The University of Iowa Dezii Translational Vision Research Group

TITLE: Definition of Raw Data and Acceptance of Electronic Documents

SOP Number: D-QA-PRO-003 Revision Number: 0

Effective Date: 09 Aug 2015

Author: _____ Date: _____

Reviewer: _____ Date: _____

QA Approval: _____ Date: _____

A. OBJECTIVE

This SOP is to define raw or source data as applied at The University of Iowa Dezii Translational Vision Research Group (DTVR). This SOP also outlines the types of documents that may be accepted by DTVR from outside sources when signed documents are needed to meet GMP requirements.

B. APPLICABILITY

This SOP shall be performed by The University of Iowa Dezii Translational Vision Research Group (DTVR) staff under the direction of the Quality Assurance Officer.

C. REFERENCES

21 CFR Part 11
21 CFR Part 58

D. DEFINITIONS

According to the Code of Federal Regulations, raw data "means any laboratory worksheets, records, memoranda, notes, or exact copies thereof that are the result of original observations and … are necessary for the reconstruction and evaluation of the report of that study." (21 CFR 58.3) Raw data may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments.

Electronic source data are data initially recorded in electronic format. They can include information in original records and certified copies of original records of clinical findings, observations, or other activities captured prior to or during a clinical investigation used for reconstructing and evaluating the investigation. For the purposes of DTVR, electronic source data are data for which the originator is clearly identified and unambiguous (e.g., entries in the LabGuru system) and which can only be altered/corrected with clear authorization and a documented audit trail.

E. PROCEDURE FOR ACCEPTANCE OF ELECTRONIC DOCUMENTS

1. From time to time data may be supplied to The University of Iowa DTVR by contract laboratories, testing contractors, suppliers, etc., to support release of raw materials, components, and finished product, protocols, agreements, and other similar documents. The following are acceptable formats:

   1.1. Original documents that contain company letterhead and original signatures and dates.

   1.2. Facsimile documents containing hand written signatures and dates.

   1.3. PDF or scanned files sent via electronic mail containing hand written signatures and dates or electronic signatures.

2. Batch records, label formats, stability protocols, and similar document approvals may also be received as in step 1.

3. Facsimile, PDF and scanned documents meet 21 CFR Part 11 documentation rules in that the holder of the original is responsible for keeping that original for review. The University of Iowa DTVR will print the documents and include them with the appropriate records supporting the items listed in step 1.

E. History

Effective Date	Revision	Change
09 Aug 2015	0	Original document