## I. NAME OF PROCEDURE:

Standard Operating Procedures and Policies (SOPs)

## II. PRINCIPLE

The purpose of a Standard Operating Procedure (SOP) for SOPs is to provide uniformity and guidance in the process of writing, maintaining, and disseminating procedures in a consistent manner in accordance with FDA, FACT, AABB, and NCCLS guidelines. The purpose of the associated SOP Manual is to ensure accurate conduct of all Cell Therapy Facility operations, including all processes, policies, quality functions, as well as to insure compliance with all relevant accreditation and regulatory standards including FDA, FACT, AABB, CAP, JCAHO and state regulations

## III. SPECIMEN N/A

## IV. RESOURCES

### A. Forms

- xxTF-I-001A New & Revised SOP Draft Review
- xxTF-I-001B Review Training for new revised SOPs
- xxTF-II-009.1 Validation Protocol Form
- xxTF-X-019 Stem Lab Process & Protocol Validation

### B. Other Essential SOPs

- xxF-I-002 Process Control
- xxF-I-005 Change Control
- xxF-I-011 Cell Therapy Facility Director – Scope of Responsibilities
- xxF-I-012 Cell Therapy Facility Manager – Scope of Responsibilities
- xxF-I-013 Cell Therapy Facility QA Coordinator – Scope of Responsibilities
- xxF-I-014 Cell Therapy Facility Medical Directors – Scope of Responsibilities
- xxF-X-015 Layout Process & Protocol in Stem Lab
- xxF-X-030 Use of Cell Therapy Facility SOP Template for MS Word

### C. Other Resources

- Cell Therapy Facility SOP Template for MS Word
  X Lab\SOPs\SOP TEMPLATE

## V. SUPPLIES AND REAGENTS N/A

## VI. PROCEDURE

### A. APPLICABILITY OF THIS SOP

All standard operating procedures / policies of the Therapy Facility which are generated or revised on or after the effective date of service of this SOP on Standard Operating Policies / Procedures must be

prepared in compliance with the provisions contained herein. SOPs generated and fully approved and placed into service prior to the effective date of this SOP may remain in current form until they are next revised. *In pre-effective-date SOPs, significant deviation from the provisions of this SOP may be grounds for requiring revision, at the discretion of the facility director.*

## B. ORGANIZATION OF THE SOP MANUAL

The Cell Facility SOP manual shall be arranged in xx volumes, each of which will be assigned a roman numeral numbering sequence, as shown in the following table:

| Number | Volume Title | Description of Content |
|---|---|---|
| I | Administration and General Policies | SOPs that describe facility organization and management, functions and responsibilities of all facility personnel, and common practices for all laboratories within the facility |
| II | Quality Assurance | SOPs that describe the Quality Program and all quality activities of the facility |
| III | Cell Engineering Laboratory | Procedural SOPs for the generation of engineered cell products, principally for use in immunotherapy applications |
| IV | Apheresis / Blood and Marrow Collection | Procedural SOPs specific to the operation of the apheresis area. Includes SOPs that describe the activities of cell therapy staff in the harvesting of bone marrow for transplant. |
| V | Stem Cell Processing Laboratory | Procedural SOPs for the preparation of blood and marrow derived cell products for use as hematopoietic progenitor cell transplant products or for transfer to the cell engineering area for generation of engineered cell products |
| VI | (High Speed Fluorescence Activated Cell Sorter) | Laboratory planned but not implemented. |
| VII | GLP Laboratory | Laboratory in planning process. |
| VIII | Cell Response / Immune Monitoring Laboratory | Laboratory Planned Procedural SOPs for tests/assays for monitoring immunologic function in patients on therapeutic trials. |
| IX | Equipment and Facility | SOPs describing the monitoring, cleaning, maintenance, and calibration of all areas within the cell therapy facility and all equipment contained therein |
| X | Computers and Data Management | SOPs describing the use of specific computer applications critical to the collection and management of data generated in the cell therapy facility, and for the maintenance of all records including this SOP manual. |

A table of contents containing an ordered list of all of the SOPs within the above listed sections must be maintained. All original SOPs, with review signatures, validation studies, and training/review documentation, must be kept on file with the QA unit. Each individual area within the facility (i.e., stem cell lab, apheresis area, etc.) must have access to the SOP's by electronic delivery.

