PBMC Laboratory Readiness Guide and Resources

Developed by the ACTG/IMPAACT Laboratory Technologist Committee

Version 2.0, 12 August 2011

Introduction

The purpose of the "PBMC Laboratory Readiness Guide and Resources" is to help PBMC processing laboratories prepare to meet Good Clinical Laboratory (GCLP) standards and/or for a Division of AIDS (DAIDS) audit. This document is based on a PBMC laboratory audit shell, and helpful guidance was added by experienced members of the ACTG/IMPAACT Laboratory Technologist Committee (LTC).

The PBMC laboratory audit shell does evolve over time, and so this resource might not address every question in the current audit shell. However, the differences will be minor. It is recommended that laboratory staff thoroughly review the current audit shell sent by the auditor in advance of the visit.

This document is intended for ACTG/IMPAACT laboratories but may be useful for other networks. Please note that the guidance and resources in this document were not developed by DAIDS or PPD.

In addition to the comments provided here, laboratory personnel will find it helpful to review the DAIDS Clinical Research Policies and Standard Procedures Documents, especially the DAIDS Good Clinical Laboratory Practices (GCLP) Standards at https://www.daidscrs.com/partners/Page_Laboratory_Management_Center/Page_GCLP_Standards/GCLP_Standards.htm. Online GCLP training is available through the DAIDS Learning Management System at https://daidslms.plateau.com/plateau/user/login.do.

If you should have further questions about how best to prepare for an ACTG/IMPAACT audit, please contact the LTC (actg.ltc@fstrf.org).

Laboratory Activities			
PBMC Processing	Yes ☐	No ☐	Comments ☐
PBMC Counting:	Yes ☐	No ☐	Comments ☐
Serum/Plasma Processing:	Yes ☐	No ☐	Comments ☐
Specimen Storage:	Yes ☐	No ☐	Comments ☐
Specimen Shipping:	Yes ☐	No ☐	Comments ☐
Other:	Yes ☐	No ☐	Comments ☐
Guidance:			

I. External Quality Assurance (EQA)

A. Does the laboratory participate in any external proficiency testing? (If "Yes", list the tests involved, frequency, proficiency program provider, and a summary of performance including the presence of corrective action if inadequate.)	Yes ☐	No ☐	Comments ☐
B. Is there documented review of EQA performance?	Yes ☐	No ☐	Comments ☐

Guidance: For PBMCs external proficiency testing:

- Processing laboratories must participate in the IQA Cryopreservation Proficiency Testing
- For survey information, a lab can contact Raul Louzao: raul.louzao@duke.edu
- The viability (V) and viable recovery (VR) requirements are network specific.
- Participation is required quarterly.
- Notification of each PBMC survey is sent out by email in advance.
- All paperwork for the "Freezing Assessment Program" needs to be kept on site for 2 years.
- All survey results must be signed and dated by the PI and kept on site for 2 years.
- All personnel who freeze PBMCs for clinical trials should be rotated through the cryopreservation program.
- Any deficiency (not meeting a network standards) will require corrective action and documentation
- Corrective action frequently requires a review of the procedure, retraining of the lab personnel and an internal testing of frozen PBMCs. All of this needs to be documented, signed, dated and approved by the PI.
- A Standard Operating Procedure (SOP) needs to be in place for dealing with all of the above. This document needs to be approved by the Laboratory Director, signed and dated at the time of initiation. It needs to be reviewed yearly for any updates, sign by the PI and all personnel doing PBMC cryopreservation.

II. Organization and Personnel

A. Is an organizational chart inclusive of all laboratory personnel involved with DAIDS-funded protocol-related activities present?	Yes ☐	No ☐	Comments ☐

Guidance:

- Design an organizational chart starting with the Laboratory Director and including all personnel who are responsible for processing specimens in DAIDS sponsored protocols.
- State the degrees each individual has acquired (M.D., MT, BS, etc.) behind their name
- Group these individuals in your institution's appropriate categories. (PI, Supervisor, Research Assistant I, II, III, IV, lab manager, technologist/technician, etc.)
- Create a flow chart indicating how these laboratory individuals interrelate with each other and interact with the clinic(s) they serve.
- Update these charts whenever there is a personnel change or yearly, whichever comes first.
- All updates need to be signed by the Laboratory Director and both the PI and all personnel need to sign all Standard Operation Procedures (SOP) yearly.
- All new personnel need to sign-off on SOPs at the time of employment.

B. Personnel Records

1. Are personnel records kept? (If "yes", describe in the "Comments" section how personnel records are kept.)	Yes ☐	No ☐	Comments ☐

Guidance:

2. Is job description/delegation of duties documentation present for all lab personnel involved with DAIDS-funded protocol-related activities?	Yes ☐	No ☐	Comments ☐

Guidance:

- Create a detailed job description for each category in the organizational chart.
- The job description needs to contain the following:
  - Appropriate qualification (education) for each position
  - Individual's responsibilities at that position
  - Their training and whether they will train others
  - Experience requirements for the position
- Copies of these jobs descriptions need to be filed in each employee's personnel file, as well as being a part of the lab manual personnel section.
- Job descriptions/responsibilities need to be reviewed yearly, changes made when necessary and signed annually.

3. For each laboratory position involved with DAIDS-funded protocol-related activities, is there a documented profile that lists requirements such as education, experience, and certification/license requirements? (If "Yes", list all position requirements in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance:

Using the job descriptions mentioned above, design a Personnel Standard Operation Procedure, which should start with your institution's heading and include:

- A place for the Laboratory Director's signature plus date signed
- The author's signature plus the date signed
- The time the SOP was placed into service
- An area for annually documented reviews or for future changes made to the SOP

See Appendix A: Example Personnel Standard Operation Procedure

4. Are education records maintained for all laboratory employees involved with DAIDS-funded, protocol-related activities?	Yes ☐	No ☐	Comments ☐

Guidance:
- A file needs to be maintained on each employee containing the following:
- Job description with duties and responsibilities clearly outlined
- Employee's Curriculum Vitae (CVs). This should be updated regularly, signed and dated by the laboratory employee and their supervisor.
- All lab training records – signed and dated
- All certifications (e.g. M.T. (ASCP), B.S., Shipping, Working with Human subjects, etc.)
- All IQA cryopreservation results for surveys in which they were the technician assigned – signed and dated
- All other personnel competency testing – signed and dated

5. Are assay-specific training records available (or kept on file) for all laboratory personnel involved with protocol-related activities?	Yes ☐ No ☐ Comments ☐

Guidance:
- Training programs need to be developed, performed by the appropriate employees, and documented:
  - Initial Training: Training that develops trainee's knowledge and skills to perform specific jobs (PBMC cryopreservation, LDMS training, etc.)
  - Continuing Training: Training that maintains, enhances, or increases the proficiency of employees.
  - Retraining: The process of providing remediation or tutoring for employees deficient in specific job functions.
- All of these types of trainings need be documented in a lab training manual, dated and signed by the employee and supervisor (or designee).
- A personnel competency testing schedule needs to be established within the manual. An employee training log could be established as a method of documentation.
- All employee personnel files should have a copy of their training records, signed and dated by the individual and supervisor (or designee).

