



Standard Operating Procedure for ***VERIFICATION OF SCRO, IACUC, IBC AND IRB APPROVALS***

1.0 PURPOSE

The SOP is designed to show how each Core Facility will ensure that all work is done with appropriate SCRO (Stem Cell Research Oversight) , IACUC (Institutional Animal Care and Use Committee) , IBC (Institutional Biosafety Committee) and IRB (Institutional Review Board) approval for both the Cores and all involved investigators (clients).

2.0 SCOPE

This SOP applies to all Directors and Managers of Core Facilities and will be performed for each service rendered by the Cores.

3.0 PROCEDURE

- 3.1 Since the 4 Core facilities differ in their requirements for regulatory approval the procedures for each will be indicated separately below. All records of services performed will be kept and maintained for a minimum of 4 years by each core facility as required by the UB Service Centers regulations.
- 3.2 SCCF, Stem Cell Culture and Training Facility. All training in cell culture will be performed under the general SCRO approval for training for the Core Facility, renewed annually. All cell lines will be treated as hazardous with appropriate containment due to possible viral/mycoplasma infection. A copy of the SCRO approval and any needed SCRO cell line registration will be obtained by the Core Director or Manager and sent to and kept as an electronic record at the WNYSTEM Administration office.
- 3.3 iPSF, induced Pluripotent Stem Cell Facility. The generation of iPS cells will be performed under IRB approval obtained by each client who wishes to use the iPSF services. Each client will obtain their own IRB approval for research subject sample recruitment and the iPS facility will only culture the cells obtained and generate iPS clones from the cells which does not require IRB or SCRO approval. All cell lines generated will be registered by the client in the SCRO cell registry. All viruses generated by or used by the iPSF will be listed in the Recombinant DNA data sheet registered with UB IBC as required by EHS policy. A copy of the client IRB approval, UB-EHS approval, and cell line registration will be obtained by the Core Director or Manager and sent to and kept as an electronic record at the WNYSTEM Administration office.
- 3.4 SCEF, Stem Cell Engraftment Facility. The SCEF will maintain an IACUC approval for cell engraftment, behavioral testing, mouse sacrifice and histochemical analysis of mouse tissues. Individual clients will be added as needed to this protocol when they have any contact with experimental animals generated by the SCEF. Individual IACUC approvals will be obtained by each client if needed for their project and a copy of each such IACUC approval and the Core IACUC approval will be obtained by the Core Director or Manager and sent to and kept as an electronic record at the WNYSTEM Administration office. For human pluripotent stem cell engraftment copies of the SCRO approval letter will be obtained from the client and sent to and kept as an electronic record at the WNYSTEM Administration office.

- 3.5 SCSF, Stem Cell Sequencing/Epigenetics Facility. The SCSF will perform analysis on DNA and RNA samples obtained from individual clients. For samples obtained from human tissues, tumors, hiPSCs and hESCs (but not standard human cell lines) copies of each client SCRO cell line registration or IRB approval for human sample collection will be obtained by the Core Director or Manager and sent to and kept as an electronic record at the WNYSTEM Administration office.
- 3.6 WNYSTEM Administration. The WNYSTEM Administration will keep copies of each SCRO, IACUC IBC or IRB approval from each core facility and will label each electronically with labels that include the Core (SCCF, iPSF, SCEF or SCSF), the type of approval/registration (SCRO, IACUC, IBC, IRB) the client name if needed and the date obtained in the format (CCCC.(SC,IC,IB,IR).Name.date (MO-DA-YR). If materials are passed from one core to another (e.g. iPSF to SCEF or SCSF) then copies of the appropriate approvals will be generated as needed and labeled appropriately. Separate copies of the approvals will be kept for each core facility service used. These will be kept available for review as needed by NYSTEM administration.

Created by Richard Gronostajski, 10/31/11.

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