**The following are the PI responsibilities and are not all inclusive:**

1. Assure that all personnel listed on the research protocol have completed the [human](http://www.utexas.edu/research/rsc/humansubjects/training/index.html) [subjects protection training.](http://www.utexas.edu/research/rsc/humansubjects/training/index.html)
2. Submit protocols for GME and if applicable IRB review and approval of proposed scholarly and research activities prior to commencing the activities.
3. Employ sound project design in accordance with standards of the PI’s discipline.
4. Assure that adequate time and resources are present before conducting a study to assure participant protections.
5. Maintain appropriate oversight of each scholarly project, as well as project staff, and appropriately delegate responsibilities and functions.
6. Ensure that the scholarly project is conducted according to the protocol, any signed agreements, in compliance with all applicable laws and regulations and organizational policies and procedures with the highest of ethical standards.
7. Submit for review and approval all proposed project and consent form changes prior to implementing the changes in the project.
8. Obtain legally effective informed consent from project participants prior to commencement of project activities, if required.
9. Ensure the rights, safety and welfare of the project participants are upheld and protected.
10. Follow reporting requirements for HIPAA breaches as outlined in Institutional policies.
11. Retain records as required by Institutional policy for the appropriate time period.
12. Follow all Institutional, Unit, and local site applicable policies.

**Principal Investigators for Resident/Student-led Research**

CFVHS requires all scholarly activities to be conducted under the guidance of a qualified Principal Investigator. As a teaching institution, residents and medical students will be engaged in conducting scholarly activities as an integral part of their educational experience. Faculty/Staff/Advisors who assume PI responsibility for resident/student-led scholarly activities must be willing to provide oversight to the activity(ies) and assume full responsibility for the conduct of the project. The Faculty/Staff/Advisor PI must be actively involved in the project, from project design to data analysis and report preparation. In many cases, it may be the student's first experience with formal activities. The success of the student's experience will be measured not only in the outcome of their projects, but also in what they learn from the faculty/staff/advisor sponsor. These experiences will help form their perception of scientific scholarly activities. The following are the Faculty/Staff/Advisor PI responsibilities and are not all inclusive:

1. To advise the resident/student on the selection of a topic, the content and preparation of their project proposal; understand the project goals, methodology, and results; guide and interact with the resident/student throughout the project.
2. To assist the resident/student with the preparation of the GME application. As the PI on the project, submit the application to the GME Research Program Administrator. Ensure the resident/student obtains all necessary approvals (i.e., GME and, if applicable, IRB) before initiating the project, implementing any changes in the activities.
3. Assume full oversight of the scholarly activity and ongoing when the resident/student leaves the institution prior to completing the scholarly activity/project.
4. Ensure that the resident/student is provided with, or has access to, information on CFVHS policies relating to administration of their protocol.
5. Assure the resident/student understands the underlying ethical principles for conducting scholarly activities/projects with human participants and the applicable local policies and procedures. Stay abreast of the status of the protocol and ensure on-going compliance with federal regulations and institutional policies and procedures relating to human participants/HIPAA covered information and required reporting.
6. Advise and assist resident/student with the preparation of abstracts, poster presentations and papers, as applicable.
7. Ensure that all project documents and data are archived at the end of the project in accordance with federal, state, and local policy and regulations.
8. Be available to the resident/student during the active project period.

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| * **I confirm that I have read this document and reviewed this project submission and approved for submission to the GME Research Program.**
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