1. PURPOSE

To provide an organizational framework for clinical research team members responsible for clinical research trial management.

2. SCOPE

This Policy applies to any clinical departments conducting clinical research studies and clinical trials (herein referred to as "clinical research study") within GWU. This Policy establishes OnCore as GWU MFA's Clinical Trial Management System (CTMS).

3. RESPONSIBILITY

This Policy sets forth the requirements for creating protocol records, uploading and maintaining a clinical research study in OnCore by the Office of Clinical Research (OCR)

4. POLICY

GENERAL

- OnCore is considered the source of truth for clinical trials and is the required CTMS for the GWU academic medical enterprise.

- GWU Clinical research teams (including, but not limited to Principal Investigators, co-investigators, sub-investigators, study coordinators, research associates, research assistants, department administrators, and other research staff) have a responsibility to ensure that clinical research studies that are industry sponsored, federally funded, funded, or investigator initiated be uploaded maintained and managed in OnCore. The study record in OnCore must be maintained and up to date with all current standings.

- Clinical research teams are individually responsible for understanding this policy, participating in any required training, fulfilling recordkeeping requirements, seeking clarification when questions arise and responding in a timely manner to requests for information associated with internal audits and investigations.