIS Q2.1).
- Include Tara in your IRB key personnel (iRIS Q3.1) as a the primary Regulatory Coordinator (RC).
- If you need Clinical Research Coordinator (CRC) assistance, please discuss options for assistance with Tara – do not name yourself, a student, or other MD as a CRC/RC.

## Who can serve as a PI on an IRB?

Only faculty who are regular rank with approved PI status can serve as a PI. For more information please see the Duke IRB website for PI qualifications https://irb.duhs.duke.edu/policies-and-regulations/policies/principal-investigator-qualifications.

Hospitalists: please follow requirements outlined in the policy "Obtaining Investigator Status to Conduct Academic Work Requiring IRB Approval within DUHS Hospital Medicine" provided to you by the Chief of Hospital Medicine.

## What are the required IRB trainings?

- Verify your email address in CITI is NetID@duke.edu and not your alias email. You can take a quick online tutorial in Duke LMS (https://hr.duke.edu/training/learning-management-system) called "**Creating and/or Properly Linking Your CITI Account to Duke Systems - DOCR (00151364)".**

- All Duke personnel listed in the IRB must verify completion and up to date CITI training under Duke Health. To verify CITI training:
  - Go to CITI website https://about.citiprogram.org/en/homepage/.
  - Click on "Log In Through My Institution".
  - Find **Duke Health** in the list and click on the link to go to the Duke log in page.
  - After you log in, you will be redirected to the CITI Program website.

- Required trainings, regardless of the type of IRB or population, include:
  - Biomedical Research with GCP - Basic/Refresher (Expires every three years from completion)

- Vulnerable Subjects - Research Involving Children (one-time completion)
- Vulnerable Subjects - Research Involving Prisoners (one-time completion)
- Vulnerable Subjects - Research Involving Pregnant Women, Fetuses, and Neonates (one-time completion)

- Once CITI training is completed, you must log in and back out of the Duke IRB system (iRIS https://iris.duke.edu/) to link the trainings behind the scene. Give it 24-48 hours to link with the Duke IRB system before adding them again.
- If personnel have completed trainings in the past and are up to date, but have never logged in to the Duke IRB system (iRIS https://iris.duke.edu/), please ask them to do so prior to submitting the IRB.
- If you still have problems adding personnel, or need them to be added asap, contact docr.help@dm.duke.edu to request assistance.

## What are other DOM mandatory trainings that must be completed?

- The Department of Medicine Science Culture & Accountability Plan (SCAP) outlines the expectations and recommendations for how the department, division, and individual investigators can guarantee the responsible management and critical review of scientific data. **This is mandatory for all faculty and staff who are or will be on non-exempt IRBs, however, we encourage everyone to complete.**
  - Please verify you have signed the SCAP attestation form via this link: http://bit.ly/SCAPattest2020

- Responsible Conduct of Research (RCR) broadly refers to a code of ethical conduct that researchers should abide by on a daily basis. RCR education strives to promote ongoing discussion and examination of research operating procedures (including experimental design, data analysis, data management), academic and collegial relationships and collaborations, and the ethical considerations accompanying studies and the research culture itself. Making ethical and practical decisions requires practice, periodic reflection and discussion to learn and experiment with different approaches. **This is mandatory for all faculty and staff who are or will be on non-exempt IRBs, however, we encourage everyone to complete.**

  **RCR 100 (one every 3 years)**
  The 100-level training is a self-directed online course. To complete a 100-level course, you must complete one of the following:
  - CITI RCR Course (how to add the "Duke RCR" institution to your account)
  - Data Management RCR Course (3 modules + 3 quizzes)
  - Research Communications RCR Course (3 modules + 3 quizzes)
  - RCR for Clinical Researchers

  **RCR 200 (one every 3 years)**
  The 200-level course is a live, instructor-led event for which you must register in advance. Please visit the RCR Workshop Calendar to register for an upcoming RCR-200 event.

## Who do I include in the IRB as the sponsor/funding source if it is not funded, or is internally funded (iRIS Section 700)?

Duke University should be listed as the funding organization.

## What are the OnCore requirements pre- and post-IRB submission?

- OnCore is the Clinical Research Management System (CRMS) supporting clinical research activities at Duke which allows for enhanced clinical research study management, robust reporting, enrollment tracking, and accurate clinical research billing. There is information required for all exempt and non-exempt IRB submissions in OnCore.

- OnCore training is required for all users to gain access to the system. Please follow the instructions to complete required prerequisite and PI trainings. https://medschool.duke.edu/research/clinical-and-translational-research/duke-office-clinical-research/clinical-research-resources-and-applications/oncore-training-support-page

- In the IRB submission, please make sure you "Sync to OnCore" (iRIS Section 700) once you have finalized your study title, listed GIM as a study organization (iRIS Q2.1), accurately listed all personnel (iRIS Q3.1), and included sponsor/funding source information (iRIS Section 700). This information is synced from the IRB application to OnCore.

- Tara will assist with completing the additional OnCore requirements for your IRB. You can log in to OnCore after completing your trainings to verify your submission synced, but do not enter any information without Tara or an assigned RC/CRC assistance.

- For all exempt and non-exempt IRBs, please contact Tara Strigo (tara.strigo@duke.edu) when your project has officially ended and all manuscripts (if applicable) have been published. You will want to close your IRB and update OnCore with the IRB closure date.

**What is a Research Data Security Plan (RDSP)?**

- RDSP is part of the non-exempt IRB submission process and contains information on "how" and "where" paper and electronic data associated with the human subject research protocol is stored, processed, accessed, or transmitted.

- After completing the main IRB questions, you will be prompted to log in and complete the RDSP using the provided link. To return to the RDSP at any time to review/edit the submission, please go to https://egrc.duhs.duke.edu.

- When submitting the RDSP, please include your CRC and RC. If you do not have a CRC or RC, please contact Tara Strigo for assistance and include her in the RDSP.

- For a list of step by step instructions and screenshots on how to complete the RDSP, please go to https://medschool.duke.edu/research/clinical-and-translational-research/duke-office-clinical-research/clinical-research-resources-and-applications/docr-imedris-support-page.

**Who do I contact for questions/assistance with all research related topics?**

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