6. Have any laboratory staff personnel undergone Good Clinical Laboratory Practice (GCLP) training? (If "Yes, indicate the training provider and total number of personnel who have been trained.)	Yes ☐ No ☐ Comments ☐

Guidance:
- It is recommended that labs, especially those that are new to DAIDS-funded protocol-related activities or are having problems meeting GCLP standards, attend a DAIDS-sponsored workshop.
- If a member of the lab has GCLP training, the employee should have their DAIDS certificate in their personnel file and a copy of the DAIDS training manual in the lab for all to use.

7. Is documentation maintained, indicating the laboratory has assessed the competency of each employee to perform his or her assigned duties? (If "Yes", report the methods utilized to assess competency, as well as the frequency of evaluation, in the "Comments" section.)	Yes ☐ No ☐ Comments ☐

Guidance:
- Working from the lab's SOP training manual, documentation for each employee's competency testing should be logged in following the guidelines stated in the SOP.
- The SOP training manual needs:
  - Method(s) of training
  - Frequency of competency training
  - Corrective Action
  - A log documenting all of the above with a place for employees' and trainers' signatures
  - A written documentation of all competency testing should be placed at the end of the training manual and in an employee's file.
  - When re-training is necessary, a corrective action report will to be generated stating how the problem(s) was resolved.
- **All** competency testing should be signed by the employee and his/her supervisor.

8. Are Staff Signature Lists (signature/initial/ID) present to verify responsible staff?	Yes ☐ No ☐ Comments ☐

Guidance:

C. Does the laboratory have a policy for employees to communicate concerns, regarding testing quality or laboratory safety to management?	Yes ☐ No ☐ Comments ☐

Guidance:
- Concerns Regarding Testing Quality: The Organizational Chart establishes the direct lines of communication for all employees. At the time of employment, a sign-off sheet, usually provided by the employer, should indicate to the new employee who they can communicate concerns.
- Research labs need to establish weekly/monthly meeting to discuss research projects. These meetings could easily start with a statement asking if there are any technical issues.
- Institutions often have manuals that are either in the lab or on-line that describe with safety issues and how to handle them. New employees are taught at the time of employment how such problems can be handled. This training is updated yearly with documentation.

D. Has the laboratory been certified by any regulatory/accrediting agency? (If "Yes", list the agency and date of certification.)	Yes ☐ No ☐ Comments ☐

Regulatory/Accrediting Agency	Dates of Certification

III. Testing Facilities Operation

A. Standard Operating Procedures

Written Procedure Name	Annual Review Completed by Lab Director/Designee?	Lab Director/Designee Signature Present?
1.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
2.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐

3.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
4.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
5.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
6.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
7.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
8.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
9.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐
10.	Yes ☐ No ☐ Comments ☐	Yes ☐ No ☐ Comments ☐

Guidance: For this section, the monitor usually chooses 10 SOPs randomly to verify that annual review and original approval by the Lab Director are present.

B. Are SOPs written in a standard format?	Yes ☐ No ☐ Comments ☐

Guidance: For an example SOP in CLSI format, see Appendix 4 of the DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards at http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf.

C. Is there a written document control plan that addresses topics such as procedural relevance, authorization process, annual reviews, and discontinuation of procedures?	Yes ☐ No ☐ Comments ☐

Guidance: See *Appendix B: Example SOP Management SOP*.

D. Are all laboratory SOPs reviewed for accuracy and relevance on an annual basis?	Yes ☐ No ☐ Comments ☐

Guidance: Ensuring that all SOPs are reviewed annually is very important. Keeping a table of annual review dates can assist in ensuring that annual reviews do not lapse. There are different opinions on whether it is better to review all SOPs at one time or better to spread them out over several months. If they are done all at one time it may be overwhelming and burdensome. Reviewing over several months, it is important to ensure no SOPs are missed.

E. Does the laboratory have a system of documenting that all personnel are knowledgeable of the contents of the laboratory's SOPs?	Yes ☐ No ☐ Comments ☐

Guidance: Documentation of personnel knowledge can be done in many ways. You may want to have a lab meeting or training retreat in which each SOP is reviewed and staff sign a 'read and understood' statement. Also acceptable is to allow staff to review SOPs on their own time and sign the 'read and understood' statement once they have finished. The latter is more difficult to ensure all staff has reviewed all appropriate SOPs. See *Appendix C: Example Read and Understood Statement Template*

F. Are the laboratory SOPs available in the work area?	Yes ☐	No ☐	Comments ☐

Guidance: Ensure that all work areas have a document controlled copy of each appropriate SOP.

G. Are superseded SOP versions identified as retired and archived in the laboratory? (If "Yes", explain the archiving process and provide the retention time in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance: Stamping old SOPs as 'retired' is an easy way to meet this requirement. The original of all retired SOPs must be maintained and it is a good idea to maintain the SOP specific read and understood documentation with the retired originals. See *Appendix D: Example Document Control SOP Template*, which includes the retiring of old SOPs.

IV. Quality Management

1. Does the laboratory have a Quality Assurance/Quality Management program? (If "No", skip to Question 3.)	Yes ☐	No ☐	Comments ☐
2. Does the program follow a documented, operational plan designed to monitor, assess, and (when indicated) correct problems identified in pre-analytic, analytic, and post-analytic systems as well as general laboratory systems?	Yes ☐	No ☐	Comments ☐
3. Are key indicators of quality monitored and evaluated, to detect problems and opportunities for improvement?	Yes ☐	No ☐	Comments ☐
4. Is there evidence that Corrective Action/Preventive Actions (CAPAs) are monitored through to resolution?	Yes ☐	No ☐	Comments ☐
5. Is Quality Management documentation surrounding key indicators of quality and CAPAs reviewed by the Laboratory Director/designee? (If "Yes", indicate the frequency of review in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance:

1 & 2. Lab should have a current written QA/QM overview document explaining the objectives of the QM program and how the effort meeting those objectives is monitored or evaluated. For an example, see Appendix 14 of the DAIDS Guidelines for Good Clinical Laboratory Practice Standards at http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf.

3. Examples of indicators of quality for a processing lab: % samples processed within expected time, IQA proficiency results, % error-free shipments to BRI or JHU, specimen quality & paperwork accuracy upon receipt in processing lab, response to lab oriented queries.

4. Corrective actions and preventive actions (CAPAs) should be documented and the outcome of those actions monitored and assessed for effectiveness. Good to involve all lab personnel.

V. Equipment

A. Is all laboratory equipment listed on an inventory document?	Yes ☐ No ☐ Comments ☐

Guidance: Equipment inventory should list item, type of equipment, model, serial number, university or facility's number (if applicable), and location in lab. Can also list PM schedule and whether PM performed by lab or outside service personnel. Note: include BSCs in the equipment list (even if considered part of the building).

B. Are there documented Preventive Maintenance (PM) and calibration plans for all laboratory equipment indicated?	Yes ☐ No ☐ Comments ☐

Guidance: SOPs listing the parameters maintained are needed for each instrument PM. You do not need to re-write the manufacturer's manual for each unit, just reference the manual. For example, if your lab has three different model centrifuges, all three likely still need the following to be checked at least annually: verify timer, verify centrifuge speed accuracy, inspect brushes, rotor, spindle, buckets , lids & o-rings, verify latch, imbalance detector & other safety interlocks, check the general condition of the cord and plug. In addition, the lab should have cleaning procedures that performed at frequent specified intervals.

C. Laboratory Equipment

Verify the following as it applies to equipment used for study-specific laboratory activities: (List the manufacturer and model of the equipment where applicable in the Comments section.)

