The University of Iowa Dezii Translational Vision Research Group

TITLE: Outside Audits

SOP Number: D-GLO-PRO-008 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This SOP is to describe the procedures to be followed when The University of Iowa Dezii Translational Research Facilities (DTVR) are audited by either a 3rd Party or the Food and Drug Administration (FDA).

B. APPLICABILITY

This SOP shall be followed by all of The University of Iowa Dezii Translational Vision Research Group (DTVR) personnel under the supervision of the Quality Assurance Director or Director of The University of Iowa DTVR.

C. DEFINITIONS

FDA: Food and Drug Administration
DTVR: The University of Iowa Dezii Translational Vision Research Group
FOI: Freedom of Information Act

D. PROCEDURE

1. GENERAL POLICIES

1.1. Personnel will cooperate fully with FDA inspectors visiting the site.

1.2. The use of cameras in the facility shall be permitted on a case by case basis. Camera use shall be determined by the Director of DTVR.

1.3. Copies of documents requested by the FDA will be provided free of charge. Copies will be made by DTVR personnel. All copies of documents requested by FDA inspectors will be reviewed by Quality Assurance personnel prior to release. A list or duplicate copy of FDA requested materials will be kept by Quality Assurance for reference.

1.4. No FDA forms 483, 484, 463 will be signed, initialed, or ratified by any employee unless the Director of DTVR decide that it is in the department's best interest. This signature or acknowledgment is not required by law. This statement shall also extend to statements written by 3rd Party auditors.

2. BACKGROUND

2.1. Confidentiality pertaining to the FDA: All documents supplied to an FDA inspector can be released to the general public under the Freedom of Information (FOI) Act. An FDA inspector can request and be furnished with any non-proprietary information excluding financial data, internal audit reports, and personnel records other than those that pertain to personnel qualifications and training. Any proprietary information supplied to the FDA inspector shall have the word "Confidential" stamped on each page of the document. Proprietary information would include protocols, identities of coded ingredients, etc., or any information that is considered a trade secret. When supplying proprietary information

verbally, the inspector should be informed that the information is confidential and is not subject to disclosure under the FOI Act.

2.2. All FDA inspectors shall be treated with courtesy and in a professional manner.

2.3. Employees should only answer questions pertaining to their area of expertise. Unsolicited information should not be volunteered. All information supplied to the FDA inspectors is admissible as evidence against an employee or DTVR in the event of any legal action.

2.4. FDA inspectors should not be offered anything of material value. FDA inspectors cannot have meals provided.

2.5. All FDA inspectors should be escorted at all times by the Director of DTVR or a designated employee whenever they walk through the facility. They should only be allowed to talk to designated employees and only about matters relating to the audit.

3. PROCEDURE

3.1 When FDA inspectors arrive at The University of Iowa DTVR, the Director of DTVR or designate shall be notified. If this is an FDA inspection the Director of DTVR or designate shall ask to see the credentials of the inspector and ask the purpose of the inspection. The FDA inspector is required by law to present a written Notice of Inspection (form FDA 482).

3.2. All inspectors are encouraged to provide an agenda so that key personnel may be notified.

3.3. It is advisable to provide a conference area for the audit and have all requested documents and personnel brought to the conference area. All documents shall be reviewed by the Director of DTVR or his designate prior to being provided to the inspector.

3.4. At the end of each day, the inspector should be asked if they have any other questions or document requests. A brief summary of the day's findings should be presented by the inspector. The next day should start with an overview of the days' agenda and any questions arising from materials reviewed from the previous day.

3.5. If samples are requested by the FDA inspector they should be furnished when possible. A receipt of the samples specifying ID number, amount, etc., should be obtained. Duplicates of samples taken by the FDA should also be taken by DTVR.

3.6. At the end of the inspection the Director of DTVR or his designate shall request an exit interview to discuss all observations. Discussion of observations or observed deficiencies prior to the issuance of the Form FDA 483 Inspection Observations, by the FDA allows any misinterpretations to be clarified. Various key personnel should be present at this discussion.

3.8. Prior to leaving the site at the end of the inspection, the FDA inspector should issue a form 483, Inspection Observations.

3.9. All written observations should be reviewed in detail for accuracy. A written request for correction of errors should be issued by the Quality Assurance Director or the Director of

DTVR. A written response prepared by the Quality Assurance Director and the Director of DTVR, outlining the corrective action, shall be sent to the regional FDA office within 15 calendar days of receipt of FD-483.

3.10. After all information is provided to the FDA replying to the FDA 483 and the FDA considers the response to be appropriate, the Establishment Inspection Report (EIR) will be sent to DTVR by the FDA, and the Notice of Approval will be sent by the EMEA.

3.11. Quality Assurance shall maintain a record of all audits and inspections and any responses to the inspection or audit observations.

E. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document