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

NCI Intramural Provider *START HERE*

Materials originally For research purposes No Yes by outside institution? from human source? No Fee for Service or **Directly obtained from** Diagnostic or Derivative humans or derivative **Correlative under** of humans?

Used by recipient in human subjects research?

Yes

No

No

Is derivative identified. or coded and NCI has access to the code?

Yes

investigators specifying material, intended use, and stating "not for

• Letter, E-mail, or memo between

Non-Human Material "Ordinary" transfer

• SLA, MTA-TO, or UBMTA that is

signed by Lab Chief or TTC Specialist

use in humans"

Agreement

0r

• IRB or OHSRP review not required

 Provide TTC with copy of agreement

MTA Not Required

Protocol?

Consult

TTC

• NCI PI must obtain **OHSRP/IRB** approval as appropriate before sending sample

Yes

Human Materials "Special Attention" transfer

- Contact TTC Specialist for MTA
- Agreement
 - NIH Human Material MTA

Directly

- Signed by: TDC (Karen Maurey) and Scientific Director
- NCI PI must obtain IRB or OHSRP approval as appropriate before sending samples

Used by Recipient in Humans "Special Attention" transfer

- Contact TTC Specialist
- Agreement
 - Modified MTA or other appropriate agreement that requires recipient compliance with 45 CFR 46.
 - Signed by: TDC (Karen Maurey) and Scientific Director
- NCI PI must obtain IRB or OHSRP approval as appropriate if NCI is collaborating with recipient

Technology Transfer Center- National Cancer Institute

9609 Medical Center Dr., Room 1E-530 · Rockville, MD 20850 Telephone: 240-276-5530 · Fax: 240-276-5504

web site: http://ttc.nci.nih.gov

Technology Transfer Center- National Cancer Institute-Frederick 8490 Progress Dr., Suite 400 • Riverside 5 • Frederick, MD 21701







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.