105.1 TRAINING, CREDENTIALS, AND CERTIFICATION OF RESEARCH PERSONNEL

I. PURPOSE

To describe the training, credentials, and certifications required of all research personnel before their participation in clinical research.

II. SCOPE

This SOP applies to all research personnel who have direct contact with research subjects:

- Principal Investigators
- Study Coordinators
- Co and Sub Investigators
- Other staff who have a significant role in the research project

III. REGULATIONS/GUIDELINES

- NIH Guide Notice: OD-00-039 states "the NIH requires education on the protection of human research participants for all investigators…involving human subjects"
- International Conference on Harmonization – Guidelines for Good Clinical Practice E6(R1) 4.1.1 states "The investigator should be qualified by education, training, and experience to assume responsibility for the proper conduct of a trial, should meet all the qualification specified by the applicable regulatory requirement(s), and should provide evidence of such qualifications through up to date curriculum vitae and/or other relevant documentation requested by the sponsor, the IRB, and or regulatory authority(ies)".

IV. ROLES/PROCEDURES

1. The Principal Investigator and all co- or sub-investigators will provide GSM Research Leadership access to, if needed, up to date copies of the following documents prior to participating in clinical research, which will be filed within applicable protocol regulatory binders (Essential Trial Documents) prior to study initiation:
    a. Curriculum Vitae
    b. Medical Licensure if applicable
    c. CITI Human Protection Certificate of Completion
    d. Financial Disclosures if applicable
    e. Conflict of Interest if applicable

2. Research Study Coordinators will maintain up-to-date copies of the following documents prior to initiation of any GSM clinical research protocol, which will be filed with applicable Essential Trial Documents prior to study initiation:
    a. Curriculum Vitae or Resume
    b. Professional Licensure
    c. CITI Human Protection Certificate of Completion
    d. Financial Disclosure (if applicable)

e. Certification of IATA – Dangerous Goods Shipping training (if applicable)

3. Ancillary personnel who have a significant role in the research study will provide the study coordinator with up-to-date copies of the following documents prior to participating in clinical research, which will be filed within the Essential Trial Document binder prior to study initiation:
   a. Curriculum Vitae or resume
   b. Professional Licensure
   c. CITI Human Protection Certificate of Completion
   d. Financial Disclosure (if applicable)
   e. Conflict of Interest (if applicable)

4. The Principal Investigator will ensure the proper training of all study team members. Documentation of protocol and procedural training (including any amendments) on a training log for all members of the study team will be completed and filed within the trial binder.

   The training log should include:
   a. Name of trainee
   b. Date of training
   c. Training topics
   d. Methods of training
   e. The name of the person providing the training
   f. Signatures for trainee and trainer

APPROVED:

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Director of Research, Graduate School of Medicine — Date

Paul J. Hauptman, MD — 09/23/2021
Dean, Graduate School of Medicine — Date