1. Are freezers present? (If "No", skip to Question 2.)	Yes ☐ No ☐ Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐ No ☐ Comments ☐
b. Are temperature readings taken/documented? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
c. Have tolerance limits been established/documented for temperature readings?	Yes ☐ No ☐ Comments ☐
d. Is an alarm system with set-point temperature ranges available? (If "Yes", report the frequency of alarm testing in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
e. Is there documentation of corrective actions taken, in response to out-of-range values?	Yes ☐ No ☐ Comments ☐

Guidance:

e. It is very important to document the corrective action taken when a unit is out of range. Sometimes a lab will just continue recording temperatures without recognizing something is out of range. It is helpful to have the defined expected range displayed prominently on the chart where temperatures are recorded.

2. Are refrigerators present? (If "No", skip to Question 3.)	Yes ☐ No ☐ Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐ No ☐ Comments ☐
b. Are temperature readings taken/documented? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
c. Have tolerance limits been established/documented for temperature readings?	Yes ☐ No ☐ Comments ☐

d. Is an alarm system with set-point temperature ranges available? (If "Yes", report the frequency of alarm testing in the "Comments" section.)	Yes ☐	No ☐	Comments ☐
e. Is there documentation of corrective actions taken, in response to out-of-range values?	Yes ☐	No ☐	Comments ☐

Guidance:

c. Tolerance limits must be appropriate for the contents. If you store a reagent that is supposed to be kept at 4-8°C, the refrigerator range cannot exceed that window, i.e., cannot be listed as 2-8°C.

e. Same as above: It is very important to document the corrective action taken when a unit is out of range. Sometimes a lab will just continue recording temperatures without recognizing something is out of range. It is helpful to have the defined expected range displayed prominently on the chart where temperatures are recorded.

3. Are liquid nitrogen freezers present? (If "Yes", describe the capacity available in the "Comments" section. If "No", skip to Question 4.)	Yes ☐	No ☐	Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐
b. Are temperature readings or nitrogen levels taken/documented? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐	No ☐	Comments ☐
c. Have tolerance limits been established/documented for temperature readings?	Yes ☐	No ☐	Comments ☐
d. Is an alarm system with set-point temperature ranges available? (If "Yes", report the frequency of alarm testing in the "Comments" section.)	Yes ☐	No ☐	Comments ☐
e. Is there documentation of corrective actions taken, in response to out-of-range values?	Yes ☐	No ☐	Comments ☐
f. Does the LN freezer room have monitoring equipment to detect oxygen levels?	Yes ☐	No ☐	Comments ☐

Guidance:

d. Same as above: It is very important to document the corrective action taken when a unit is out of range. Sometimes a lab will just continue recording temperatures without recognizing something is out of range. It is helpful to have the defined expected range displayed prominently on the chart where temperatures are recorded.

f. LN2 freezers must be stored in well ventilated areas and should not be in confined rooms with poor air flow. If LN2 units are housed in a closed room, an oxygen monitor device must be employed. If LN2 units are in well ventilated areas, an institutional environmental health & safety expert may evaluate the area and determine whether or not an oxygen monitor is warranted. If the area is found to not require an oxygen monitor, written documentation of those findings should be available for the auditor. The intent is to be sure there is adequate ventilation at all times, even when active ventilation systems are not working at peak levels.

4. Are incubators present? (If "No", skip to Question 5.)	Yes ☐	No ☐	Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐
b. Are temperature readings taken/documented? (If "Yes", report the frequency in the Comments section.)	Yes ☐	No ☐	Comments ☐

c. Have tolerance limits been established/documented for temperature readings?	Yes ☐	No ☐	Comments ☐
d. Is there documentation of corrective actions taken, in response to out-of-range values?	Yes ☐	No ☐	Comments ☐

Guidance:

d. Same as above; it is very important to document the corrective action taken when a unit is out of range. Sometimes a lab will just continue recording temperatures without recognizing something is out of range. It is helpful to have the defined expected range displayed prominently on the chart where temperatures are recorded.

5. Are water baths present? (If "No", skip to Question 6.)	Yes ☐	No ☐	Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐
b. Are temperature readings taken/documented? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐	No ☐	Comments ☐
c. Have tolerance limits been established/documented for temperature readings?	Yes ☐	No ☐	Comments ☐
d. Is there documentation of corrective actions taken in response to out-of-range values?	Yes ☐	No ☐	Comments ☐

Guidance: See V-B above. Remember to state the timing of temperature reading, i.e. daily, each use etc.

6. Are centrifuges present? (If "No", skip to Question 7.)	Yes ☐	No ☐	Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐
b. Is calibration performed/documented for each centrifuge? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance: See V-B above. Frequency is routinely every six months.

7. Are biosafety cabinets/laminar air flow hoods present? (If "No", skip to Question 8.)	Yes ☐	No ☐	Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐
b. Has each cabinet/hood been certified? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance: See V-B above. Biosafety cabinets/laminar air flow hoods should be certified yearly and the date of certification posted on the cabinet. See the operators manual to determine what the certification and preventive maintenance should consist of.

8. Are pipettors present? (If "No", skip to Question 9.)	Yes ☐	No ☐	Comments ☐
a. Are calibration procedures performed for all pipettors? (If "Yes", report the frequency in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance: See V-B above. Check for volumetric accuracy and reproducibility, and recalibrate as necessary before placing in service initially and at specific defined intervals. DAIDS requires that pipettors be checked for accuracy and reproducibility and recalibrated at least once every six months. Pipettor malfunction is one of the most common sources of laboratory error. Therefore, DAIDS strongly recommends that laboratories perform checks for accuracy and reproducibility and recalibrations four times per year, with at least two of the four performed by an external contracted service provider. It is helpful to have the date of calibration posted on the centrifuge.

9. Are thermometers present? (If "No", skip to Question 10.)	Yes ☐	No ☐	Comments ☐
a. Is a known standard thermometric device available (NIST certified)?	Yes ☐	No ☐	Comments ☐
b. Have all non-certified thermometers been tested against a standard device before being placed in service?	Yes ☐	No ☐	Comments ☐

Guidance: For NIST-certified (or equivalent) thermometers, follow manufacturer's recommendations for calibration and expiration date.

10. Are balances present? (If "No", skip to Question 11.)	Yes ☐	No ☐	Comments ☐
a. Are calibration procedures performed, as described by the manufacturer?	Yes ☐	No ☐	Comments ☐

Guidance:

11. Are microscopes available? (If "No", skip to Question 12.)	Yes ☐	No ☐	Comments ☐
a. Are Preventive Maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐

Guidance:

12. Is a hemacytometer available? (If "No", skip to Question 13.)	Yes ☐	No ☐	Comments ☐
a. Has the laboratory demonstrated and documented the ability to perform reliable counts for the manual cell counting method used in the laboratory?	Yes ☐	No ☐	Comments ☐

Guidance:

13. Is an automated cell counting method and instrument in use in the laboratory? (If "No", skip to Question 14.).	Yes ☐	No ☐	Comments ☐
a. Are Preventive maintenance activities performed/documented?	Yes ☐	No ☐	Comments ☐
b. Has the laboratory verified or established and documented analytical accuracy and precision of the automated cell counting method?	Yes ☐	No ☐	Comments ☐
c. Has the laboratory verified or established and documented an analytic measurement range (linearity)?	Yes ☐	No ☐	Comments ☐
d. Is sensitivity and specificity documentation present?	Yes ☐	No ☐	Comments ☐

e. Is the instrument calibrated? (If "Yes", describe the frequency of calibrations in the "Comments" section. If calibrations are not performed, skip to Question 14.)	Yes ☐	No ☐	Comments ☐
f. Are calibration materials stored as required by the manufacturer?	Yes ☐	No ☐	Comments ☐
g. Are calibration materials properly labeled, indicating content and calibration value?	Yes ☐	No ☐	Comments ☐
h. Is a backup method available for automated cell counting?	Yes ☐	No ☐	Comments ☐
i. Are there periodic comparison checks between the primary and backup methods?	Yes ☐	No ☐	Comments ☐

Guidance: See V-B above. See operator's manual for automated cell counting instrument. Preventive maintenance consists of daily, weekly, monthly maintenance performed by the operator and a 6-12 preventive maintenance check performed by the manufacturer.