**C. Electronic copies shall be maintained in read-only format on XXX**

All SOP's will be written in size 12 or 14 font in Times New Roman or Arial font using the box style pages that the present document is prepared in. A template, prepared in MS Word file format, is available in the SOP root directory on the network drive. Instructions for use of this template, which includes pre-defined styles, are in SOP # CTF-X-201 Use of Cell Therapy SOP Template in MS Word.

Following are the elements of the SOP layout, including the areas of the block format on every page, and the specific sections that all SOPs must contain, and the review signatures that must be present on all *active* SOPs.

1. COMPLETION OF BLOCKS IN THE PAGE LAYOUT – ALL PAGES

At the TOP of each page must appear the facility name and address, the department name, the SOP number and the subject of the SOP. If the SOP has been implemented to replace a previously used SOP, then the SOP superceded must also be identified. The specifics of each of these top of the page items is as follows:

Facility name and address: xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx
SOP Number: This is a unique number assigned to the procedure. All SOPs in the Facility begin with the prefix 'CTF-'. The second part of the SOP number is the roman numeral denoting the volume it falls within, followed by another hyphen. The last part of the SOP number is the specific number within the volume, recorded as a three digit number, including leading zeroes. Procedures which have been revised beyond the original must also have a revision number, denoted by a final decimal point and revision number. The complete SOP number takes the form:

*CTF-<volume number>-<number within volume>.<revision>*

(for example, the second revision of this procedure is "CTF-I-001.2").

Insofar as practical, procedures should be organized within each volume in a logical sequence and listed in a master table of contents, plus an individual volume table of contents at the beginning of each SOP volume. *IF AN SOP IS TAKEN OUT OF SERVICE, IT'S UNIQUE NUMBER MAY NOT BE REUSED.*

SUBJECT: Generally, the subject is the specific name assigned to the SOP. For SOPs with long titles, the subject should be shortened by using abbreviations (for example, the subject for this SOP could be shortened to 'SOPs') and/or by eliminating less informative words in the title (examples, 'the', 'a', 'for').

At the bottom of each page the blocks must have the name and location of the word processor file containing the SOP text, the page number and the total number of pages, and on the hard copy, the dated initials of the Facility Director to evidence annual review.

FILE: The computer file name and location on intranet assigned to the SOP, placed at the top of the left hand box at the bottom of each page.
PAGE: The page and total number of pages, at the lower right corner of each page.

Facility Director initials with date to evidence annual review. Initials must be in the left hand box at page bottom, directly beneath the file name and location information. A new initial and date must be made for each year an SOP is in service.

2. SOP OUTLINE

The text of all SOPs shall be placed in the central area of each page, follow the outline detailed below. Each required section of the procedure is to be outline numbered with roman numerals and typed in bold face type and all caps (e.g. 'II. PRINCIPLE').

If any section does not apply to a particular procedure, write "N/A" or "Not Applicable" under the section. None of the required sections may be deleted from a written SOP.

The specific sections which must be included, and the information they must contain are as follows:

