Federal regulations (45 CFR 1.02(f)) define a human subject as a living individual about whom an investigator conducting research obtains 1) data through intervention or through interaction with an individual or 2) identifiable private information.

Private information must be individually identifiable (i.e., the identity of the subject is or may be readily ascertained by the investigator, or associated with the information) to meet the definition of human subject.

The Office of Human Research Protections has further clarified that “non-identifiable” material must be submitted to a repository (e.g., ATCC) without any identifiable private data or information. That is, no codes or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained.

NOTE: If (1) a cell line is obtained through intervention or through interaction with a living individual or (2) the cell line can be linked to identifiable private information pertaining to a living individual, then an IRB application must be submitted and approved by the IRB prior to obtaining the cell line.

Examples:

- If the individual from whom the cell line (e.g. HeLa) was derived is deceased, then an IRB application is not required.
- If culture cell lines are obtained from a commercial source such as ATCC and they do not have personal identifiers, codes or linkages maintained by ATCC, consult the IRB Administrator at lmoll@clemson.edu or 656-6460 to see if an IRB application is needed.