

**UNIVERSITY OF TENNESSEE HEALTH SCIENCE CENTER
INSTITUTIONAL REVIEW BOARD
USE OF ANONYMIZED HUMAN CELL LINES**

I. PURPOSE

To document the procedures used by University of Tennessee Health Science Center Institutional Review Board to review and evaluate submissions for the use of anonymized human cell lines.

II. SCOPE

This SOP applies to the IRB administrative staff, Board members, and investigators.

III. BACKGROUND

Federal regulations for the protection of human subjects are not applicable to the use of human materials if those materials are derived from non-living individuals or individuals whose identity cannot be ascertained by the investigator. The use of anonymized human cell lines represents one use of human materials to which the regulations are not applicable. However, the determination that the regulations do not apply must be made by someone other than the investigator, and the IRB is the designated entity at UTHSC.

In order to ease the paperwork burden for investigators using anonymized human cell lines, the IRB has determined that the federal regulations for the protection of human subjects do not apply to the use of anonymized human cell lines purchased from specific commercial vendors. The IRB has given “not human subjects research” (NHSR) status to the use of anonymized cell lines purchased from specific commercial vendors in a separate policy entitled “UTHSC IRB NHSR Status for the Use of Selected Commercial Vendors and De-identified Specimen & Data Repositories.” However, requests to use anonymized cell lines purchased from sources other than the commercial vendors listed in that policy must be made to the IRB using the rapid cell line registration process detailed below.

In Accordance With:

For studies approved under the revised Common Rule:
45 CFR 46.102(e); and

For studies approved under the Pre-2018 Common Rule:

[45 CFR 46.102\(f\)](#)

Compliance with this policy also requires compliance with state or local laws or regulations that provide additional protections for human subjects.

IV. PROCEDURES

1. UTHSC investigators using anonymized cell lines from commercial vendors listed in a separate policy entitled “UTHSC IRB NHSR Status for the Use of Selected Commercial Vendors and De-identified Specimen & Data Repositories” do not need to undertake any interaction with the IRB provided that the only use of human materials in the study involves these cell lines. **However, all obligations to interact with the IBC and IACUC remain in place.** For example, because work with human cells must adhere to OSHA Bloodborne Pathogen Standards it must be conducted at Biosafety Level 2. All work at Biosafety Level 2 must be registered with the IBC.
2. Use of anonymized human cell lines from sources other than the commercial vendors listed in a separate policy entitled “UTHSC IRB NHSR Status for the Use of Selected Commercial Vendors and De-identified Specimen & Data Repositories” must be registered with the IRB using the rapid cell line registration process detailed below, so that the IRB can confirm that the conditions for NHSR status are satisfied.
 - a. **Investigator Procedures:**
 - i. The cell line registration form must be submitted for IRB review via Form 1 Application within iMedRIS, the IRB electronic system.
 - ii. The investigator will complete the 1st five sections of the Form 1 application and then in Section (418) IRB Submission, the investigator should select the option, “I am registering the use of an anonymized human cell line purchased or acquired from commercial vendors, IRB approved repositories or government tissue banks” to access the cell line registration form.
 - iii. Once the cell line registration form is complete, only the investigator needs to apply his/her electronic signature to the submission and submit the form for IRB review and approval.
 - b. **IRB Procedures:**
 - i. Upon receipt of the anonymized cell line registration form, the IRB administrative staff will assign it an IRB number and the form will be assigned to an IRB Analyst for review.
 - ii. Upon confirmation of the use of an anonymized cell line, an NHSR determination letter will be issued via iMedRIS to the principal investigator and, if requested, to the Institutional Biosafety Committee

- (IBC) Chair. The Institutional Biosafety Officer will have access to iMedRIS as well.
 - iii. The UTHSC IRB will maintain copies of the anonymized cell line application and corresponding IRB communications in the electronic IRB file.
 - iv. Documentation of the IRB review and approval will be included on the IRB meeting agenda.
3. Use of human cell lines from identifiable individuals must undergo review and approval using the regular IRB application process and is not eligible for the rapid cell line registration process. See SOP: UTHSC IRB NHR or Exempt Status: Determination, and SOP: UTHSC IRB Expedited Review.