

PRACTICE AGREEMENT FOR RESEARCH PRINCIPAL INVESTIGATORS

By signing below, I agree / certify that:

1. I will protect the rights and welfare of human subjects

- a. Understand and uphold the regulatory, institutional, sponsor and protocol requirements of the study including adherence to Good Clinical Practice guidelines;
- b. Complete IRB human subject protection training as required;
- c. Comply with all MultiCare Health System (MHS) and IRB policies and reporting requirements;
- d. Follow all Federal regulations (e.g. Dept. of Health Human Services, FDA, etc.);
- e. Comply with the HIPAA regulations and requirements to protect subject privacy.

2. I will follow the rules and regulations for conduct of research at MHS

- a. Conduct each research study in strict accordance with all submitted statements;
- b. Review and approve billing compliance assessments to identify charges that are to be billed to the study, patient or third party payers prior to the enrollment of subjects;
- c. Ensure adequate resources and facilities to carry out the proposed research;
- d. Perform and supervise procedures within my scope of practice, training and licensure;
- e. Ensure current and accurate records of research source documentation, data, and outcomes are maintained;
- f. Consent to an audit of any research records to assure compliance with all applicable regulations and policies;
- g. Train appropriate staff involved in any aspect of the conduct and management of the study.

3. I will guarantee appropriate administration of the informed consent process

- a. I will not enroll any individual into any research study without documentation of current IRB approval;
- b. I will not enroll any individual into any research study until their written informed consent has been obtained; or, if applicable, the written informed consent of their authorized representative;
- c. Discussing all aspects of study participation with potential subjects, answering all questions and allowing the subject time to review the consent form;
- d. Always using the correct IRB approved consent form;
- e. Ensuring that all signatures, dates and times in the consent form are filled in appropriately;
- f. Documenting the consenting process in the patient's medical records.

Signature

Date

Printed Name