

Office of Clinical Trials Research

Initial Credentialing Procedure for UVM Personnel Engaged in Clinical Research at the University of Vermont Medical Center

Clinicians and support personnel carrying out diagnosis, prognosis or treatment of patients at the University of Vermont Medical Center are credentialed through standardized protocols administered by the UVM Medical Center Medical Staff Office. However, UVM Medical Center is also committed to support and further medical research, much of which takes place on volunteers or patients within the UVM Medical Center system. Personnel involved in such clinical research can include physicians, nurses, nurse practitioners, physician's assistants, ancillary medical staff, non-physician investigators (e.g. PhDs), clinical research coordinators, participant recruiters, research laboratory technicians and data managers. The purpose of this policy is to establish a standard baseline credentialing process for all individuals involved in clinical research at the UVM Medical Center. In addition, and depending on the skill level and complexity of the research process, certain individuals involved in clinical research may be required to provide additional evidence of training and competency to be credentialed for more complex research procedures.

Definitions

Clinical and translational research includes laboratory-based research and research in human subjects, populations and communities. Translational research, bench to bedside/laboratory to human, includes laboratory-based research aimed at clarifying mechanisms of disease, developing measures or markers of disease presence, severity or improvement, and developing drugs or devices to treat disease or improve health. Clinical research includes studies in human subjects including surveys, cross-sectional studies, case series, case-control studies, first-in-human, proof of principal, observational, obtaining tissue or blood for laboratory studies and all phases of clinical trials. Translational research, bedside to the community/evidence to practice, includes studies that: identify community, patient, physician and organizational factors that serve as barriers and facilitators to translation; develops novel intervention and implementation strategies to increase translation, such as quality improvement programs or policies; and evaluates the impact of strategies to increase translation of relevant healthy behaviors and processes of care. Clinical Research is defined as the pursuit of generalizable and publishable new knowledge.

Direct clinical contact: In the context of clinical research activities, direct clinical contact is defined as talking with or otherwise interacting with a patient who is a participant or volunteer as part of the performance of clinical research.

Credentialing for Clinical Research Activities

Clinical research frequently involves the collection of information or data, some of which is obtained by direct measurement of various patient parameters. The level of patient contact/interaction and complexity of these procedures, the degree of risk and the necessary training to perform these procedures is quite variable. Accordingly, these activities are classified into three levels.

Level I: Administrative and technician level responsibilities which involve activities with minimal contact with study participants. Examples of minimal risk activities include but are not limited to the following:

- Scheduling participants for research related visits
- Prospective collection of biological specimens for research purposes by noninvasive means
- Collection of data through noninvasive procedures

- Research involving materials (data, documents, records, or specimens) that have been collected or will be collected for non-research purposes (such as medical treatment or diagnosis).

Level I procedures can, in addition to being carried out by clinically-trained staff, also be performed for research purposes by appropriately trained Research Coordinators or Research Technicians or other personnel. In such cases, training must be provided or obtained and substantiated with evidence of training and wherever possible, documentary evidence such as certificates of completion should be maintained in the employee records.

Prior to initiating patient contact in a clinical research protocol, all personnel will be required to have a research credentialing file created and routinely maintained by the Principal Investigator or administrative supervisor, on file with the Office of Clinical Trials Research which contains:

- Job Description.
- CV or resume detailing their experience and training.
- Documentation of completion of CITI training for Protection of Human Subjects in Research Tutorial, Human Subjects tutorial for clinical research, and Good Clinical Practices..
- Documentation of completed UVM Medical Center mandatories in the eLearn system concordant with the individual's role and level of responsibility being performed (Appendix 1)
- Acknowledgement that they have read and understand the UVM Medical Center "Grievance Policy -OPFA 100".
- Completion of the UVM Medical Center Non-Employee Confidentiality Agreement.
- Copies of any position-specific credentialing or licensure, as appropriate for level.
- Evidence of an annual evaluation with documentation of ongoing competency or an Appointment letter.

The responsibility for updating this file belongs to the researcher and a complete and current version must be on record with the OCTR office or the employee cannot participate in any clinical research. Once the file is deemed complete and current by the OCTR, UVM Medical Center Human Resources will issue a badge to the UVM employee. This badge will expire annually on June 30th to coincide with the UVM fiscal year. In order to obtain a new badge, the file contents will need to be current and deemed completed by OCTR.

Additional Credentialing for More Complex Clinical Research Activities

Level II: Specialized research staff and faculty with specific training and experience responsibilities. Examples of moderate or prolonged patient contact activities (e.g. study visits) include but are not limited to the following:

- Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture,
- Resting metabolic rate,
- Functional testing or measurement of muscle strength,
- Lung function testing,
- Dual emission x-ray absorptiometry,
- Ultrasound examinations and neuropsychological testing

Evidence of training, experience and maintenance of the skill set including documentation of certification must be maintained in the employee record.

Level III: Procedures may only be carried out by licensed clinical or credentialed professionals such as Physicians, Physician's Assistants, Nurse Practitioners, and Nurses. Clinical professionals applying for

privileges to undertake these research procedures will generally be clinicians with previous subspecialty training in the procedure in question and substantial experience in its performance.

Examples of Level III procedures include, however are not limited to, the following:

- Administration of experimental drugs,
- Muscle or fat biopsy,
- Hyperinsulinemic euglycemic clamps
- Exercise testing in the elderly or in subjects with a known history of cardiovascular disease,
- Bronchoscopies,
- Colonoscopies, and studies involving functional magnetic resonance imaging.

Some research procedures are rarely performed for clinical purposes (e.g. hyperinsulinemic euglycemic clamp or fat biopsy) and in such cases clinical professionals will receive training from other credentialed research staff or in certain instances be sent for training to other research centers wherein the procedure is routinely performed. In all cases, evidence of training and competency will be required to be submitted to the Medical Staff Office to support the request to perform such research procedure. The individual performing at this level will be required to have been credentialed through the formal UVM Medical Center medical staff credentialing process.

APPENDIX I - UVM Medical Center Mandatories *(to be completed by level role or responsibility)*

Level I- Administrative and technician level:

- General Safety
- Emergency Management
- Fire Safety
- Hazard Communications
- Privacy
- Patient Safety
- Bloodborne Pathogens
- General Infection Prevention
- Information Security

Level II- specialized research staff with specific training and experience

Level III - licensed clinical professionals such as Physicians, Physician's Assistants, Nurse Practitioners and Nurses: (Same as Level I – plus these additional modules to be taken):

- Victims of Abuse
- Age Specific
- Integrity and Compliance
- Utilities Main Campus

Link to UVM Research Credentialing – [New Checklist](#)