The University of Iowa Dezii Translational Vision Research Group

TITLE: Handling of Adverse Reactions and Patient Complaints

SOP Number: D-GLO-PRO-021 Revision Number: 0

Effective Date: 27 Apr 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

To define the procedure to be followed in handling and documenting complaints and adverse reactions

B. APPLICABILITY

This procedure shall be performed by The University of Iowa Dezii Translational Vision Research Group (DTVR) personnel as directed by the Director of Quality Assurance or designate. This SOP applies to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps) as well as Gene Replacement Therapy (GT) products processed in DTVR. Since all HCT/P and GT products processed by DTVR will also be applied strictly by DTVR personnel and are not submitted into a distribution channel, the potential for complaints is limited to those instances where an adverse reaction to the product may take place.

C. REFERENCES

D-GLO-PRO-013 Investigating and Reporting Discrepancies and Performing CA/PA
FDA Guidance for Industry: MedWatch Form FDA 3500A: Mandatory Reporting of Adverse Reactions Related to Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)

D PROCEDURE

1. Cause of Complaints:

1.1 As noted in Section B, the only anticipated source of complaints in DTVR is from the occurrence of an adverse reaction to an HCT/P or GT product during human use.

2. Handling of Complaints

2.1 Although clinical investigators, physicians, other health professionals and patients may offer concern about a HCT/P or GT product or procedure, only those specific written or oral complaints involving adverse reactions received by DTVR will be investigated.

2.2 Complaints will be received by The University of Iowa DTVR Director of Quality Assurance (QA) or, when absent, his/her designate(s). When the Director of QA is absent, appropriate contacts will be delineated in e-mail and/or voice mail. The complaints will be documented as indicated in section 3 of this procedure.

2.3 Investigations will be initiated by Quality Assurance. Assistance will be sought from the appropriate unit(s) as needed for each individual complaint.

3. Documentation

3.1 A complaint file will be established and maintained by Quality Assurance. This file will be reviewed annually by Quality Assurance. The review will be verified by The DTVR Director.

3.2 Upon receipt of a complaint, the product name, lot number, name of the individual registering the complaint, and to whom (within The University of Iowa DTVR) the complaint is referred for investigation, will be recorded. Results of the investigation will also be kept in the complaint file.

3.3 Documentation of complaints will be maintained for ten years from the date of receipt of the complaint.

4. Investigation

4.1 If an investigation is deemed necessary, a report, following SOP D-GLO-PRO-013, detailing the nature and findings of the investigation will be documented and added to the complaint file.

4.2 Under 21 CFR 1271.350 (a), DTVR must investigate any adverse reaction involving a communicable disease related to an HCT/P processed and administered by DTVR. According to the regulations, DTVR must report to FDA an adverse reaction if it involves a communicable disease related to an HCT/P if it:

1. Is fatal
2. Is life-threatening
3. Results in permanent impairment of a body function or permanent damage to body structure or
4. Necessitates medical or surgical intervention, including hospitalization.

4.3 If the adverse reaction is found to meet the criteria described in Section 4.2, the DTVR will report the event to the FDA using MedWatch Form FDA 3500 (see http://www.fda.gov/safety/medwatch/howtoreport/downloadforms/default.htm). Report of the adverse event must be conveyed to the FDA within 15 calendar days of the identification of the adverse reaction.

4.4 If no investigation is deemed necessary, that information and the name of the responsible person(s) making the determination will be recorded in the complaint file. A report will be generated justifying that no investigation was necessary. All relevant information will be kept with the report.

E. History

Effective Date	Revision	Change
27 Apr 2015	0	Original document