SOP 502I: Human Cell Lines & Cloned DNA/RNA

1. POLICY

The IRB shall review research utilizing human cell lines or cloned DNA and RNA from which the original donors may be readily identified, including materials that retain links, such as a code, to the original source material.

The IRB / Privacy Board, reviews research involving established human cell lines and human cloned DNA/RNA from which the identity of the donor(s) can be readily ascertained by the investigator. See SOP 1001 for Privacy Board policy information.

Specific Policies

1.1 Identifiable Human Cell Lines or Human Cloned DNA/RNA

Research involving human cell lines or human cloned DNA/RNA where the donor(s) may be readily identified, including materials that retain links, such as a code to identifying information is generally considered human participant research because the donors are human participants. IRB approval is required for such research.

1.1.1 In vitro research and research in animals using already established human cell lines or human cloned DNA/RNA that retain a link to identifying information ordinarily would not be considered human participant research if: (1) the investigator and the University do not have access to identifiable private information related to the cell line or cloned DNA/RNA; and (2) a written agreement is obtained from the holder of the identifiable private information related to the material stating that such information will not be released to the investigator under any circumstances. In this case, the research may be considered not to involve human participants because the identity of the donor(s) could not be readily ascertained by the investigator or associated with the material. In these cases, IRB review of research using the cell line or cloned DNA/RNA is not required.

1.1.2 In some cases, an investigator who obtains coded private information or specimens about living individuals that have not previously required IRB review may (1) unexpectedly learn the identity of one or more living individuals or, (2) for unforeseen reasons now believe that it is important to identify the individuals. If, as a result, the investigator knows or may be able to readily ascertain the identity of the individuals to whom the previously obtained private information or specimens pertain, then the research activity now involves human participants and requires IRB approval before continuation.

1.2 Unidentifiable Human Cell Lines or Human Cloned DNA/RNA

*In Vitro* research and research in animals using unidentifiable cell lines or unidentifiable human cloned DNA/RNA is not subject to IRB review.
2. SCOPE

This SOP applies to all research that involves cell lines and cloned DNA/RNA.

3. RESPONSIBILITY

3.1 The HRPP Director is responsible for maintaining up-to-date review tools for review of research pertaining to cell lines and cloned DNA/RNA based on new and evolving applicable regulations and guidelines and must notify the appropriate entities if the IRB disapproves the research project.

3.2 The IRB Chair or IRB designee is responsible for providing IRB members with adequate submission review training and ongoing guidance and for selecting primary and secondary reviewers with the relevant expertise to perform reviews and make necessary recommendations on approval decisions by the IRB. If the IRB Chair or IRB designee cannot select primary and secondary reviewers with the relevant expertise, the IRB Chair or IRB designee defers the review to another IRB with primary and secondary reviewers with the relevant expertise or obtains consultation for that expertise.

3.3 The IRB Chair is responsible for conducting appropriate review of research planned for this category in consultation with any appropriate experts and resources.

3.4 The IRB is responsible to assure there are adequate safeguards for the confidentiality of the participant.

3.5 The IRB Administrator is responsible to request changes from the investigator and send the results of the IRB review to the investigator.

4. APPLICABLE REGULATIONS AND GUIDELINES

45 CFR 46
21 CFR 50, 56
OHRP Guidance Document, IRB Guidebook

5. REFERENCES TO OTHER APPLICABLE SOPs

SOP 301: Research Submission Requirements

SOP 403: Initial Review – Criteria for IRB Approval

SOP 1001: Health Insurance Portability and Accountability and Accountability Act (HIPAA Privacy Rule) – Privacy Board

6. ATTACHMENTS

301-A IRB Application

203-A HSC Reviewer Checklist
7. PROCESS OVERVIEW

7.1 Research involving human cell lines and cloned DNA / RNA is submitted to the IRB using the electronic information system and indicating the use of human cell lines. This activity typically does not qualify as human participants research if the identity of the original donor of the cell lines cannot be ascertained.

7.2 The submission is received in the IRB Office and processed (see SOP 301: Research Submission Requirements and SOP 403: Initial Review – Criteria for IRB Approval). The IRB Administrator conducts a pre-review of the submission and verifies all necessary documents are received.

7.3 The IRB Chair or IRB designee reviews the research project submission on behalf of the IRB to determine the risk level of the research and potential health information disclosures. The IRB Chair or IRB designee determines if the investigator’s assessment of potential review by the Institutional Biosafety Committee (IBC) is appropriate. If the IRB Chair or IRB designee determines IBC review is required, the IRB Administrator notifies the investigator and the IBC of this determination.

7.4 The IRB review process is not finalized until the IRB receives notification of IBC review. The IRB Administrator then forwards the research project submission and IBC determination to the IRB Chair or IRB designee for final approval.

7.5 Following review of the submission, the IRB Administrator updates the outcome of the IRB review and communicates the outcome and any stipulations to the Investigator. The IRB Administrator posts the final IRB determination to the next appropriate IRB agenda.

7.6 Enrollment into the research project may not commence until all required institutional committees have completed their review and the contract is signed, if applicable.

APPROVED BY: __________________________ DATE: 08/31/2014

NEXT ESTABLISHED REVIEW DATE: AUGUST 2016