A PI plans to obtain a human pluripotent stem cell line[1] from a collaborator at another University[2] to derive a mini-brain model that will be transplanted into a monkey brain[3] at Johns Hopkins and shared back with the collaborator[4] who provided the cell line.

1

JHM IRB: Institutional Review Board

The IRB is responsible for reviewing all research projects that involve human biospecimens. This includes cell lines derived from human cells.

ISCRO: Institutional Stem Cell Research Oversight

Because the PI intends to transplant a mini-brain model that was derived from a human pluripotent cell line into a monkey brain, ISCRO approval is required. See the following ISCRO jurisdiction:

- Research using other hPSCs (e.g. iPSCs, hEGCs), where research involves:
  - Introduction of such cells into the central nervous system of non-human primates

IBC: Institutional Biosafety Committee

Research using human-derived tissue must be registered with Biosafety Office.

2

ORA: Office of Research Admistration

The ORA oversees the research-related agreements, including incoming and outgoing Material Transfer Agreements, which are necessary for the PI to receive the cell line and send back the model with and from the collaborator.

3

ACUC: Animal Care and Use Committee

ACUC review is necessary because the PI plans to transplant a model derived from human cells into a monkey.

4

JHM IRB: Institutional Review Board

Because the PI plans to share back their biospecimen with the collaborator, they must request approval to send study data or specimens to an outside site. This is reviewed by the Biospecimens Transfer Committee, but approval is requested through the IRB application.

BTC: Biospecimens Transfer Committee

The BTC is an ancillary review committee that reviews requests to send biospecimens transferred to outside entities. Requests are sent through the IRB application.

A PI plans to use Somatic Cell Nuclear Transfer (SCNT)[1] with a commercial somatic cell line[2] and an oocyte obtained from an IVF clinic[3] to derive a human embryonic stem (hESC) line.[4]

1

ISCRO: Institutional Stem Cell Research Oversight

All research involving SCNT involving human cells requires approval from ISCRO. See the following under ISCRO jurisdiction:

- All research involving somatic cell nuclear transfer involving stem cells

2

Office of Procurement Services

The commercial cell line may be acquired through Procurement.

IBC: Institutional Biosafety Committee

Research using human-derived tissue must be registered with Biosafety Office.

JHM IRB: Institutional Review Board

The IRB is responsible for reviewing all research projects that involve human biospecimens. This includes cell lines derived from human cells.

3

REITC: Reproductive Endocrinology and Infertility Tissue Committee

The REITC is an ancillary committee triggered through the IRB application that reviews the procurement of human embryos, eggs, or sperm. The REITC also evaluates whether the proposed research using such material should be conducted.

4

ISCRO: Institutional Stem Cell Research Oversight

ISCRO approval is required because the PI plans to derive a hESC line. See the following under ISCRO jurisdiction:

- All research using human embryonic stem cells

A PI plans to transfer a human stem cell line she generated[1,3] and licensed to an Outside Company[2,3] for development of a novel assay.

1

JHM IRB: Institutional Review Board
An IRB application is necessary to determine whether provenance of the cell line was appropriate, to ensure review of FDA requirements for development of the assay, and to include review by the Biospecimens Transfer Committee.

BTC: Biospecimens Transfer Committee
The BTC is an ancillary review committee that reviews requests to send biospecimens transferred to outside entities. Requests are sent through the IRB application.

2

COI: Committee on Outside Interests
To facilitate review of financial interests in research and to comply with federal regulation, faculty members and all investigators must disclose personal financial interests that reasonably appear to be related to their institutional responsibilities. Detailed disclosure requirements can be found here. Because the PI plans to transfer a line she generated and licensed for financial interests, she must disclose her plans to the COI within 30 days of acquiring or discovering the offer.

JHTV: Johns Hopkins Technology Ventures
Because this is a licensed technology, JHTV may also need to review the transfer plans to determine if any licensing issues are triggered.

3

CRC: Clinical Research Contracting
The CRC oversees the negotiation of all commercially sponsored clinical research. Because the PI plans to transfer the human stem cell line she generated to an Outside Company, she should do so through the CRC.

A PI plans to use placental tissue[1] obtained prospectively[2] in order to derive an induced pluripotent stem cell line[3] to study Fabry disease.

1

MFMTC: Maternal Fetal Medicine Tissue Committee
Because the PI plans to use placental tissue, their research proposal must be reviewed by the MFMTC, which evaluates all proposed research protocols involving fetal tissue, cord blood, or placenta.

IBC: Institutional Biosafety Committee
Research using human-derived tissue must be registered with Biosafety Office.

2

Pathology (Tissue/Specimen Use Committee)
Pathology will review the PI's request for the prospective collection of the tissue obtained as part of a clinically indicated treatment of diagnostic process.

3

JHM IRB: Institutional Review Board
The IRB is responsible for reviewing all research projects that involve human biospecimens. Because the PI plans to use human (placental) tissue, their research project must be reviewed by the IRB. The IRB will also determine whether the cell line derivation is consistent with JHU policy.