Massachusetts General Hospital *Translational and Clinical Research Centers*	**Standard Operating Procedure**	Effective Date: 12/7/2016 Reviewed: 1/20/19 Version: 1.4

Translational and Clinical Research Centers (TCRC)
Delegation of Responsibilities, Training and Record Keeping

1. OBJECTIVE

1.1. To describe the process for delegating responsibilities, maintain regulatory documents and TCRC staff training

2. SCOPE

2.1. This SOP applies to the delegation of study-specific activities, TCRC staff training and record keeping.

3. DEFINITIONS/ABBREVIATIONS

3.1. **TCRC Staff:** TCRC staff, including Nurse Practitioners (NP), Registered Nurses (RN), Registered Dietitians (RD), laboratory personnel and support staff responsible for carrying out activities of the study.
3.2. **CNS/NPS:** Clinical Nurse Specialist/Nurse Practice Specialist
3.3. **Delegation Log:** Log utilized by PI to record when and to whom study responsibilities have been delegated.
3.4. **Doctor's Orders:** All standard Doctor's Orders (paper and electronic) for a study.
3.5. **MNR:** Metabolism & Nutrition Research department of the TCRC.
3.6. **ND:** Nurse Director
3.7. **Principal Investigator:** Principal Investigator (PI) of a study.
3.8. **Study Staff:** All members of the Principal Investigator's research team, including Principal investigators, Co-investigators and study coordinators.

4. RESPONSIBILITIES/PROCEDURES

4.1. TCRC Staff are responsible for performing protocol-dictated research activities and attendant clinical activities according to their job roles and as allowed by their scope of practice, licensure and/or job description.
4.2. TCRC licensed clinical staff (Nursing, MNR) may delegate activities to other staff, as appropriate.
4.3. Nursing and MNR Directors along with the unit CNS/NPS are responsible for ensuring competencies and training are completed and documented.
4.4. The TCRC Nursing and MNR Directors are responsible for the integrity and accuracy of study-specific activities performed by their staff.
4.5. The study PI is responsible for overall conduct of the study.
4.6. As indicated, the PI is responsible for training of TCRC staff members in study-specific activities, as necessary, or may delegate this responsibility to the CNS/NPS, Nursing Director or MNR Director to ensure proper understanding and conduct of the study.

4.7. The PI may delegate activities to designated TCRC staff (NP, RN, RD) members. The PI or designee will conduct the study visit, based on the current set of ***approved*** Doctor's Orders.

4.7.1. The designated TCRC staff member(s) will carry out activities or delegate where appropriate, following the most recently approved and signed Doctor's Orders.

4.7.2. Study staff and TCRC staff will keep records of all study-related activities in Medical Records, EPIC or other documents as appropriate.

5. DELEGATION LOG

5.1. Delegation log – to be signed by ND and CNS/NPS on behalf of NP/RN staff, MNR Director on behalf of nutrition staff, and Laboratory Supervisor on behalf of laboratory staff.

5.2. MGH TCRC staff are MGH employees and as such are not required to be added as study staff with the IRB

6. TRAINING AND LICENSURE REQUIREMENTS

6.1. Staff licensure(s), credentials, CV, CITI/GCP training and associated clinical and/or non-clinical competencies are maintained by ND/MNR Director and unit CNS/NPS, as per MGH policies and procedures.

6.2. Regulatory document binder will be reviewed every 2 years. The date of document collection will be noted on the front of the binder(s). This is for items that do not routinely expire and have a date (CV)

6.3. It is the TCRC staff's responsibility to provide the Nurse Director with licensure, certification, CITI/GCP documents as they are renewed.

6.4. Copies of staff regulatory documents are not provided to study teams unless the TCRC staff are listed as study staff with the IRB. For example, NPs who are consenting and are listed as study staff or Co-Is and on the delegation log.

6.5. TCRC contact information, email address, etc. will not be provided to entities outside of Partners.

6.6. TCRC leadership maintains staff training logs. This includes HealthStream, Training Tracker and in person trainings. These can be made available for review by sponsors, monitors, etc. as needed.

6.7. For online training modules, TCRC Nursing and Nutrition leadership (who sign the delegation log on behalf of staff training) will access and review study specific training module(s) on behalf of TCRC staff.

6.8. Study specific trainings, be it web based or clinical skills training can be

reviewed in a group format with applicable staff (RN, RD, Technician, Lab) utilizing sponsor specific training materials. Multiple trainings may take place. Attendance at such trainings will be recorded

6.9. Trainings will be uploaded to the TCRC secure "training tracker", staff will access, review and attest to their completion and understanding

6.10. Auditing of completion and attestation of staff training can be provided to study teams/sponsors upon request

7. REFERENCE(S)

7.1. TCRC Memorandum: Regarding TCRC staff licensure, trainings and competencies