I. NAME OF PROCEDURE/POLICY: The specific name assigned to the SOP. The title must contain sufficient wording to be unambiguous.
II. PRINCIPLE: The objective of the procedure or policy and the general process or method used, if applicable must be written. A list of keywords may be appended to this section to aid in searching.
III. SPECIMEN: List specimen type and/or source material.
IV. RESOURCES: Identify all forms and essential additional SOPs that are associated with the SOP. List all equipment and what laboratory area needs to be employed for the procedure.
V. SUPPLIES AND REAGENTS: List all supplies and reagents needed for procedure.
VI. POLICY / PROCEDURE: Concise, clear description of each step of the procedure or each point of the policy. Describe in detail the steps to be followed in order to perform the procedure correctly. Procedures must be written in sufficient detail so that anyone with the appropriate background can read the SOP, follow it, and arrive at the intended outcome or end product.
VII. EXPECTED RESULTS/TROUBLESHOOTING/CORRECTIVE ACTION: A description or explanation of how to read, score, record results and interpretations, when applicable will be written in the SOP. Examples of calculations will be included in the SOP. Expected ranges (normals) will also be defined, when applicable. Steps to take to troubleshoot instances of incorrect or out-of-range outcomes should be included when possible. A complete list of corrective actions, including notifications and record keeping requirements must be included.
VIII. RESULT REPORTING: Specific directions as to how the results of the procedure and the conclusion are to be reported manually and/or electronically.
IX. DISCUSSION OR LIMITATIONS: Key notes or special comments on factors that may critically affect the procedure.
X. QUALITY CONTROL: Specific parameters to be monitored during processing or policy implementation by the performing personnel.
XI. DISTRIBUTION: A list of the specific manuals within the facility that the SOP must be included in. If appropriate, the statement 'All Cell Therapy Area SOP Volumes' may be used.
XII. REFERENCES: Specific citations that substantially support the policy / procedure and its objective. Wherein appropriate, standards and regulations should be cited.
XIII. SOP HISTORICAL OUTLINE: A separate last or second to last (depending on the presence or absence of appendices) page of all SOPs shall contain a tabular outline showing the inception, revisions and personnel making revisions over the entire history of the SOP. The information required in this table is described in the following subsection.

XIV APPENDICES (only if applicable) a separate page listing all appendices shall be present for all SOPs with appended forms or other documents.

## D. HISTORICAL OUTLINE

The final (second to final if appendices are present) page of all SOPs must contain an historical record in tabular format. Each line of the table shall be for a specific revision of the SOP. The table columns shall be used as follows:

DATE: Date of first writing, revision, review and removal of service.
WRITTEN/REVISED: Name of person who wrote or revised that procedure.
REVISON DESCRIPTION: Description of the revisions of that procedure.
MANAGER REVIEW: Signature block for the facility manager to indicate review of the policy / procedure.
FACILITY DIRECTOR REVIEW: Signature block for the facility director to indicate review of the policy / procedure.
MEDICAL DIRECTOR REVIEW: Signature block for the relevant medical director(s) to indicate review of the policy procedure.

*Because procedural SOPs are for the generation of products for human administration, their production may have medical implications.. Accordingly, all procedural SOPs must be reviewed and signed by the relevant medical director (i.e. – BMT medical director to sign for BMT specific SOPs, the immunotherapy medical director to sign for immunotherapy specific SOPs). Administrative, Quality, Maintenance and Computer SOPs do not generally have medical implications, and, on the determination of the facility director, may be placed in service without medical director or principal investigator review. In these instances the medical director signature block must be completed with the words NOT REQUIRED, and must be initialed by the facility director.*

PRINCIPAL INVESTIGATOR REVIEW: Signature block for the principal investigator of IND/IDE associated clinical trials to indicate review of the policy/procedure.

*Only SOPs that are associated with clinical trials and/or IND/IDE require principal investigator review and signature. SOPs that are determined by the Facility Director to not require this review must have this block completed with the words NOT REQUIRED, and must be initialed by the facility director.*

## E. ASSOCIATED FORMS AND APPENDICES

All forms associated with an SOP must follow that SOP as appendices. In the hard copy file, the form must be completed with mock data to serve as an example for completion. Forms must also be numbered, with the numbering system as follows:

- Forms numbers must be based on the associated SOP number, but are designated as forms by the prefix ‘F’. Thus, the second revision of a form associated with this SOP would be numbered FCTF-I-001.2.
- If there is more than one form associated with a particular SOP, then they should be distinguished by alphabetic suffixes. For example, because there are multiple forms associated with this SOP, they are numbered FCTF-I-001A, FCTF-I-001B.3, etc

Other appendices may follow an SOP, behind any associated forms. Examples of appendices are tables of values, nomograms, and copies of reference materials that are not otherwise easily accessed.

