

DRAFT OF PROPOSED AMENDMENTS TO THE GUIDELINES WITH RESPECT TO THE
USE OF CELL LINES DERIVED FROM SOMATIC CELLS

This is an attempt at language to implement the Committee's recommendations from our last, telephone, meeting. These need to be examined more closely, by the Department and others, but I think they may accomplish the goals of that meeting's conclusion.

Amend Section 6 of the Guidelines defining "acceptably derived" covered stem cells lines to add a new subsection (f):

- (f) The stem cell line is derived from non-identifiable human somatic cells under the following conditions:
 - (1) The derivation did not result from the transfer of a somatic cell nucleus into a human oocyte (SCNT) or the creation of use of a human embryo; and
 - (2) The somatic cells have no associated codes of links maintained by anyone that would identify to the investigator(s) the donor of hte specimens, or, if such codes or links exist, that the identity of the donor is not readily ascertainable because, for example:
 - (i) The key to decipher the code or link is destroyed before the research beings;
 - (ii) an agreement prohibits release of hte key to the investigators under any circumstances;
 - (iii) IRB-approved written policies and operating procedures for a repository or data management center prohibit releasing the key under any circumstances,; or
 - (iv) the release of the key to the investigators is forbidden by law.

Amend Section 7 of the Guidelines dealing with new derivations of covered stem cell lines to add a new subsection (b)

- (b) Subsection (a) of this section does not apply to research intended to derive a covered stem cell line from somatic cells when the SCRO committee has determined the requirements of Section 6(f) have been met