Glossary

Clinical Trial/Study: Any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy, an/or to investigate the characteristics of novel imaging methods.

Code Blue: Occurs when a person (volunteer/patient or experimental support personnel) is found to be not responding, not breathing AND has no pulse.

Data Coding: The practice of removing all personal identifying information from an image or data set and replacing it with an anonymized identification number that cannot be traced back to a particular individual without a key.

Facility Co-Directors: The individuals who provide overall scientific and operational direction to the Centre for Translational Radiographic Research, and supervise the core facility staff. At present, these individuals are Dr. David Holdsworth and Dr. Matthew Teeter.

Facility Manager/Technologist: The operational manager of the CTRR facility, and also the senior X-Ray Technologist for the core facility. At present, this individual is Mr. Rudy Baronette.

Incidental Pathological Finding: Any finding in an image or data set that is anomalous or unexpected for the study.

Investigator: An individual who conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of the team.

Operator: An individual who has completed level two of the CTRR training and is operating the radiographic equipment.

Personal Health Information Protection Act: PHIPA is legislations that outlines privacy regulations for health information custodians in Ontario. These acts regulate the collection, use and disclosure of personal information, including materials pertaining to one's healthcare.

Personal Information Protection and Electronic Documents Act: PIPEDA is a Canadian law relating to data privacy. It governs how private sector organizations collect, use, and disclose personal information in the course of commercial business. The act contains various provisions to facilitate the use of electronic documents.

Pre-Clinical Trial/Study: Any investigation in laboratory animals intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational

product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy, an/or to investigate the characteristics of novel imaging methods.

Principal Investigator (PI): The lead scientist or engineer for a particular well- defined science (or other research) project, such as a laboratory study or clinical trial. It is often used as a synonym for "head of the laboratory," not just for a particular study. In the context of USA federal funding from agencies such as the NIH or the NSF, the PI is the person who takes direct responsibility for completion of a funded project, directing the research and reporting directly to the funding agency. For small projects (which might involve 1-5 people) the PI is typically the person who conceived of the investigation, but for larger projects the PI may be selected by a team to obtain the best strategic advantage for the project. In the context of a clinical trial a PI may be an academic working with grants from NIH, other funding agencies, or may be effectively a contractor for a pharmaceutical company working on testing the safety and efficacy of new medicines.

Qualified Investigator: The person responsible to the sponsor for the conduct of the clinical trial at the clinical trial site, who is entrusted to provide health care under the laws of the province where that clinical trial site is located, and who is a physician and a member in good standing of a professional medical association.

Radiologist: A physician whose specialization is to use a variety of medical imaging techniques to diagnose and treat disease.

Standard Operating Procedures (SOPs): Detailed, written instructions to achieve uniformity of the performance of a specific function.

Support Staff: Any person who assists with a research project.

Visitor: Any person without security access to the Facility, and/or not participating in the current experiment.

Volunteer/Subject/Patient: Any person being imaged in the CTRR Facility as part of an ethics approved research study. A person is still to be treated as a volunteer/patient when being scanned, even if they are involved in the study (or another study at the Facility) as investigator or experimental support personnel.

X-ray Technologist: A regulated health care professional who employs ionizing radiation to create images that are part of diagnostic imaging examinations under an exemption set out in a regulation made under the Regulated Health Professions Act.