MEDICAL COLLEGE OF WISCONSIN CANCER CENTER

Cancer Center Clinical Trials Office

GLOSSARY OF COMMON TERMS AND DEFINITIONS	
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Amendment**:** Any change or modification to an IRB approved project that is made after the initial IRB review and approval.

CPR: Continuing Progress Review; A renewal of the research study by the IRB, usually annual.

Contract: An agreement between Sponsor, Institution and PI.

CCCTO: Cancer Center Clinical Trials Office

CCCTO Budget Office: Cancer Center Clinical Trials Office staff including the financial analyst, financial assistant, and business manager.

DSMB/DSMC: Data Safety Monitoring Board/Committee; an independent group of experts who monitor patient safety and treatment efficacy data while a clinical trial is ongoing.

eBridge**:** FH/MCW IRB electronic study management system. This website allows the MCW faculty and researcher staff to submit, track, report and archive applications involving funding proposals as well as human subject and animal research conducted at MCW.

Employee: CCCTO Staff member

FH: Froedtert Hospital

Grants & Contracts Office: MCW Grants & Contracts Office Staff, including Director of Grants & Contracts and Senior Dean of Research and their supporting staff.

ICF: Informed consent form; an IRB approved document disclosing the risks, benefits, and alternatives of a research study.

MCW: Medical College of Wisconsin

OnCore: Electronic Clinical Trials Management Software.

PI: Principal Investigator; the physician designated to oversee the research project.

Protocol Deviation: any departure from the study design or procedures defined in the IRB-approved protocol.

Regulatory Staff: CCCTO staff member or members overseeing the regulatory aspects of the study (including IRB submissions, regulatory documents, and other tasks as assigned).

Sponsor(s): The entity that oversees the global conduct of the clinical trial, or their designated affiliates.

Study Staff: Any/all staff members of the CCCTO, Physician Investigators in their respective departments, and their supporting staff that are involved in the conduct of a clinical research trial.

Supervisor: Research Manager, Team Lead, or Administrative Director of the CTO

Study/Studies: CTO clinical trials, IITs, chart-review protocols. These include pending, active, active for follow up, or trials open for data analysis only.

Study Coordinator: CCCTO staff member that is responsible coordinating the study.

UPIRSO: Unanticipated Problem Involving Risks to Subjects or Others; Any incident, experience or outcome that meets all of the following criteria:
1.) Unexpected (in terms of nature, severity, or frequency)
2.) Related or possibly related to participation in the research
3.) Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.