

Human Subjects Research Guidance

Physical Medicine & Rehabilitation Research University of Alabama, Birmingham

Empowering clinicians to Be Successful Researchers



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Empowering Clinicians to be Successful Researchers

At the Department of Physical Medicine and Rehabilitation at UAB, Birmingham, UAB Institutional Review Board (IRB) approval is required prior to collecting any data related to human subjects research. *One of the first steps to empowering yourself to be a success as a researcher* is to ask yourself the question below.

Am I Doing Human Subjects Research?

Human subjects research is defined as a systematic investigation designed to develop or contribute to generalizable knowledge where an investigator obtains data through interaction or intervention with a living individual or identifiable private information from a living individual.

Quality assurance activities or quality improvement (QI) projects may or may not be considered human subject research.

Human subjects data can include:

- Biological samples
- Information in the person's medical record
- Epidemiological data
- Surveys
- Interviews
- Focus group data
- Cognitive or psychological assessment data

If you are using, or plan to use, any of the methods or sources listed above in collecting data, then you are involved in human subjects research.

University policy requires that all research involving human subjects be reviewed and approved by the UAB IRB before the research begins. This requirement applies to all human subjects research conducted by faculty, staff, and students, on- and off-campus, regardless of funding. It also applies to activities in preparing to do research.

Contact the UAB Institutional Review Board regulatory office (phone # or email) to confirm whether or not your protocol requires IRB approval. For further guidance please visit IRB Office online: <https://www.uab.edu/research/administration/offices/IRB/Pages/Home.aspx>

Or the site for the Integrated Research Administration Portal (IRAP) with the Handbook for Investigators: IRB/Human Subjects

https://web.ad.uab.edu/research/administration/offices/IRAP/IRAPTraining/Documents/IRAP_My_Human_Subjects_Investigator_Handbook-1.pdf

What is the Institutional Review Board?

The IRB is an ethics committee that reviews, approves, and rejects or recommends changes to protocol submissions. The IRB ensures that research participants' rights are protected. ***You may NOT conduct research at UAB or the Department of Physical Medicine and Rehabilitation without a UAB IRB approved protocol***

Preparing an IRB Application

IRB application forms are available online. The IRB Submission Checklist, found at <https://www.uab.edu/research/administration/offices/IRB/Pages/Home.aspx> under Forms.

You can submit your application through the Director of Research, Dr. Janet Niemeier's Office and Sherricka Embery, Research Manager. Your research application packet will be reviewed upon submission. This takes approximately 4 weeks. If corrections and/or additions are required, it will be returned to you.

If you have an IRB approved protocol from another institution, you will need to submit that protocol to UAB IRB. Research cannot be conducted at UAB Department of PM&R without UAB IRB approval.



Another important step in empowering yourself to be a successful researcher is to undergo required training.

Training is required for investigators and other personnel involved in research projects at the Department of Physical Medicine and Rehabilitation and UAB. Documentation of completed training and standard operating procedure (SOP) review must be scanned and emailed to the Department Director of Research, Dr. Janet Niemeier and the Department Research Manager, Sherricka Embery (sembery@uabmc.edu).

Research Training requires:

- CITI Biomedical Research Course or Social and Behavioral Research Course (depending on the field of study)
- CITI Financial Conflict of Interest Course
- Good Clinical Practice Course
- Additional Courses may be required depending on the type of research and field.
- Research operating procedures and guidelines are also on the UAB IRB and IRAP links provided earlier in this brochure.

A simple guide to accessing online training:

Go to www.citiprogram.org

Click on Log in through my institution or the box in the middle that says, “Log in via SSO.”

1. Scroll down to University of Alabama at Birmingham (#53) and click UAB.
2. This takes you to the Blazer ID sign in page, sign in.
3. A pop up screen will come up, click continue.
4. Select the option for “I don’t have an account and need to create one.”
5. Click on blue link at the bottom.
6. Click on add a course.
7. Take the required modules.
8. Scan and send your certificates of completion to sembery@uabmc.edu





If you are new to the world of research, a Third step toward becoming a successful researcher at UAB PM&R is to choose a research mentor.

Experienced research mentors can help you plan and prepare as well as conduct research. They will help you with determining the feasibility and process steps of your study, which will save you a lot of time and angst. **Other aspects of research that mentors can help with:**

Ideas

If you have an idea for a research project, first review the literature, determine what others have discovered and then fine-tune your project. Discuss your idea with your mentor and they can also guide your search.

Research Process Steps

Start with your idea

Determine if the project involves human subject research

Write the research protocol

Submit the protocol to the UAB IRB

Collect and analyze the data

Disseminate the findings

Things to Consider Before Starting the Process Steps

Can I recruit the number of study participants needed to obtain statistical significance?

Do I have the time to recruit them?

Do I have the resources to conduct the study?

Do I need funding?

Who will consent persons to participate. Do they have capacity to consent or will I need a legal guardian or legally authorized representative to sign for them?

Research items to Prepare

Research design

Recruitment plan

Statistical plan

Budget

Consent

Unapproved Human Subjects Research

If you are involved in human subjects research at PM&R or UAB that has NOT been approved by the UABIRB, contact the office immediately to determine steps to obtain approval. The IRB may suspend or terminate research studies that are not approved. Failure to gain IRB approval prior to conducting a study may also

- Be considered scientific misconduct. Scholarly publications may not be allowed to be published.
- Result in the Department or University to be fined or conducting any research for a period of time
- Result in the loss of grant funding

For More information visit or call the UAB IRB

<https://www.uab.edu/research/administration/offices/IRB/Pages/Home.aspx>