

**Cell Manipulation Core Facility
New Cell Therapy Development and Review Policy**

In order to facilitate the development of manufacturing procedures and to ensure compliance with FDA and FACT regulations, all new cellular products processed in the CMCF under a new IND or IDE will be reviewed in accordance to the **New Cell Therapy Development and Review Policy**.

The policy will consist of:

- A. Acquire the following documents from the PI or sponsor of the clinical trial for review
 1. IND/IDE approval letter from FDA
 2. Pertinent sections of CMC (Chemistry, Manufacturing, and Control Data) from the IND with description of the procedures
 3. Investigators Brochures
 4. SOP for product processing provided by the sponsor of the protocol
 5. Copy of clinical protocol (can be in draft format if pending IRB submission)
 6. Copies of ongoing IND/IDE amendment letters to FDA
- B. Training and development of CMCF standard operating procedure (SOP)
 1. Review of clinical protocol, IND/IDE or SOP provided by the PI or sponsor.
 2. Developing CMCF SOP and product COA (Certificate of Analysis) based on onsite training provided by the sponsor of the clinical protocol.
 3. Perform validation runs.
 - a. The procedures must be performed within CMCF.
 - b. For products manufactured outside of CMCF but to be stored or issued by CMCF, the validation run will include procedures for product packaging, shipping, labeling, and receiving.
- C. Requirements for patient enrollment
 1. Obtained records stated in section A.
 2. Complete qualification of all research grade reagents used during product manufacturing.
 3. Complete a minimum of three successful validation runs with data reviewed and approved by CMCF Technical Supervisor, QA Manager, Technical Director, Assistant Medical Director, and Director.
 4. Finalized CMCF SOP and COA based on successful validation runs that are approved by CMCF Technical Supervisor, QA Manager, Technical Director, Assistant Medical Director, and Director.
- D. Adverse event reporting of infused cellular products.
 1. All non-conforming products released by CMCF will be approved by both the protocol PI and CMCF Assistant Medical Director/ Director.
 2. All infusion related reactions should be documented and/or reported to CMCF.
 3. CMCF should be notified of any product related patient adverse event that is reported to IRB or FDA.