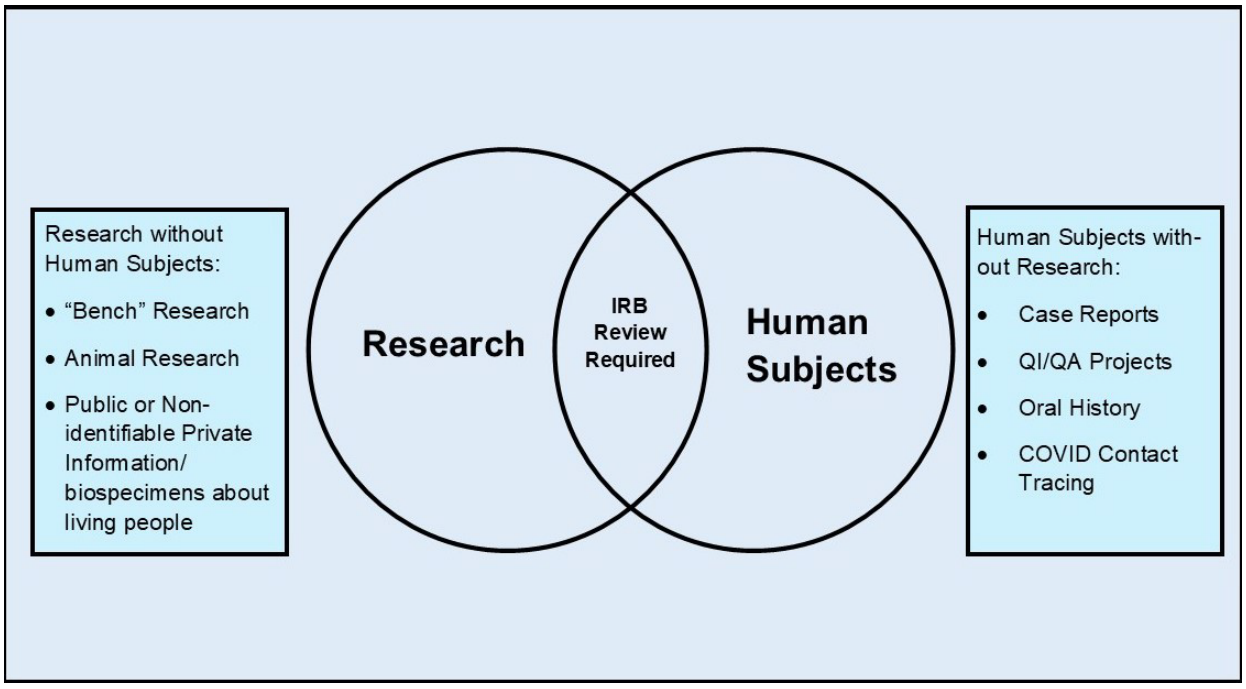
Purpose: To outline the process for development and review of scholarly activity and research projects prior to requesting an IRB determination or approval, if applicable.

Instructions: All CFVH Fellows, Residents and Students involved in the Graduate Medical Education Program (GME) and other teaching programs are required to complete scholarly activities. The fellow/resident/student should work with a faculty advisor on all scholarly projects. At CFVH faculty are required to be the Principal Investigator (PI) on GME and IRB applications. Fellows/Residents/Students can be Co-PIs. The GME Research Program Director and Administrator are available to assist advisors, fellows, residents, and students with the preparation and facilitation of scholarly activities and research. For study development, design, and analyses contact Dr van Tilburg, for GME Research Program/IRB related matters contact Shawn Leming, contact information listed below.

Scholarly activity encompasses many activities which may or may not be considered research and if the activity meets the definition of ***research,*** it may or may not meet the federal definition of human subjects research. Only the latter requires IRB overview. However, some non-human subjects research still requires an IRB determination or legal review here at CFV.



To be able to determine what type of scholarly activity you plan to develop and what kind of oversight it needs, please visit the following guidance documents which can be found on the external IRB website:

a. ***GME Human Subjects Research Determination Worksheet*** to determine if the project meets the definition of research and if the project will engage in human subjects research. This worksheet includes instructions on which type of GME, or IRB application form will need to be completed and submitted.

b. ***IRB Guidance: Characteristics of Research vs Quality Improvement*** provides additional guidance on how to distinguish a research project from a QI project IRB website. If you think you are performing a QI project, please consult ***IRB Guidance: Quality Improvement Projects***

c. **IRB Guidance: Case Reports/Series** Note that case reports/series require oversight by the GME Research Program and Legal Services CFVH

d. **IRB Guidance on Research Activities/Conduct** to assist you in determining what type of research you are conducting are available on the **IRB website.**

Determination of what kind of project you perform is not easy. The IRB office is here to help. Please contact Shawn Leming.

Submission to the GME Research Program or IRB

1. After a preliminary determination of which type of review is required please visit the IRB website for GME and IRB application forms, consent documents and further guidance. Below is a summary of required forms/documents.

Not Research/Non-Human Subject Research:

- **Case Report/Series:** Read the ***IRB Guidance: Case Report/Series*** and use the ***GME Case Report Form***. Additional supporting documents may be required. *Please note these are being updated to reflect new procedures. The IRB no longer requires submission of case reports before starting the project. Rather, case reports should be submitted after patient consent is obtained and the report is written. Any written material that leaves CFVH (e.g., conference abstracts, posters, papers) require approval by the GME office and legal. Please submit the written report with the GME Case Report Form to the Research Program Administrator.*
- **Quality Improvement/Assurance/Program Evaluations:** Read the ***IRB: Guidance: QI/QA/PE*** and use the ***GME Quality Improvement Project Form***. Additional supporting documents may be required.
- For all other categories please use the ***IRB: NHSR Application Form***. Additional supporting documents may be required.

Human subject research

- **Exempt Research:** Some research is exempt from IRB overview. Please note that only the IRB can make a determination if your project is exempt. Investigators need to submit applications for all exempt projects. Read IRB Guidance Documents found on the IRB website. For further information and details and submit one of the following:
  - ***Exempt Protocol Application Form*** (Categories 1 – 6); or
  - ***Exempt Category 4 Application Form*** (secondary use of information/biospecimens, e.g., medical record review), if applicable.

- **Expedited/Full Committee research:** See ***IRB New Protocol Application Form*** and ***Research Plan Guidance Document*** for detailed information and instructions.

2. In addition to the above forms, all project members are required to complete training before submitting a project proposal. Review the **GME Guidance: Scholarly Activities & Human Research Protection Training**.

3. Completed forms and all supporting documents must be submitted to the Research Program Administrator. If at any time you need assistance in completing any of the GME/IRB documents, a meeting can be scheduled. We request that both the PI and the fellow/resident/student attend the meeting.

4. Once all GME/IRB documents have been logged and reviewed by the Research Administration, your submission will be forwarded to the IRB, if applicable.

Multiple other guidance documents are available that can help you with your IRB submission. These can be found on the IRB website. Please contact the GME Research Program Administrator if you need additional information.

Contact Information:

Shawn Leming, BA, CIP
Research Program Administrator/IRB Administrator
Medical Education
Cape Fear Valley Health System
910-615-5839
sleming@capefearvalley.com