## F. GENERATION OF NEW SOPs

1. Authority

New SOPs are to be generated at the discretion of the facility director. The director will authorize and oversee the generation of new SOPs based on findings of the Quality Assurance program, or on the recommendation of the medical directors, the facility manager, the facility quality assurance department, or on the direction of the center director or any associate center director of the Research Institute

2. General

All new SOPs must be prepared in draft form. Writing of draft SOPs may be assigned by the facility director to an appropriate member of the facility staff. Representative personnel who may possess knowledge regarding the desired product of the SOP, or who may be responsible for its administration (stakeholders), must review draft SOPs. At minimum this must include the facility manager, the facility director, a QA coordinator or specialist, and medical directors and principal investigators if applicable. It is the responsibility of the facility director to insure that all stakeholders review drafts SOPs.

The circulating draft SOP must be accompanied by form zzTF-I-001A (New or Revised Draft SOP Review), and each reviewer must indicate on the form that they have read the draft SOP, and indicating what changes, if any, they have made to it. Changes may be made directly to the electronic document, but must be clearly noted prior to passing the document to the next reviewer.

All new SOPs must be validated (what range of results is obtained if the SOP is followed, and is it acceptable?). These tests are described in detail in the next section.

3. Generation of New Procedural SOPs

Procedural SOPs are to be developed according to the flow diagram in Figure 1.

New procedural SOPs generally will start in pre-clinical studies wherein the methodology associated with scaling up from research lab to clinical production must be worked out. The technologist performing the pre-clinical studies will write the initial draft SOP.
The facility manager, who is responsible for production from the finalized SOP, will do initial review on the SOP, and make preliminary edits to put it into a form consistent with production requirements.
The facility director will review the draft, as edited by the facility manager, and circulate for review to the relevant medical director and principal investigator(s).
The reviewed SOP will be returned to the facility manager who will assign it to one of the facility technologists. The technologist will first determine if the SOP is understandable. If it is not, it will be returned to the manager for further editing, and then will also recirculate to the facility director, medical director and principal investigator(s). The same technologist will also work with the facility manager and director to develop draft worksheet forms for the SOP, and using those forms will verify and validate the SOP (see section on verification and validation below), and record findings on form zzTF-II-009.1 (Validation). Failure in either verification or validation requires that the SOP be returned to the pre-clinical testing technologist.

SIMULTANEOUSLY with the SOP verification and validation process, the facility director will oversee the establishment of processes and a protocol in the Stem Lab database system. The process and protocol layout will be validated using the data generated by the validation tests of the SOP. In addition, a set of non-sense and or incorrect data will be tested against the StemLab data entry structures to insure that this type of data is handled appropriately. A report will be generated to insure that all data that has been entered is retained completely and accurately within the system.

Following successful verification and validation, and successful creation of the StemLab data structures necessary for retaining the data associated with the new SOP, the facility director, medical directors and principal investigator(s) will make a final review; the SOP will be assigned a number, and will be placed into the manual.

The facility manager, director and the technologist performing validation will determine the training necessary and devise a training checklist. The manager will assign technologists for training and the SOP will be placed into service.