14. Is equipment for PBMC rate control freezing available?	Yes ☐	No ☐	Comments ☐
a. Are Preventive maintenance activities performed/documented where appropriate?	Yes ☐	No ☐	Comments ☐

Guidance:

14. Is additional equipment used for protocol-related assays present? (If "Yes", describe in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance:

D. Is there a written policy/procedure in place, explaining how temperatures are monitored during the absence of laboratory staff?	Yes ☐	No ☐	Comments ☐

Guidance: Labs with automated monitoring systems will need to have a concise description of the system, detailed acceptable ranges for each monitored piece of equipment, remedial action plan for out-of range events or equipment breakdowns and access to electronic monitoring logs. If daily manual monitoring is used then you'll need a low tech monitoring device such as a min/max temperature monitor that is read after each absence (evenings and weekends/holidays). Freezers can be monitored for temperature excursions leading to potential thaws also with min/max and/or biphasic dye tubes.

E. Are all maintenance, repair, and calibration records reviewed and signed monthly by a supervisor or designee?	Yes ☐	No ☐	Comments ☐

Guidance: Temperature logs should be reviewed daily and signed monthly by a designee. Maintenance and repair logs should be signed after each repair or annual (semi-annual) maintenance event. Same would be true for scheduled micropipette or other equipment calibrations.

F. Are there records to verify that a back-up power source (generator, Uninterrupted Power Supply) is in place and operational? (If "Yes", list the parameters checked, PM activities monitored, as well as frequency of testing.)	Yes ☐	No ☐	Comments ☐

Guidance: Generator testing information is typically held by local engineering of facilities, maintenance groups. Most surveyors do not require immediate access to the records however some surveyors may require that they be provided within an hour or within a 24-hour period. Make arrangements with your local maintenance groups to provide access at least within a 24-hour period or copies of each generator test as needed.

VI. Test and Control Articles

A. Reagent Quality			
1. Are reagents labeled to indicate identity, lot number, storage requirements, date prepared/opened and expiration date?	Yes ☐	No ☐	Comments ☐
2. Are all reagent storage requirements being followed according to manufacturer's recommendations?	Yes ☐	No ☐	Comments ☐
3. Are all reagents used within their listed expiration date?	Yes ☐	No ☐	Comments ☐
4. Are documented procedures used to check or monitor the integrity of new lots of reagents prior to being placed into service? (If "Yes", describe in the "Comments" section.)	Yes ☐	No ☐	Comments ☐
5. Are there manufacturers' Certificates of Analysis (CoA) present for specimen processing reagents? (e.g. FBS, DMSO, HBSS or PBS or RPMI 1640, and Ficoll or Histopaque or Accuspin)?	Yes ☐	No ☐	Comments ☐

Guidance:

1-3. Make sure that you have product insert information on hand that provides storage details.

4. Not all reagents require cross validation. Identify those that do, such as enzymes, controls, FBS lots (use ACTG lots) etc, and document the number of validation events and results of those events.

B. Quality Control Materials			
1. Does the laboratory use an automated cell counting method? (If "No", skip to Section C.)	Yes ☐	No ☐	Comments ☐
2. Are all Quality Control materials dated within the manufacturer's assigned expiration dates?	Yes ☐	No ☐	Comments ☐
3. Are all Quality Control materials properly stored as required by the manufacturer?	Yes ☐	No ☐	Comments ☐
4. Are all Quality Control materials properly labeled to indicate identity, lot number, storage requirement, date prepared/reconstituted, and expiration date?	Yes ☐	No ☐	Comments ☐
5. Are control materials used at more than one level? (If "Yes", indicate the number of levels used in the "Comments" section.)	Yes ☐	No ☐	Comments ☐
6. Are controls tested in the same manner as patient samples?	Yes ☐	No ☐	Comments ☐
7. Is a log present documenting control results? (If "No", skip to Question 9.)	Yes ☐	No ☐	Comments ☐
8. Does the technologist performing the QC initial and date the log?	Yes ☐	No ☐	Comments ☐
9. Are charts utilized to document QC Data (i.e. Levy Jennings charts)?	Yes ☐	No ☐	Comments ☐

10. Is there monthly review of the QC data by the Supervisor or designee?	Yes ☐	No ☐	Comments ☐
11. Are all QC documents available for the past two years?	Yes ☐	No ☐	Comments ☐

Guidance:

2-4. Same comment as in section A.

5. At least 2 control levels are required for most applications. Include a normal control with either a high or low control (deemed most appropriate internally). Levy-Jennings logs usually work well. (For an example, see *Appendix 6 of the DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards at* http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf.) Controls should always be run like patient samples unless there is a very good reason for not doing so –such as a direct manufacturer's instruction. QC data should be monitored daily and signed monthly or at the end of a lot.

C. Quality Control Failure/Corrective Action Log			
1. Is there documentation of Corrective Actions taken in response to all QC failures? (If no documentation is present, skip to Section D.)	Yes ☐	No ☐	Comments ☐
2. Has a supervisor/designee reviewed and signed the records for QC failures? (If "Yes", note the frequency in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance:

1 & 2. Corrective actions must be taken for any QC failure and testing/preparation of patient samples should not proceed until the problem is resolved with documentation of the resolution. The failure and resolution should be signed for each event. It is best to "bookmark" these events to demonstrate your local process for a surveyor.

D. Manual Cell Counting Quality Control			
1. Does the laboratory perform manual cell counts? (If "No", skip to Section E.)	Yes ☐	No ☐	Comments ☐
2. Has the lab established limits to determine whether the cell counts between squares are comparable?	Yes ☐	No ☐	Comments ☐
3. Are cell counts verified by another technologist periodically? (If "Yes", list the frequency of verification in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance:

2. Establishing counting variability can be done by taking the same sample and preparing 5 chambers with 4 independent corner counts per chamber. Establish the mean count and standard deviation. Do this with each technician. Generally counts that are 3 or more standard deviations greater than the mean are considered unacceptable. Each lab can create their own limitations but then must adhere to the criteria that they established.

3. This should be done at least twice a year. Cross technician verification can also be combined as part of technical competency review. If this approach is taken, make sure that results are filed in each technician's competency folder and as part of the cell counting quality assurance documentation.

E. Water Quality

1. Does the laboratory testing require specific water types for certain procedures? (If "Yes", describe in "Comments" section. If "No", skip to Section F.)	Yes ☐ No ☐ Comments ☐
2. If specific water types are required, is there a documented policy that defines standards for water and frequency of water testing?	Yes ☐ No ☐ Comments ☐

Guidance:

2. Water quality should include regular microbiological assessment (DI water systems prior to and after cartridge changes. Distilled water 2-4 times annually). DI systems with ohm meter readings should be recorded on a regular basis. All water sources used for laboratory testing should be monitored by a certified water analysis laboratory annually. See *Appendix E: Example Quality of Water Policy*.

