1 PURPOSE

1.1 This guidance describes the obligations of Principal Investigators conducting human research overseen by FAU's local IRB.

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2.1 Do not commence research until you have the IRB approval letter and obtained all other required approvals, such as radiation safety approval, biosafety approval, and approvals of departments or divisions that require approval of the use of their resources.

2.1.1 If there are any questions about whether you are conducting research involving human subjects, submit form Human Subjects Research Determination (Form 106) and wait for the IRB's determination before commencing the study.

2.2 Comply with all requirements and determinations of the IRB, as well as Federal, state, and local laws, regulations. initial human subjects

research protection training and continuing training at least every three years.

2.4.2 If the s

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2.23 Update the IRB with any changes to study personnel.

2.24 If you are the lead investigator of a multi-site study, ensure there is a plan to manage information that is relevant to the protection of subjects such as unanticipated problems involving risks to subjects or others, interim results, and protocol modification, and submit the plan to the IRB with your protocol.

3 REFERENCES

3.1 §56

3.2 45 CFR 46