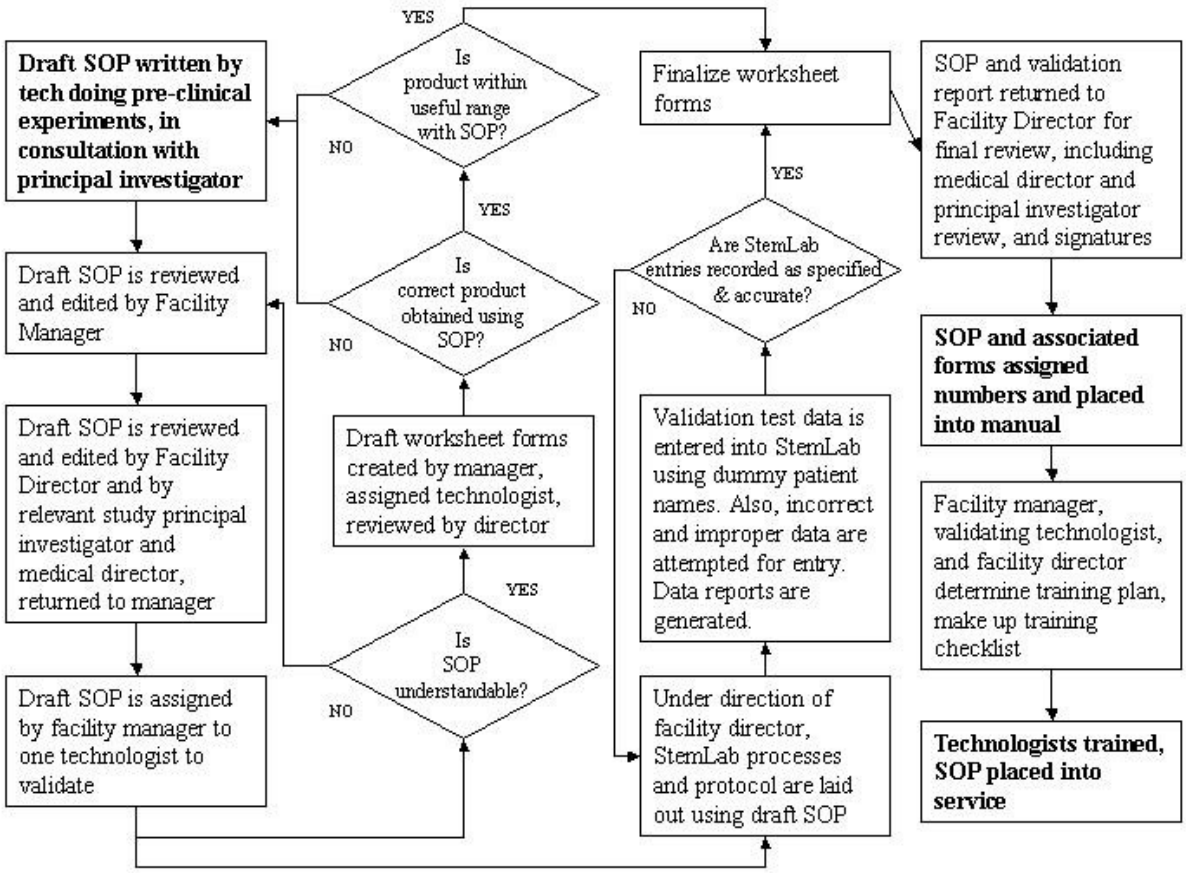


**Figure 1 – Flow chart for development and implementation of new procedural standard operating procedures.**

4. Generation Of New Administrative, Quality, Maintenance or Computer SOPs

New SOPs that are not designed to produce a specific end product are implemented according to the flowchart in Figure 2.

Under the direction of the facility director, a new SOP and necessary forms for documenting it's use are drafted.
The draft SOP is given to the facility director for review. If the person drafting the SOP was the facility manager, then this step is omitted.
The facility director reviews the SOP, and determines whether a medical director review is required. If medical director review is required, the facility director will circulate the draft SOP to the relevant medical director. If the SOP is a quality assurance related SOP, then the quality assurance department must also review.
The reviewed and modified SOP will be assigned to two or three members of the facility staff for verification and validation. Verification will consist of determining that the SOP is understandable, and determining that following the SOP will produce the intended outcome. Validation will consist of multiple technologists following the SOP and determining that all of them arrive at the same outcome. QA SOPs will be verified and validated by the QA Department. A validation report form zzTF-II-009.1 will be completed for all validation attempts.
The validated SOP will be assigned a number and placed in the manual
The manager and director will determine the need for training. If training is determined to be necessary, a training checklist will be created, and all technologists who are assigned to work on the SOP will have to complete the checklist before they may engage in the procedures described. Once training is complete the SOP will be placed into common service.
If training is determined to be unnecessary, the SOP will be placed in the 'Changes/New Procedures' notebook, and all technologists must sign an attached signature page indicating review and understanding.
Generally StemLab data structures are not created for non-procedural SOPs. However, the facility director may determine the need for such a structure, and the steps outlined in the above section would apply.

