



Office of the
Vice President
for **Research**
at the university of georgia®

Guidance for review of studies involving HCT/Ps and IND Basics

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What are HCT/Ps

Human Cells, Tissues, and Cellular and Tissue-Based Products:

Articles containing or consisting of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient.

**Sometimes the FDA requires
pre-market approval and
sometimes they do not**

How is this
determined?????

Requirements

Minimal Manipulation

- For structural tissue, Processing that does not alter the original relevant characteristics of the tissue relating to the tissue's utility for reconstruction, repair, or replacement; and
- For cells or nonstructural tissues, processing that does not alter the relevant biological characteristics of cells or tissues.

Homologous Use

Repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues is being performed with an HCT/P that performs the same basic function in the recipient as in the donor

Manufacture

The manufacture of the HCT/P cannot involve the combination of the cells or tissues with another article, such as a drug.

Registration

Unless the HCT/P is manufactured under an IDE or IND, the HCT/P manufacturer must be registered with the FDA.

Systemic Effects

- The HCT/P does not have a systemic effect and is not dependent upon the metabolic activity of living cells for its primary function.
- Autologous use, allogenic use in a first degree or second degree blood relative or, reproductive use.

If the product /use does not meet those criterion, then pre market approval is required and an IND or IDE should be sought from the FDA

IND Basics

The submission of an IND application is required for any clinical research study that proposes the use or evaluation of an unapproved drug

Clinical investigations involving the use or evaluation of an FDA approved drug for the clinical indications specified in the FDA approved product labeling:

IND is not required.

Clinical investigation involving the use or evaluation of a FDA approved drug for a clinical indication that is not currently specified in the FDA approved product labeling:

**May be exempt from the IND requirement
If....**

1. The drug is lawfully marketed in the US
2. There is no intent to report the investigation to the FDA to support new labeling or change in labeling
3. Investigation is not intended to support a change in advertising
4. The investigation does not involve a route of administration, dose, patient population or other factor that increases risk

5. The investigation is conducted in compliance with the requirements for review by an IRB
6. The investigation is conducted in compliance with the requirements of 21 CFR 312.7 which states that the investigation is not intended to promote or commercialize the drug product by charging the research participant (or his/her insurance provider) for the drug under evaluation