F. Is there an inventory control system in operation for the laboratory reagents and supplies?	Yes ☐ No ☐ Comments ☐

Guidance: Most large laboratory systems have inventory control systems that include "par values" for each inventory item. This is not practical for small laboratories but each small lab should have an equipment inventory (see *Appendix F: Example Laboratory Inventory*) detailing equipment owned by the lab and a Chemical inventory that should be tied to a MSDS listing or accessible MSDS website. Both can be created using a spreadsheet. A short policy for ordering materials will be helpful when used in tandem with an "Order board" – electronic or paper/chalk/erasable board. For example: the policy might state that orders should be submitted when the next to the last box of an item is opened and the request must go to a designated person at that time so that an order can be placed. Establish a policy that fits the routine in your specific laboratory.

VII. Records and Reports

A. Are copies of network lab-specific manuals, protocols, and appendices available?	Yes ☐ No ☐ Comments ☐

Guidance: The lab manual and LPC's may be available both on-line and at the bench. The appendices and protocols are available on-line:

ACTG/IMPAACT Laboratory Manual:
(http://www.hanc.info/labs/labresources/procedures/Pages/actgImpaactLabManual.aspx)

ACTG Protocol Search (ACTG protocols and LPCs; ACTG password required):
https://member.actgnetwork.org/study

IMPAACT Studies (IMPAACT password required): http://www.impaactgroup.org/studies

B. Is there a written policy or procedure for updating network documents, to assure the most recent issue is in circulation?	Yes ☐ No ☐ Comments ☐

Guidance: Periodic review to ensure documents are current should be performed. Copies of pertinent emails, memos and other communications should be maintained with protocol documents in an accessible location.

C. Is specimen chain of custody adequately documented?	Yes ☐ No ☐ Comments ☐

Guidance: See the Specimen Management and Laboratory Processing Plan on the ACTG web site at http://aactg.org/committees/resource/site-management-clinical-care/sops. Basically, the specimens are collected by the nurse, taken to clinic lab, placed in plastic bag along with req. and CRF's, and specimen logged into a log book, the specimen is then picked up by transporter or lab personnel and signed off on in the log book and taken to the processing lab where it is logged into the LDMS.

D. Does the laboratory archive Specimen Tracking/Requisition forms and results data (result printouts, processing worksheets, etc.)? (If "Yes", explain how archiving is accomplished and how long data is archived. If "No", skip to Section VIII.)	Yes ☐ No ☐ Comments ☐

Guidance:

ACTG: See the Storage of Documents example procedure on the ACTG SOPs page (https://actgnetwork.org/committees/resource/site-management-clinical-care/sops) to create a local SOP. Keep on site, or store at a secure, readily accessible location until study is terminated and indefinitely after that time on/off-site or until requested by FSTRF to destroy.

IMPAACT: Refer to the DAIDS Policy on Storage and Retention of Clinical Research Records for minimum requirements. Additionally, retain records off site indefinitely.

E. Are the archived records accessible to only authorized personnel?	Yes ☐ No ☐ Comments ☐

Guidance: Archived documents should be stored in a secure, access-controlled location.

F. Are records protected from flood and fire?	Yes ☐ No ☐ Comments ☐

Guidance:

VIII. Physical Facilities

A. Is there sufficient space in the laboratory to support PBMC Processing and Shipping and Handling? (If "No", provide an explanation in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
B. Is there sufficient storage space, either within or separate from, the laboratory space? (If "No", provide an explanation in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
C. Are ambient room temperature readings taken/documented? (If "Yes", report the frequency in the "Comments" section. If "No", skip to Section IX.)	Yes ☐ No ☐ Comments ☐
D. Have tolerance limits been established/documented for ambient room temperature?	Yes ☐ No ☐ Comments ☐

Guidance: Room temperature tolerance limits are usually established depending on the reagents stored in that room and the temperature should be documented daily (holidays and weekends excluded if not open on those days).

IX. Laboratory Capacity

A. How many participants are processed for PBMC isolation/storage per week?	
B. How many shipments does the lab send per week?	
C. Does the laboratory support multiple clinics? (If "Yes", indicate the number of clinics supported in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
D. Does the clinic coordinate the protocol workload with the laboratory in advance?	Yes ☐ No ☐ Comments ☐

Guidance:

X. Specimen Transport and Management

A. Are there documented guidelines for specimen collection in the *laboratory and areas dedicated for specimen collection?	Yes ☐ No ☐ Comments ☐

Guidance:

B. Is there a documented policy/procedure for identifying and assessing the quality of specimens received in the laboratory?	Yes ☐ No ☐ Comments ☐

Guidance: Refer to the LDMS specimen condition codes and Cross-Network PBMC SOP.

C. Specimen Transport	
1. Is there a documented policy/procedure in place for transporting samples (transported in a sturdy, non-breakable, closable container labeled "biohazard")?	Yes ☐ No ☐ Comments ☐
2. Is there a documented policy present addressing transportation within the facility?	Yes ☐ No ☐ Comments ☐
3. Is there a documented policy present addressing transportation between off-site clinics and the laboratory?	Yes ☐ No ☐ Comments ☐

Guidance: Specimens should be transported in an IATA approved secondary container with absorbent pad(s) capable of absorbing the total volume of liquid being transported. Is there a copy of spill containment and clean-up available in the lab?

D. Is the laboratory located in proximity to the clinic to support processing within time constraints?	Yes ☐ No ☐ Comments ☐
1. Are there scheduled times for specimen transport from the clinic to the laboratory? (List the frequency in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
2. Has the laboratory established time limits for processing PBMC specimens?	Yes ☐ No ☐ Comments ☐

Guidance: Refer to the Cross-Network PBMC Processing SOP for processing time requirements (http://www.hanc.info/labs/labresources/procedures/Pages/pbmcSop.aspx).

E. PBMC Handling			
1. Are PBMCs handled in a manner to prevent thawing or warming from its frozen status during relocation? (If "Yes", explain procedures for maintenance of cold chain in the "Comments" section.)	Yes ☐	No ☐	Comments ☐

Guidance:

F. Outgoing Shipments Quality Control			
1. Are samples checked against the prepared shipping manifest prior to shipment?	Yes ☐	No ☐	Comments ☐

Guidance: Follow the instructions in the LDMS User manual and Quick Reference Guide (https://www.fstrf.org/apps/cfmx/apps/ldms/manual/manual.html) for the quality control of sample shipments.

G. Shipping Certification/Training			
1. Is there a training plan in place for shipping certification?	Yes ☐	No ☐	Comments ☐
2. Is there documentation of persons trained for shipping?	Yes ☐	No ☐	Comments ☐
3. Are shipping certifications renewed every 2 years?	Yes ☐	No ☐	Comments ☐
4. Is there a policy in place for shipping samples internationally?	Yes ☐	No ☐	Comments ☐

Guidance: Where are the shipping certificates filed in the lab? Who has a copy of the current IATA regulations at your site?