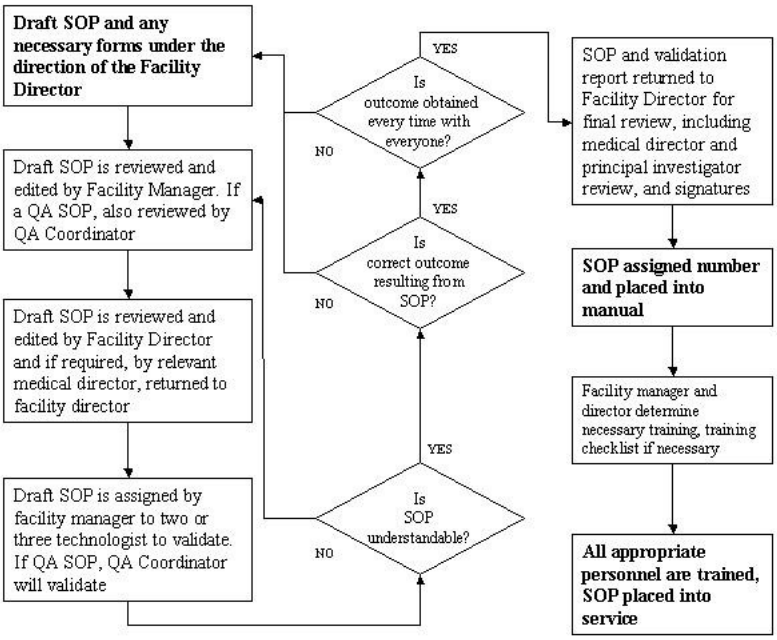


**Figure 2 – Flow diagram for the development of new SOPs that do not produce a specific product.**

5. Provisional SOPs

Provisional SOPs are SOPs where not all aspects have been completely validated. For example, SOPs for new investigational products are validated with test products, but may be found to require changes when applied to actual patient products. In those instances it is not practical to finalize such SOPs until a reasonable amount of different patient products have been manufactured and all variations are included in the SOP. The frequent changes in these SOPs are mainly concerned with the performance of individual patient products and are geared to maintain the requirements of the protocol. Provisional SOPs need to be reviewed only by the production Manager, the QA department and the Facility Director. A provisional SOP is deemed as such for a period of 90 days from its initial validation. During this period, there will be no need to write a deviation for each adjustment made to it. All changes must be documented, including what was changed, why it was changed and the date the change was made. At the end of the 90 days, the SOP can be either finalized or extended as a provisional SOP for another period of 90 days. An SOP should not remain in provisional status for more than 180 days. Provisional SOPs must be clearly labeled as such in the header of the SOP.

## G. SOP REVISION

SOPs must be revised only on the basis of determined need, following the guidelines established in xxF-I-005 (Change Control).

Once it has been determined that an SOP must change, generation of the revised SOP must follow the steps for generation of a new SOP, with the exception that not all changes in procedural SOPs will require pre-clinical testing, in which case the revision process begins with manager, director, medical director, and principal investigator review of the revised SOP, followed by the validation process.

The SOPs' format will be updated only as there is a need for the SOP revision. SOPs that have not been revised and therefore still in an earlier format will need to be changed within 5 years of the implementation of revision 4 of this SOP on SOPs.

Emergency procedural changes and deviations:
The need for an authorized expedited change in a procedure may arise where it is not practical to withhold the change in practice until all the parties have documented their review of the draft SOP. These changes must be requested and/or authorized by either the Facility Director or Medical Director, and can be managed in two ways.
Planned deviation report: This mechanism must be used if the planned deviation will affect only one product.
Procedural Updates document: This mechanism must be used if a change in procedure is time sensitive and will affect all products from that point forward. All the changes made using this mechanism should be added to the relevant SOP and properly reviewed within 6 months of implementation. The procedural Updates document will be kept and updated by the QA Department. An email will be sent to all personnel every time the document is updated and the update will also be published in the Laboratory's communications board. Data from the procedure change will serve as an ongoing validation for the revised SOP.

