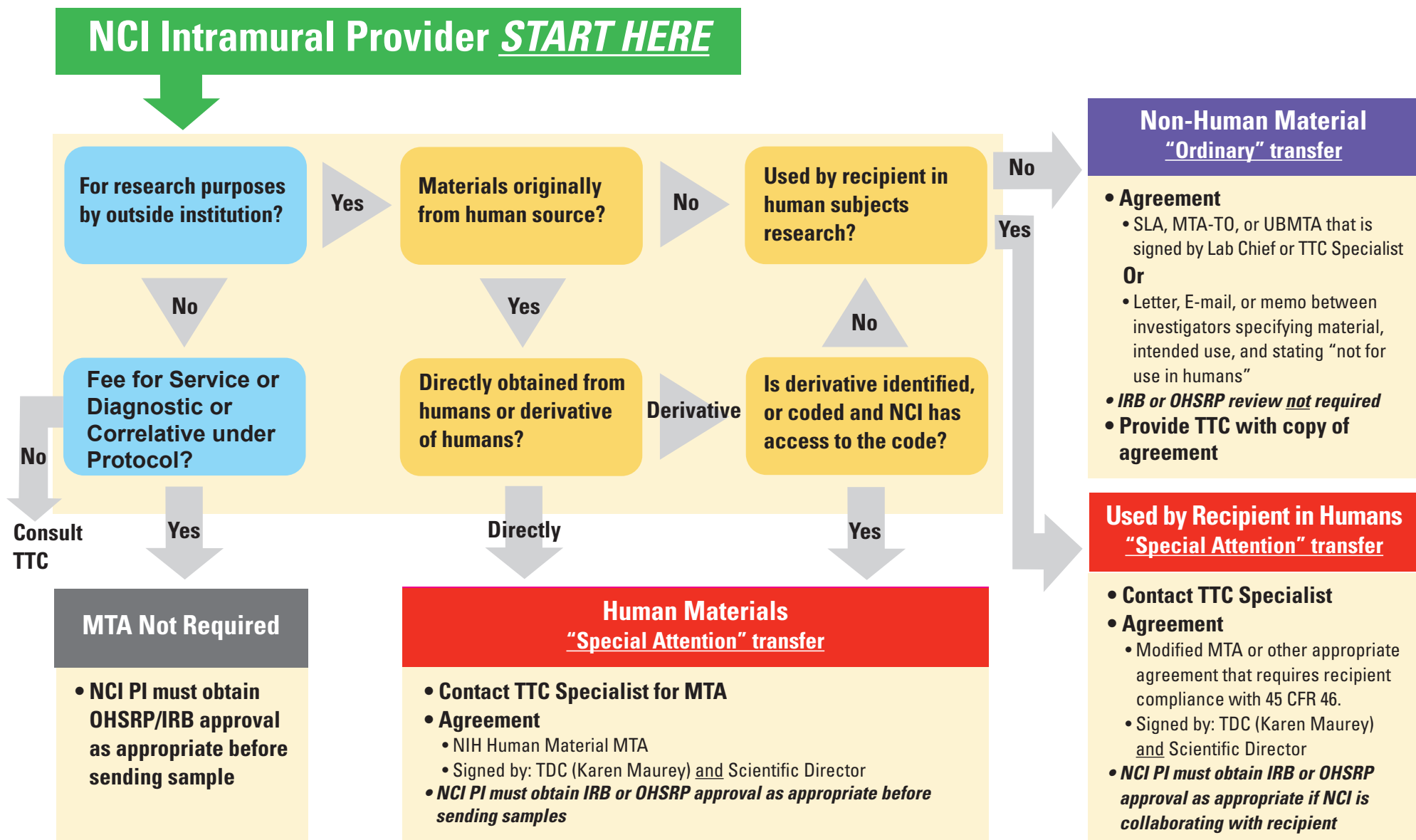


Policy for the Transfer of Materials from NIH Intramural Laboratories: Effective March 30, 2010



Definitions of “Materials from humans”:

Those obtained **directly from humans**

including, but not limited to:

- tissue (e.g., bone, muscle, connective tissue, skin),
- organs (e.g., liver, bladder, heart, kidney),
- blood,
- gametes (e.g., sperm and ova),
- embryos,
- fetal tissue, and
- waste (e.g., urine, feces, sweat, hair and nail clippings, shed epithelial cells, placenta),

as well as extracted or subcomponent parts of these materials, including

- whole genomic DNA,
- plasma,
- protein fractions, or
- fractionated cells.

Derivatives of materials originally obtained from humans

including:

- human cell lines,
- recombinant DNA clones of human genes, and
- isolated infectious agents from humans.

General definitions pertaining to human materials:

Unlinked:

Materials that were initially collected with identifiers that, before research use, have been irreversibly stripped of all identifiers by use of an arbitrary or random alphanumeric code and the key to the code is destroyed, thus making it impossible for anyone to link the samples to the sources. This does not preclude linkage with existing clinical, pathological, and demographic information so long as all subject identifiers are removed prior to distribution or receipt.

Coded:

Materials that are unidentified for research purposes by use of a random or arbitrary alphanumeric code but that may still be linked to their sources through use of a key to the code available to the NIH provider or collaborator.

Identified:

Materials that are still attached to a readily available subject identifier such as name, social security number, study number, hospital number, medical record number, address, telephone number, etc., such that the identities of the subjects can be ascertained.