XI. Personnel Safety

A. Safety-Related Incidents			
1. Is there documentation of all safety-related incidents? (If no documentation is present, skip to Question 3.)	Yes ☐	No ☐	Comments ☐
2. Is the documentation reviewed and signed monthly by the Laboratory Director or designee?	Yes ☐	No ☐	Comments ☐
3. Does the Quality Management Program have a mechanism to evaluate safety incidents?	Yes ☐	No ☐	Comments ☐
4. Is prophylaxis treatment available?	Yes ☐	No ☐	Comments ☐
5. Does a physician provide a documented review of all exposure events?	Yes ☐	No ☐	Comments ☐

Guidance: Additionally, is there a review by Institutional BioSafety Committee, Environmental Health & Safety Department of Institution, or other employee safety governing body (acting for OSHA)? If so, this report should be included with lab documentation of safety-related incidents.

Identifying and performing corrective action must be part of SOP and documentation.

See *Appendix G: Example Incident Report Form Template*.

B. Is there an initial and ongoing safety-training program with documented participation of laboratory personnel? (If "Yes", list who provides the training, as well as the frequency of training.)	Yes ☐ No ☐ Comments ☐

Guidance:

1. If additional training is required for HIV laboratories it should be documented for all laboratory personnel, including faculty, post-docs, fellows, research associates, technologists, technicians, and students.
2. Physical security of employees should be addressed in employee safety SOP, such as access to building at all times, after-hours work, emergency contact information should be posted at entrance to each room.

See *Appendix H: Example Laboratory Safety Annual Training Topics Template*; *Appendix I: Example Bloodborne Annual Training Topics Template*. For an example training attendance log, see Appendix 2 of the DAIDS Guidelines for Good Clinical Laboratory Practice (GCLP) Standards at http://www.niaid.nih.gov/LabsAndResources/resources/DAIDSClinRsrch/Documents/gclp.pdf.

C. Material Safety Data Sheets (MSDS)	
1. Are MSDS on file? (If "No", skip to Section C.)	Yes ☐ No ☐ Comments ☐
2. Are MSDS readily available to all laboratory personnel?	Yes ☐ No ☐ Comments ☐

Guidance: See *Appendix J: MSDS Fact Sheet*.

D. Safety Policies	
1. Is a written Standard/Universal Precautions Policy available?	Yes ☐ No ☐ Comments ☐
2. Is a written Chemical Hygiene/Hazardous Materials Plan available?	Yes ☐ No ☐ Comments ☐
3. Is there a written policy for the handling and disposal of biohazardous materials and sharps?	Yes ☐ No ☐ Comments ☐
4. Are safety policies and procedures readily available to all staff?	Yes ☐ No ☐ Comments ☐
5. Is there evidence of annual review of all safety policies and procedures by the laboratory director/designee?	Yes ☐ No ☐ Comments ☐
6. Are policies, procedures, and practices in place for use of dry ice (solid carbon dioxide)?	Yes ☐ No ☐ Comments ☐
7. Are policies, procedures, and practices in place for use of liquid nitrogen?	Yes ☐ No ☐ Comments ☐

Guidance: See attached *Appendix K: Example Dry Ice (Carbon dioxide, solid) Safe Handling Procedure Template*; *Appendix L: Example Policies and Procedures for Use of Liquid Nitrogen Template*; *Appendix M: Biological/Medical Waste Fact Sheet*; *Appendix N: Example Chemical Waste Management Fact Sheet Template*.

E. Is safety equipment such as eyewashes, safety showers, fire extinguishers, and sharps containers present in the lab? (If "Yes", comment on the frequency of documented functional checks for the equipment.)	Yes ☐ No ☐ Comments ☐

Guidance:

F. Is an evacuation plan in place and posted?	Yes ☐ No ☐ Comments ☐

Guidance: Annual review of the evacuation plan by lab employees should be included in annual lab safety training.

G. Personal Protective Equipment (PPE)	
1. Is Personal Protective Equipment (gloves, gowns, masks, eye protectors, etc.) available to and utilized by laboratory staff? (If "No", explain in "Comments" section and skip to Section XII.)	Yes ☐ No ☐ Comments ☐
2. Is Personal Protective Equipment maintained in a sanitary and reliable condition in all technical work areas in which blood and body substances are handled, and in circumstances during which exposure is likely to occur?	Yes ☐ No ☐ Comments ☐

Guidance: *See Appendix O: PPE Gloves and Lab Coats Fact Sheet*.

XII. Laboratory Data Management System (LDMS)

A. Does this laboratory facility contain a LDMS or other specimen repository system? (If "No", disregard the rest of Section XII and explain in the "Comments" section how specimen storage/shipping data is maintained.)	Yes ☐ No ☐ Comments ☐

Guidance:

B. LDMS Reports Obtained By the Auditor:	
1. Primary Specimens Received Report or equivalent	Yes ☐ No ☐ Comments ☐
2. Storage Detail Report or equivalent	Yes ☐ No ☐ Comments ☐
3. Shipped Specimen Report - Detail or equivalent	Yes ☐ No ☐ Comments ☐

Guidance:
- See *Appendix P: Example of Primary Specimens Received Report*.
- See *Appendix Q: Example of Shipped Specimen Report*.
- See *Appendix R: Example of Storage Detail Report*.

C. Specimen Verification	
1. Can the PID, date, protocol, derivative, and additive for specimens be verified with the repository system in use?	Yes ☐ No ☐ Comments ☐

2. Is the laboratory staff able to demonstrate specimen storage locations in repository system?	Yes ☐	No ☐	Comments ☐
3. Does the repository system accurately reflect the number, type, and volume of all specimen aliquots as well as their storage location and shipping record?	Yes ☐	No ☐	Comments ☐
4. Can the physical presence of specimens be verified with the Storage Detail Report or equivalent report?	Yes ☐	No ☐	Comments ☐

Guidance:

D. Is the user manual for the repository system available in the laboratory?	Yes ☐	No ☐	Comments ☐

Guidance: It is sufficient to bookmark the LDMS User Manual and Quick Reference Guide (https://www.fstrf.org/apps/cfmx/apps/ldms/manual/manual.html) in the web browser of a common-use laboratory computer.

E. Back-Up			
1. Is the system backed up weekly?	Yes ☐	No ☐	Comments ☐
2. Is the system back-up device stored in a different location than the LDMS computer?	Yes ☐	No ☐	Comments ☐

Guidance: See *Appendix S: Example LDMS Back-Up Log Template*.

F. Is the system connected to a back-up power source?	Yes ☐	No ☐	Comments ☐

Guidance:

XIII. Vertical Audit of SOP/Practice

Title of SOP:	**Procedure Observed:**	**Person Observed:**

A. Pre-Test Specimen Handling			
1. Are specimens submitted for testing as required by the SOP?	Yes ☐	No ☐	Comments ☐
2. Does the specimen receiving procedure preserve the chain of custody for the samples?	Yes ☐	No ☐	Comments ☐
3. Are specimens submitted for testing within the timeframe required for processing?	Yes ☐	No ☐	Comments ☐
4. Are specimens maintained at appropriate conditions (e.g. temperature) until testing can be performed?	Yes ☐	No ☐	Comments ☐

Guidance:
- Make sure your SOP states your acceptance and rejection criteria. Confirm that the sample(s) meets the criteria when received.
- See *Appendix T: Example Chain of Custody Template* for wording to include on your requisition. Clinic staff, courier and receiving tech initials and date are captured on this form to preserve the chain of custody.
- Make sure your SOP states processing time limits.
- Make sure your SOP states the temperature the sample must be maintained after collection and during transport.

