

**UNIVERSITY OF TENNESSEE  
GRADUATE SCHOOL OF MEDICINE  
INSTITUTIONAL REVIEW BOARD  
USE OF ANONYMIZED HUMAN CELL LINES**

**I. PURPOSE**

To document the procedures used by University of Tennessee Graduate School of Medicine 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 UTGSM.

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 ATCC®; therefore, the IRB has given “not human subjects research” (NHSR) status to this activity. As a result of this determination, UTGSM investigators using anonymized cell lines from ATCC® do not need to undertake any interaction with the IRB. Use of anonymized human cell lines from sources other than ATCC® must be registered with the IRB using the rapid cell line registration process, so that the IRB can confirm that the conditions for NHSR status are satisfied.

**In Accordance With:**

45 CFR 46.101(b)

Research Using Human Specimens, Cell lines or Data  
<http://grants.nih.gov/grants/policy/hs/specimens.htm>

Human Subjects Research – Human Specimens, Cell Lines or Data FAQs  
[http://grants.nih.gov/grants/policy/hs/faqs\\_specimens.htm](http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm)

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

#### IV. PROCEDURES

1. UTGSM investigators using anonymized cell lines from ATCC® 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 ATCC® must be registered with the IRB using the rapid cell line registration process, so that the IRB can confirm that the conditions for NHR 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 1<sup>st</sup> 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 NHR determination letter will be issued via iMedRIS to the principal investigator and, if requested, to the Institutional Biosafety Committee (IBC) Chair.
    - 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: UTGSM IRB NHSR or Exempt Status: Determination, and SOP: UTGSM IRB Expedited Review.