

CHREB Cell Line Application Guidance

- 1). The TriCouncil Policy Statement 2010 (TCPS) mandates review of research using human biological materials. Cell lines are a biological material.
- 2). Cell line research using material from identifiable donors requires review even if the line itself has been deidentified or anonymized (TCPS 2010 Article 2.4)
- 3). If the cell line has been generated from an anonymous donor, REB review is not required (TCPS 2010 Article 2.4)
- 4). If the cell line is described as anonymized or de-identified (i.e., the progenitor was at some point known, but this information is no longer directly associated with the cell line) REB review is required even if the researcher does not know the identity of the donor.
- 5). If the cell line has been obtained from a commercial company, researchers can request information on whether or not the cell line is anonymous, anonymized or deidentified (i.e., progenitor anonymous or identity known/de-identified) from the company. Again, only anonymous lines are exempt from the REB review requirement.
- 6). If the researcher is uncertain about the identifiability of the source, the study should be submitted for review.

In the Study Objectives and Design, please ensure the following elements are included:

- the rationale, objective and methods
- the human cell lines that will be used
- the procurement route/provenance of the human cell line
- a statement that the human cell donors' identity is unknown to the investigators; or if the identity of the donor(s) is known, then attach a specific cell donor consent form
- a statement that there is no chimeric or human embryonic stem cell work; or: statement that SCOC approval is in place (or has been applied for)
- If it is the HeLa cell line, a statement that the HeLa Genomic Research rules will be observed

(<http://www.genomicslawreport.com/index.php/2013/08/27/genomic-research-ethics-special-rules-for-hela-cells/>)

- http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v1.p1

7). TCPS certificates are required for student protocols. If they are graduate student protocols, supervisory committee sign off and the proposals are required. Impact signatures may be required for labs, biosafety regulations/requirements may also apply.

Interpretation from the PRE:

To be compliant with TCPS 2, research involving cell lines requires REB review (Article 12.1). In general, all research involving human biological materials requires REB review, irrespective of the source. However, research is exempt from REB review if the research relies exclusively on secondary use of anonymous human biological materials, “so long as the process of data linkage or recording or dissemination of results does not generate identifiable information” (Article 2.4). The TCPS 2 definition states that anonymous human biological materials are materials that “... never had identifiers attached to them and risk of identification of individuals is low or very low” (Section A, Chapter 12). If the cell lines in your example have ever had identifiable information associated with them, then the cell lines are not considered to be anonymous, even though the researcher may not have access to those identifiers.