B. Reagent Preparation and Storage	
1. Are reagents prepared in accordance with the SOP?	Yes ☐ No ☐ Comments ☐
2. Are reagents maintained at appropriate conditions, until testing can be performed?	Yes ☐ No ☐ Comments ☐
3. Are reagents labeled with identity, prepared date/opened date, storage requirements, and expiration date?	Yes ☐ No ☐ Comments ☐

Guidance:
- If reagents are not stored at specified conditions, confirm with manufacturer and ask for documentation approving this type of storage (ie: temp).
- Suggest making labels containing preprinted identity, storage requirements, expiration date and a line to prompt for prepared (if applicable) and open date. See *Appendix U: Example Label Template*.

C. PBMC Processing	
1. Are specimens processed within the timeframe, as defined in the SOP?	Yes ☐ No ☐ Comments ☐
2. Are appropriate conditions maintained to perform the PBMC processing (e.g. sterile, biohazard containment)?	Yes ☐ No ☐ Comments ☐
3. Are tubes/plates pre-labeled prior to processing? (If “Yes”, indicate how far in advance in the “Comments” section.)	Yes ☐ No ☐ Comments ☐
4. Are tubes/plates labeled appropriately with sufficient identification to prevent mix-up?	Yes ☐ No ☐ Comments ☐
5. Is appropriate equipment (e.g. pipettes, vortex mixer, etc.) available at the start of the procedure to avoid delay?	Yes ☐ No ☐ Comments ☐
6. Are reagents and samples added in the appropriate order and at appropriate times?	Yes ☐ No ☐ Comments ☐
7. Is the laboratory staff able to demonstrate proper use of label-making software?	Yes ☐ No ☐ Comments ☐
8. Is processing performed according to the SOP?	Yes ☐ No ☐ Comments ☐

Guidance:

- Work with your clinic to set cut-off times to receive samples to allow enough time to process within SOP stated timeframe.
- Make sure you have room temp thermometers (NIST certified/traceable) and record this daily to ensure appropriate temperature conditions for PBMC processing are followed. Ensure maintenance/PM equipment records are maintained and are signed by maintenance personnel and lab staff. NOTE: when service is performed on equipment, make sure a lab staff member signs and dates the report to indicate the staff member reviewed what was done. Use of a daily BSC start up/shut down log is necessary to document hood sterility. See *Appendix V: Example BSC Check Log Template*.
- Tubes/plates must be pre-labeled prior to working with samples.
- Utilizing one color sharpie/patient/anticoagulant is a useful tool to help avoid mix-ups. Use of separate racks is also helpful. Label tubes/plates with study and PID.
- Ensure laboratory area is stocked with appropriate labware/equipment prior to start of processing.
- Do not deviate from the SOP.
- Ensure all lab staff is trained in the use of the LDMS.

D. Analysis Phase	
1. Are cells counted, as required by the SOP? (Note method of cell counting in "Comments" section.)	Yes ☐ No ☐ Comments ☐

Guidance:

E. Manual Counting Methods	
Are manual counting methods used during analysis? (If "No", skip to Section F.)	Yes ☐ No ☐ Comments ☐
1. Is viability performed during the cell counting procedure?	Yes ☐ No ☐ Comments ☐
2. Which squares are counted on the hemacytometer?	Inner square ☐ Outer square ☐
3. How many squares are counted in order to calculate the cell count?	(enter number here)
4. Does the final dilution of specimen result in an adequate number of cells counted in each square? (In the "Comments" section, list the range documented by the laboratory, and verify laboratory practices.)	Yes ☐ No ☐ Comments ☐
5. Are cell numbers between individual squares comparable? (Describe in the "Comments" section how this is determined.)	Yes ☐ No ☐ Comments ☐
6. Are counts verified? (Describe the method used in the "Comments" section.)	Yes ☐ No ☐ Comments ☐
7. Is cell yield documented for specimens? (Describe in the "Comments" section.)	Yes ☐ No ☐ Comments ☐

Guidance:

Make sure you have a counting SOP.

1. Use trypan blue for viability counts via hemacytometer.
2. Recommend counting the four outer squares (16 squares/larger square).
4. Recommend making PBMC-dye dilution to yield >50 but <200 cells/16 grid square.
5. Establish a tolerance limit in your SOP.
6. Establish a hemacytometer intralaboratory comparison QC to ensure all lab staff are counting similarly. Establish a tolerance limit. A second tech should confirm calculations are correct.
7. Document cell counts and yield on processing worksheet. Make sure this worksheet captures the tech(s) initials or ID number.

F. Automated Counting Methods	
Are automated counting methods used during analysis? (If "No", skip to Section G.)	Yes ☐ No ☐ Comments ☐
1. Is the analyzer set up, as required by the SOP?	Yes ☐ No ☐ Comments ☐
2. Are appropriate controls available and tested?	Yes ☐ No ☐ Comments ☐
3. Does the dilution of specimen result in an adequate number of cells counted by the analyzer? (In the "Comments" section, list the range limits documented by the laboratory, and verify laboratory practices.)	Yes ☐ No ☐ Comments ☐
4. Is cell yield documented for specimens? (Describe in the "Comments" section.)	Inner square ☐ Outer square ☐

Guidance:

2. Run and document the manufacturers' abnormal low, normal and abnormal high controls as required.
3. Establish in your SOP the typical dilution factor required to result in an adequate number of cells for your analyzer. This dilution factor can be determined by estimating 1 x 10^6/ml PBMC and using the analyzer's operating range. It is also recommended to establish a tighter range than the analyzer's operating range using an abnormal low and an abnormal high control.
4. Document cell counts and yield on processing worksheet. Make sure this worksheet captures the tech(s) initials or ID number.

G. Freezing Samples	
1. Is a freezing device container (i.e. Stratacooler) used? (If "No", skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2. If freezing containers are used, are they equilibrated at the appropriate temperature?	Yes ☐ No ☐ Comments ☐
3. Are cryovials labeled before freezing media is added to PBMC pellet?	Yes ☐ No ☐ Comments ☐
4. Is freezing media pre-chilled, added to the PBMC pellet, and aliquoted as described in the SOP?	Yes ☐ No ☐ Comments ☐
5. Are PBMC aliquots moved into the freezing chamber/freezer within the timeframe defined by the SOP?	Yes ☐ No ☐ Comments ☐
6. Is the duration of processing documented?	Yes ☐ No ☐ Comments ☐
7. If a timeframe is defined in the SOP, are specimens with out-of-range times documented and corrective action taken?	Yes ☐ No ☐ Comments ☐

Guidance:

1. StrataCoolers and CoolCells are recommended since they are self-contained and do not require changing 2-proponal. If using Mr. Frosty, document freeze/thaw usage and 2-proponal changes. *See Appendix W: Example Mr. Frosty Change Chart Template*.

2. Follow manufacturer's or local/network SOP instructions.

4 and 5. Follow SOP.

6. Record processing start and completion times on PBMC processing worksheet and in LDMS.

7. Make sure to document all deviations on your corrective action log and in LDMS.

H. Calculations and Results Reporting	
1. Are manual calculations performed? (If "No", skip to Question 3.)	Yes ☐ No ☐ Comments ☐
2. Is the derivation of the final result available?	Yes ☐ No ☐ Comments ☐
3. Are results transmitted from analyzer to a central LIS? (If "No", skip to Question 5.)	Yes ☐ No ☐ Comments ☐
4. Do the results obtained by the analyzer match those in the LIS?	Yes ☐ No ☐ Comments ☐
5. Are worksheets verified by alternate personnel?	Yes ☐ No ☐ Comments ☐

Guidance:

2. Show calculations on processing worksheet.

5. All calculations should, whenever possible, be checked by a second technician. If second tech is not available, processing tech should step away for a minute and then recheck the calculations.

