The University of Iowa Dezii Translational Vision Research Group

TITLE: Record Retention Policy for The University of Iowa DTVR

SOP Number: D-GLO-PRO-019 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This SOP is to outline the steps to be taken for retention of records generated for production and laboratory operations in support of the production/processing of Human Cell, Tissue, and Cellular or Tissue Based Materials (HCT/P) or Gene Therapy (GT) products.

B. APPLICABILITY

This procedure will be performed by The University of Iowa Dezii Translational Vision Research Group (DTVR) personnel at the direction of the Director of DTVR.

C. REFERENCES

D-GLO-PRO-018	Generation, Review and Archiving of Batch Records
D-GLO-PRO-009	Laboratory Documentation and the LabGuru System
D-GLO-PRO-014	Generating Unique GMP Identifiers
D-GLO-PRO-015	Ordering, Incoming Material, Labeling, Release, and Disposition

D. DEFINITIONS

DTVR: The University of Iowa Dezii Translational Vision Research Group

E. PROCEDURE

1. Executed batch records and their masters will be stored following D-GLO-PRO-018.

2. Raw Material and component inventory records will be stored following D-GLO-PRO-015.

3. Quality Control generated data will be stored following SOP D-GLO-PRO-009.

4. Equipment and Room Use, Maintenance and Cleaning Logs shall be stored on LabGuru for a minimum of 5 years..

5. Validation data for equipment and systems will be stored as long as the equipment or system is in use. The data will be held for a minimum of 5 years after the equipment or system is decommissioned.

6. Certificates of calibration and preventive maintenance will be kept for a minimum of 5 years.

7. Support data (e.g. Environmental Monitoring, Pressure Differentials, Cleaning Verification, etc.) shall be kept for a minimum of 5 years.

8. Back up data, either electronic or printed, will be kept for a minimum of 5 years.

9. Printed documents that pertain directly with projects will be kept for a minimum of 7 years after the receipt of the document.

10. Electronic documents that pertain directly with projects can be stored in the following manner:

    10.1. A printed copy of the e-mail can be made. The printed copy will be kept for a minimum of 7years after the receipt of the document.

    10.2. If a printed copy is not made, then the electronic copy will be maintained for a minimum of 7 years after the receipt of the document.

11. Documents requested for litigation purposes will be stored until no longer needed.

12. Documents that do not directly affect the manufacturing of batches or the disposal of product will be kept for the duration chosen by the individual receiving the documentation.

F. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document