The University of Iowa Dezii Translational Vision Research Group

TITLE: Deviations to Approved Processes

SOP Number: D-GLO-PRO-016 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This Standard Operating Procedure (SOP) outlines the steps to be taken when the procedures detailed in an approved clinical batch record, protocol, analytical method, or SOP needs to be altered or changed.

B. APPLICABILITY

This procedure will be performed by the permanent staff of the University of Iowa Dezii Translational Vision Research Group (DTVR) as directed by the Quality Assurance department. Careful consideration must be given to any deviation from the established procedures for Human Cell, Tissue, and Cellular or Tissue Based Materials (HCT/P) or Gene Replacement Therapy (GT) products, especially for any cases where validated processes are affected. Typically, only planned deviations to a validated process that have been through quality review will be allowed. Unless specifically directed to prepare a deviation report in approved documents concerning a DTVR product, deviations that are unplanned will normally require that investigations be performed.

C REFERENCES

Form F-D-GLO-PRO-023 Unplanned Deviation Report
Form F-D-GLO-PRO-024 Planned Deviation Form
Form F-D-GLO-PRO-042 CAPA Progress report
SOP D-GLO-PRO-013 Investigating and Reporting Discrepancies and Performing CAPA

D. PROCEDURE

1. When the need to deviate from the procedures detailed in an approved clinical batch record, protocol, analytical method, or SOP occurs personnel will prepare or obtain a form for the activity. Note this procedure does not apply to typographical/grammatical errors (these types of errors will be corrected, initialed and dated where they occur) or to exceptions allowed by SOP (i.e. method deviation as allowed to achieve system suitability).

2 The person preparing the deviation form will contact Quality Assurance who will then assign a tracking number to the report. Quality Assurance will log the deviation into the Deviation Log Report. The person preparing the deviation form will fill out Form F-D-GLO-PRO-024 for a planned deviation or Form F-D-GLO-PRO-023 for an unplanned deviation.

2.1. A planned deviation occurs when a change in the process, protocol, test method, or procedure, is deemed necessary, prior to performing the process, protocol, test method, or procedure, (e.g., new information indicates a benefit from a change in storage conditions after a gene therapy batch record has been signed off). Form F-D-GLO-PRO-024 must be filled out prior to execution of a planned deviation. The person completing the form will indicate the product and lot number impacted (where appropriate), describe the deviation, provide the rationale/justification for the deviation, describe the potential impact of the deviation, indicate any remediation(s) planned and sign and date the page. If a corrective action is necessary, check the correct box on the form that states a CAPA is necessary and fill out form F-D-GLO-PRO-042. A person within the appropriate DTVR group will review, sign and date the planned deviation form. If possible, Quality

Assurance will complete their portion of the page prior to implementing the described deviation.

2.2. An unplanned deviation occurs when an unexpected result occurs during the performance of a process, the execution of a protocol, while conducting a test method, or when performing a procedure (e.g., a material must be screened, type of mixing device must be changed, data gathering device must be changed, etc.). Form F-D-GLO-PRO-023 must be filled out prior to execution of an unplanned deviation. The person completing the form will indicate the product and lot number impacted (where appropriate), describe the deviation, provide the rationale/justification for the deviation, describe the potential impact of the deviation, indicate any remediation(s) planned and sign and date the page. If a corrective action is necessary, check the correct box on the form that states a CAPA is necessary and fill out form F-D-GLO-PRO-042. A second person within the department will review, sign and date the unplanned deviation form. It is not necessary for Quality Assurance to complete their portion of the page prior to implementation of the described deviation for non-validated processes. Typically, unplanned deviations to a validated process will require that an investigation be performed.

3. The Unplanned Deviation Report and the Planned Deviation Form will be routed to Quality Assurance. Quality Assurance will indicate in the form whether or not an investigation is required (unplanned deviation only), then sign and date the page (both planned and unplanned deviations). If an investigation is required, an investigation number will be assigned by QA following SOP D-GLO-PRO-013.

4. The completed Unplanned Deviation Report and Planned Deviation Form, when necessary, will be included in the finished batch record, executed protocol, laboratory notebook, logbook, or appropriate file, as dictated by the nature of the deviation.

5. The deviations will be trended quarterly by Quality Assurance, and a trend report will be written and distributed to the director and all department managers.

E. HISTORY

Effective Date	Revision	Change
09 Aug 2015	0	Original document