## H. VERIFICATION AND VALIDATION OF SOPS

Validation of SOPs is to be performed under the direction of the cell therapy facility director. The director will

- Determine what validation tests are to be performed
- Determine statistical methods to be employed to assess the outcome of the tests
- Complete the top part of form xxTF-II-009.1, indicating what validation studies are to be done, and the expected outcomes.

The facility personnel who perform the verification and validation testing will complete the remainder of the form. All documentation of results must be attached to the form, and the complete package must be kept on file as an appendix to the SOP in the main copy in the facility manager's office.

## I. REVIEW OF COMPLETED SOP

1. Director / Medical Director / Manager Review

Prior to initial SOP implementation, the facility director, manager and as required, relevant medical director, must sign in the appropriate boxes in the SOP historical record table at the back of the SOP, indicating review and approval.
If the facility director has determined that medical director review is unnecessary on an SOP, the boxes for medical director must be filed in with the words "Not Required" and initialed by the facility director.
If the facility director has determined that a principal investigator review is unnecessary on an SOP, the boxes for principal investigator must be filled in with the words "Not Required" and initialed by the

facility director.

2. Facility personnel review

The facility director and manager must determine whether staff training is necessary, or whether review of the new or revised SOP is sufficient. This determination must be recorded on form zzTF-I-001B (Training / Review Sign-off for New / Revised SOPs).
If the director and manager have determined that training is necessary for a new SOP or revised SOP, then training session(s) shall be conducted and training checklists completed. Each staff person completing training must also sign form zzTF-001B to indicate that they have received training.
When training is not required, as determined by the manager and director, new and changed SOPs will be placed in the change / new procedure book for facility staff to read and to sign on to form zzTF-I-001B to confirm that they have reviewed the SOP. Technologists not reading / reviewing / signing within 10 working days from the date of SOP finalization will receive written daily reminders until they do so. Copies of these reminders will be placed in the individual employees training folder and will be taken into consideration in employee evaluations.
At the conclusion of training / review, form zzTF-I-001B will be placed behind the SOP in the master SOP manual kept in the facility manager's office.

3. Annual Review

The facility director must review all pages of all SOPs at least once per 12 calendar months. This review must be evidenced by initialing and dating each page of the SOP, starting from the left lower corner of the page.
Laboratory personnel must attest to their familiarity with the SOP documents by signing the signature cover sheets for each section of the SOP manual at least once per 12 calendar months.

## J. Retired SOP Retention

Following replacement by a revised SOP, all SOPs shall be placed into secure storage. Retired SOPs are to be indefinitely. Electronic files containing retired SOPs shall be transferred to CD-ROM for permanent retention, and stored in a separate location from the paper versions. Storage areas for retained SOPs shall be secure and safe from potential adverse environmental effects such as flooding or fire. Off site storage at contract facility is permissible for records greater than two (2) years old.

## K. COMPUTER FILE STORAGE

SOPs shall be stored in MS Word (or compatible) formatted files (either .doc or .rtf format).

Files shall be saved according the following guidelines:

- SOP documents are to be saved in the limited access network directory **CellTherapyLab\SOPs\YYYY** (where YYYY is the specific subsection of the SOP manual that the specific SOP goes in).
- File names for SOP documents should be of the format *<SOP#> <brief name> <mm-yyyy>*. Thus the file name associated with the second revision of this document is xxx-I-1.2 Standard Operating Procedures 07-2003.doc.
- Retired SOPs must be saved to the 'Retired' folder within each section of the SOPs (*it is recommended that before modifying an SOP that this be done first using Windows Explorer to prevent inadvertent file modification*)

