

# STANDARDIZED TERMINOLOGY FOR SOURCE ORGANS, CELLULAR THERAPY, AND REGENERATED TISSUES

ON BEHALF OF THE CELLULAR THERAPY CODING AND LABELING TECHNICAL ADVISORY GROUP\* AND THE TISSUE ENGINEERED PRODUCTS TECHNICAL ADVISORY GROUP\*\*

Authors: Zbigniew Szczepiorkowski<sup>1</sup>, Ineke Slaper-Cortenbach<sup>2</sup>, Pat Distler<sup>3</sup>, Paul Ashford<sup>3</sup>

<sup>1</sup>Dartmouth-Hitchcock Medical Center, Lebanon, United States, <sup>2</sup>University Medical Center Utrecht, Utrecht, The Netherlands, <sup>3</sup>ICCBBA, San Bernardino, United States

## INTRODUCTION AND AIM

The International Cellular Therapy Coding and Labeling Advisory Group (CTCLAG) was formed by ICCBBA with support of professional organizations including ISCT. In 2007, the output of this group, standardized cellular therapy (CT) terminology, was published and thereafter AABB, FACT, JACIE, and NMDP required use of this terminology. Terminology for CT was updated, and new terminology was developed for regenerated products and organs used as a source of cells for regenerated products.

## METHODS

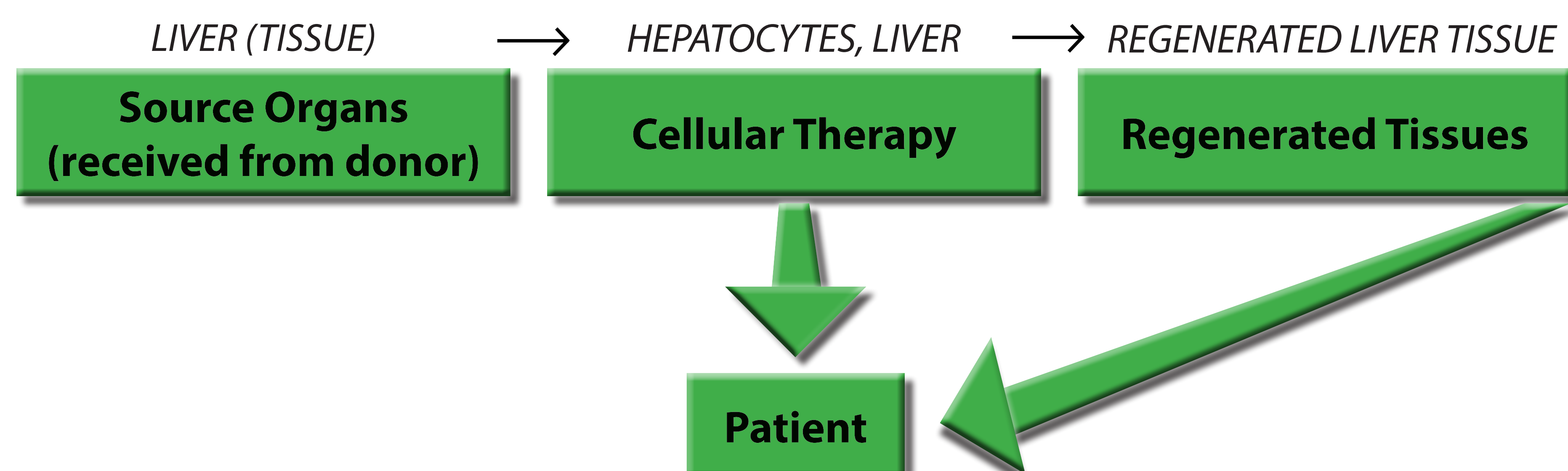
CTCLAG and expert advisory groups for tissues and tissue engineered products work through a consensus process to develop additional terminology. Drafts of terminology are distributed to relevant professional societies for their comments and published on the ICCBBA website for public comment.



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## CONCLUSIONS

Through the efforts of advisory groups comprising experts in relevant fields, terminology has been developed for CT, tissue, and regenerated products. This terminology is made publicly available through the ICCBBA website ([www.iccbba.org](http://www.iccbba.org)), and its use for communication and labeling is encouraged.



## RESULTS

Three sets of terminology were addressed:

- The proposed class name of organs—used as a cell source for production of cell and tissue products—is in the format of organ name followed by the word “TISSUE” in parentheses [e.g., HEART (TISSUE)]. “(TISSUE)” is added to distinguish organs intended for further processing from those intended for transplant. Organs for transplant have only the organ name (e.g., HEART).
- CT terminology was updated in 2013 to follow a standard format for class name: cell type, source (e.g., MNC, APHERESIS).
- The proposed class name of regenerated products is in the format “REGENERATED” followed by the tissue type (e.g., REGENERATED EPIDERMIS). Additional details—such as cell type, delivery mechanism, ancillary substances, excipients, and storage temperature—are added as attributes (e.g., REGENERATED EPIDERMIS, from keratinocytes, in the form of a sheet, with ancillary substances present).

### ISBT 128 Example Terminology

Term	Definition
<b>Source Organs</b>	
Liver (TISSUE)	Recovered portion of the liver for processing into a cellular therapy or tissue product. Not intended to be used for organ transplantation.
PANCREAS (TISSUE)	Recovered whole or part of the pancreas for processing into a cellular therapy or tissue product. Not intended to be used for organ transplantation.
HEART (TISSUE)	Recovered whole heart, with associated vascular tissue, for processing into a cellular therapy or tissue product. Not intended to be used for organ transplantation.
<b>Cellular Therapy</b>	
HEPATOCYTES, LIVER	A cell product containing hepatocytes obtained from the liver.
EPITHELIAL CELLS, ORAL MUCOSA	A cell product containing epithelial cells obtained from the oral mucosa.
FIBROBLASTS, SKIN	A cell product containing fibroblasts obtained from the skin.
<b>Regenerated Tissues</b>	
REGENERATED LIVER TISSUE	Viable liver cells constructed into tissue.
REGENERATED ORAL MUCOSA TISSUE	Viable oral mucosa cells constructed into tissue.
REGENERATED SKIN TISSUE	Viable skin cells constructed into tissue.