The University of Iowa Dezii Translational Vision Research Group

TITLE: Initial Listing and Annual Update for HCT/P Products

SOP Number: D-QA-PVL-001 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This SOP is to provide instruction for listing all Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) and Gene Replacement Therapy (GT) products processed by the University of Iowa Dezii Translational Vision Research Group (DTVR) in accordance with 21CFR1271.22. This SOP also describes the requirement and procedure for annual review and, where necessary, update of the HCT/P list with the FDA in accordance with 21CFR1271.21(b,c).

B. APPLICABILITY

This SOP shall be performed by Quality Assurance Personnel, with the assistance of Operations Personnel, as appropriate.

C. REFERENCES

21 CFR Part 1271 Sections 21, 22 and 25
FDA Form 3356 and associated instructions

D. BACKGROUND

1. The University of Iowa DTVR carries out processing, functionality testing, and/or stability testing for Human Cells, Tissues, and Cellular and Tissue-Based (HCT/P) and Gene Replacement Therapy (GT) Products for the treatment of inherited diseases of the eye.

2. The laboratories in DTVR have been certified as a Clinical Laboratory Improvement Amendments of 1988 (CLIA) laboratory. As such, the DTVR meets quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health.

3. The Federal regulations (21CFR1271.21(a)) require that DTVR must register and submit a list of every HCT/P that DTVR manufactures within 5 days after beginning operations.

E. PROCEDURE

1. QA must submit the initial DTVR List of HCT/P products with the submission for Establishment registration using FDA Form 3356, “Establishment Registration and Listing for Human Cells, Tissues and Cellular and Tissue-based Products (HCT/Ps)”, as described in the FDA instructions:

   (see: http://www.fda.gov/cber/tissue/tisreg.htm)

2. If a change occurs in the HCT/P list for DTVR, the QA Officer will update the HCT/P list:

   2.1. At the time of the change, or

   2.2. Each June or December, whichever month occurs first after the change

3. The DTVR HCT/P listing update must include:

   3.1. A list of each HCT/P that DTVR has begun recovering, processing, storing, labeling, packaging, distributing, or for which DTVR has begun donor screening or testing, that has not been included in any list previously submitted.

   3.2. A list of each HCT/P formerly listed for which DTVR has discontinued recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing. The FDA requests but does not require including the reason for discontinuance.

   3.3. A list of each HCT/P for which a notice of discontinuance was submitted and for which DTVR has resumed recovery, processing, storage, labeling, packaging, distribution, or donor screening or testing (21 CFT 1271.25(b)).

   3.4. Any material change in any information previously submitted. Material changes include any change in information submitted on Form FDA 3356, such as whether the HCT/P meets the criteria set out in 1271.10.

F. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original Document