- Forms shall also be kept in MS Word formatted files, stored in the 'Forms' subfolder within each section of the SOPs directory. Filenames for forms must follow the same convention as for SOPs, i.e. *<Form#> <brief name> <mm-yyyy>*. Retired forms shall be stored in the 'retired' folder within the 'forms' folder.
- For security purposes, *all SOP, forms and supporting document files must be kept in read-only files locked by the hospital's IT department. Only the facility director, facility QA Department and facility manager may have write access to these files.*

## VII. EXPECTED RESULTS/TROUBLESHOOTING/CORRECTIVE ACTION

Final review of SOPs must insure that all steps for generation and revision have been appropriately followed. If there is insufficient documentation to demonstrate this, an investigation must take place into whether the steps have been followed, and the documentation must be updated. Further action towards SOP implementation must be suspended until such investigation is completed.

## VIII. RESULT REPORTING

SOP implementation, revision and retirement shall be reported in the monthly quality reports for the cell therapy facility.

## IX. DISCUSSION or LIMITATIONS

Careful generation of SOPs and attention to making sure that they are followed is the best assurance that errors will not occur. However, poorly crafted SOPs will cause errors. Therefore, it is critical to apply careful review and all controls called for in this SOP.

There are multiple circumstances wherein an SOP from another facility needs to be kept *for reference purposes only*. Under such circumstances, an SOP entitled "EXTERNAL SOP ON ……" may be created, and the external SOP in its entirety will be an appendix to that SOP. The SOP, in format designated by this SOP on SOPs must identify the source of the external SOP and what reference purpose it serves.

## X. QUALITY CONTROL

In addition to the validation process, SOPs must be subject to ongoing quality monitoring. All deviation investigations must include examination of the associated SOPs for possible inaccuracies, ambiguities, or contradictions.

## XI. DISTRIBUTION

All Cell Therapy Facility Area SOP Manuals

## XII. REFERENCE

1. Transfusion Service Manual of Standard Operating Procedures, Training Guides, and Competence Assessment Tools, Bethesda, MD: American Association of Blood Banks.
2. Foundation for Accreditation of Cellular Therapy standards. Second edition.
3. 21 CFR 211.100

4. 21 CFR 1271.180

## XIII. SOP Historical Record

| Rev# / Date | Written/Revised By | Revision Description | Supervisor Review | Facility Director Review | Medical Director Review | Principal Investigator Review |
|---|---|---|---|---|---|---|
| 0. Written: 3/2001 | M.T. | NA | | | | NOT REQUIRED |
| 1. 5/2001 | M.T. | Changed title block and Medical Direct. of Cell Response Lab. | | | | NOT REQUIRED |
| 2. 4/2002 | M.T. | Added font type & size required | | | | NOT REQUIRED |
| 3. 7/2003 | PhD | Added information RE numbering of SOPs and form, naming format & location of computer files | | | | NOT REQUIRED |
| 4. 8/2003 | PhD | Added requirement for associated forms and SOPs to be enumerated under RESOURCES; reorganized sections on organization and format to insure that example forms are attached to SOPs; Clarified number format; Defined who may initiate new SOP or SOP revision; establish review pathways and tracking for new / revised SOPs; establish mechanism for determining training requirements with SOP | | | | NOT REQUIRED |
| 5. 3/2006 | | Revised to allow for emergency procedural changes and format changes. | | | | NOT REQUIRED |
| 6. 8/2006 | | Revised to add provisional SOPs and changed QA coordinator to QA Department. Revised for practicality and clarified wording. | | | | NOT REQUIRED |
| 7. | | | | | | NOT REQUIRED |
| 8. | | | | | | NOT REQUIRED |
| 9. | | | | | | NOT REQUIRED |
| 10. | | | | | | NOT REQUIRED |
| Removed: | | | | | | NOT REQUIRED |

# XIV. APPENDICES

## A. FORMS

- XXXF-I-001A New & Revised SOP Draft Review
- XXXF-I-001B Review Training for new revised SOPs
- XXXF-X-019 StemLab Process and Protocol Validation