

The University of Iowa Dezii Translational Vision Research Group

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TITLE: Protocol for Standard Forms

SOP Number: D-GLO-PRO-002

Revision Number: 0

Effective Date: 09 Aug 2015

2. Each standard form should have a header with The University of Iowa Dezii Translational Vision Research Group followed by the standard form title on each page. The title should be descriptive of the purpose of the form.
3. The footer of the standard form should contain the standard form number, revision number, effective date and pagination (page # of #) on each page.
4. Standard forms will be numbered with the convention F-D-DEP-CAT-XXX, where “D-“ signifies that the form is applicable to DTVR, DEP is a two or three letter code for the designated department, CAT is a two or three letter code designating the category to which the standard form applies and XXX is a sequential numbering of the form.
 - 4.1. See SOP D-GLO-PRO-001 for the department and category codes. Each standard form should have the same DEP and CAT codes as the SOP to which it is tied.
 - 4.2. Forms will start with revision 0 for the original document.
5. Tables should be used as much as possible to organize the information.
 - 5.1. The top row of a table should have a simple word or phrase that describes the information for each column.
 - 5.2. The first column of a table may contain simple words or phrases that describe the information for each row.
6. Basic instructions may be included on the form but longer explanations on how to fill out the form should be located in the associated SOP.

F. RESPONSIBILITIES

1. A standard form may be created by any of the permanent staff or by a contractor working with a permanent staff member.
 - 1.1. For revisions, the author should capture all changes on the Change Control Form for SOPs and Forms (F-D-GLO-PRO-001).
 - 1.2. If there are many changes to the form, the change control form may read ‘see attached’ and a copy of the form marked with the changes will be included. In this case, the copy of the form with the noted changes must remain with the change control form.
 - 1.3. The author should conduct the preliminary impact assessment.
 - 1.4. When writing or revising a form the author will solicit input on the procedure from the individuals who will be subject to it and/or are experts on the subject matter. Where a form crosses departmental lines input will be solicited from other department heads, and individuals, as deemed appropriate by their supervisors. This process may be accomplished through one-on-one communication or through the Quality Meeting.
2. The reviewer should be the departmental supervisor or a subject matter expert.
 - 2.1. The reviewer should check the new or revised form to determine the accuracy of the instructions in the SOP and to ensure that all necessary information will be captured.

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- 2.2. For revisions, the reviewer should check the change control form for accuracy. The change control form (or attached form with noted changes) should capture all changes.
- 2.3. The reviewer should also check for grammar and typographical errors.
3. The Quality Assurance (QA) approver should check the form against regulatory documents, if necessary, to ensure that all required information is captured.
 - 3.1. The QA approver should check the appropriateness of the form title and number, if necessary.
 - 3.2. For revisions, the QA approver should sign the Change Control Form for SOPs and Forms (F-D-GLO-PRO-001) and verify the impact assessment. If the impact assessment is not accurate, the QA approver will change the impact assessment. The QA approver will notify necessary personnel of the impact assessment for equipment validation, Calibration Manager entries or other processes affected by the impact assessment.
 - 3.3. The QA approver should also check for grammar and typographical errors.

G. REVISIONS

1. Effective standard forms may be revised at any time to reflect changes or clarifications to procedures or equipment. A change is instituted by filling out a Change Control Form for SOP and Forms (F-D-GLO-PRO-001). The change control form will list all changes, the reason for the change and a departmental review. The change control form shall become the document history.
2. Any submitted changes require an impact assessment as the changes may affect other forms, SOPs and Calibration Manager entries, etc.
 - 2.1. Changes to global forms will be submitted to all affected departments before revision to assess the impact to each department.
 - 2.2. A review of other SOPs and forms that may be impacted will be made. Those SOPs and forms reviewed will be listed on the change control form. Affected SOPs and forms will be listed.
 - 2.3. Assess if entries into LabGuru, other than for the new or revised form, are affected by the proposed changes. Record any affected entries to LabGuru on the appropriate line (e.g. if a revision to an SOP and form on equipment qualification, validation, calibration or preventive maintenance would add or delete activities, the LabGuru entries for that equipment would also need to be updated).
 - 2.4. Assess if changes to the form will affect procedures or other functions (e.g. equipment cleaning procedures, facility procedures, etc.).
3. The change control form shall be submitted to QA for approval.
 - 3.1. For extensive revisions to forms, the form may be copied and marked up with the changes and attached to the change control form. This marked up copy of the form must remain with the change control form.