I. Transfer/Retrieval of Frozen Specimens	
1. Are specimens handled in a manner to prevent thawing or warming from its frozen status, during relocation?	Yes ☐ No ☐ Comments ☐
2. Can the physical location of the specimens be verified? (If "Yes", provide details in the "Comments" section.)	Yes ☐ No ☐ Comments ☐

Guidance:

1. Handle the cryovials on dry ice during relocation.

2. When aliquots are stored in the LDMS, it is helpful to write the freezer/box/space locations on a tracking slip that can be used for reference during the relocation of the cryovials from the StrataCooler or Mr. Frosty to storage in a freezer.

Appendices

Appendix A: Example Personnel SOP

Procedure Title:
Procedure Number:
Version:
Effective Date:

SOP Development		
Author's Name and Title	Signature	Date
Approver's Name and Title	Signature	Date

Revision History		
Version Number	Date	Summary of Changes

Annual Review		
Reviewer Name	Signature	Review Date

SOP User Knowledge		
I acknowledge that I read, understood and agree to follow this SOP.		
Employee Signatures	Date	Initials

TABLE OF CONTENTS:

1.0 Purpose

The purpose of this section is to relate the organization of laboratory personnel, provide a clear picture of their responsibilities within the organization and document the information that should be kept on file for each of these individuals.

2.0 Scope

The scope of this document lists those who supervise and work directly in the laboratories located on the 10th floor of the Biomedical Research Building (BRB Rooms 1048B, 1051, 1052 and 1042). It encompasses the laboratories under several NIH funded grants which include: ACTG (AIDS Clinical Trials Group), ISL (Immunology Support Laboratory for the ACTG), MTN (Microbicides Trial Network), the Immunology Assessment Laboratory and the CFAR (Center for AIDS Research) Immune Function Core. It also outlines the relationships existing between the Laboratory, University Hospitals Case Medical Center and Metro Health Medical Center.

3.0 Organizational Charts

AIDS Clinical Trials Laboratory
And
Microbicides Trial Network
Principle Investigator
XXXXX
Laboratory Supervisor
XXXXXX
Research Assistant III
XXXX
Research Assistant I
XXXX

4.0 Personnel Documentation

All personnel files are required to have the following documentation. It is to be signed by the employee and either by the director or his/her designee. All files must be reviewed yearly and updated where necessary.

1.1 Laboratory Director or Assistant Laboratory Director
- 1.1.1 A copy of his/her State Medical Board of Ohio license or a copy of his/her Ph.D. diploma.
- 1.1.2 A copy of a recent CV
- 1.1.3 A copy of all his/her DOES Continue Education
  - 1.1.3.1 Chemical Safety
  - 1.1.3.2 Bloodborne Pathogens
- 1.1.4 A copy of his/her CREC (Continuing Research Education Credit) for working with human subjects in a research setting.
- 1.1.5 All documents will need to be signed and dated by the director.

1.2 Laboratory Supervisor
- 1.2.1 A copy of his/her BS degree or MS degree or state certification - Medical Technologist, American Society of Clinical Pathologists - M.T. (ASCP).
- 1.2.2 A job description listing responsibilities.
  - 1.2.2.1 Needs to be updated regularly
  - 1.2.2.2 Needs to be signed and dated by the supervisor and the director.
- 1.2.3 A recent CV or resume that is updated yearly
- 1.2.4 A copy of all certification
  - 1.2.4.1 GCLP certification
  - 1.2.4.2 A copy of M.T. (ASCP) license
  - 1.2.4.3 Shipping Dangerous Goods certification
- 1.2.5 A copy of the employee's yearly job evaluations
- 1.2.6 A copy of his/her documented continuing education
- 1.2.7 Any health or employee incident reports

1.3 Research Assistant I, II, III personnel files
- 1.3.1 All CWRU hiring information on that individual
- 1.3.2 A copy of the employee's resume and/or CV
- 1.3.3 A job description with a listing of responsibilities.
  - 1.3.3.1 Needs to be update regularly

1.3.3.2 Needs to be signed by the employee and the lab supervisor
1.3.4 A copy of DOES training for chemical safety and bloodborne pathogens
1.3.5 A copy of his/her yearly online DOES re-training
1.3.6 All applicable laboratory certifications and training records
1.3.6.1 Dangerous Goods Shipping Certification
1.3.6.2 GCLP certification
1.3.6.3 Any flow cytometry training records
1.3.7 All yearly employee evaluations
1.3.8 Any health or employee incident reports
1.3.9 All CWRU paperwork dealing with separation of employment
1.3.10 All employee's records will be kept on site for at least 2 years before they are achieved to an offsite location.

5.0 Appendix: Example Job description for a Research Assistant I

POSITION DESCRIPTION

Title: Research Assistant 1

Department: Infectious Diseases UH

School: Medicine

Location:

Supervisor Name and Title:

POSITION OBJECTIVE

Working under moderate supervision, provide clinical and research laboratory support for the AIDS Clinical Trials Unit (ACTU) at University Hospitals Case Medical Campus. The position requires working with specimens containing Human Immunodeficiency Virus (HIV-1), processing these specimens for immunological and viral assays, for storage and for shipping. It also includes working on new research projects that can lead to an increased understanding of the HIV- 1 infection.

ESSENTIAL FUNCTIONS

- Process ACTG blood specimens for analysis/storage in accordance with the appropriate protocol.
- Maintain accurate records in the LDMS database system of all patient samples participating in Clinical Trails.
- Ship dangerous goods across the country under IATA and state guidelines.
- Position requires laboratory maintenance, such as cleaning/disinfecting equipment and work area, discarding biohazard waste, and cleaning lab ware.

NON-ESSENTIAL FUNCTIONS

Perform other duties as assigned.

CONTACTS

A. Within the department

Regular contact with principle investigators and research assistants

B. Within the university

Contact with university personnel, doctors, nurses and secretaries at the AIDS Clinical Trials Unit.

C. External to the university

Interaction with AIDS Clinical Labs across the Country.

D. Students

When appropriate, the position requires working with and over students hired by the lab.

EXPERIENCE

0 to 3 months of experience in a laboratory, preferably in the area of immunology or related fields

EDUCATION

Bachelor's of Science degree

ESSENTIAL SKILLS

- Good communication skills, both verbal and written.
- Good organizational skills; able to budget time effectively
- Able to do multiple tasks at the same time
- Ability to train new staff members and students

TECHNICAL SKILLS

- Isolating peripheral blood mononuclear cells (PBMCs) from whole blood
- Plasma and serum harvesting/labeling/storage
- Running quality control for reagents and assays
- Basic Laboratory skills including, but not limited to pipetting, routine laboratory mathematical calculations, aliquoting and centrifugation.
- Blood borne pathogens handling skills
- Computer skills, especially using LDMS system

WORKING CONDITIONS

The employee is exposed to bloodborne pathogens, chemicals, paraformaldehyde, Staphylococcal Enterotoxin (SEB), infectious agents (HIV-1), UV light and laser. Appropriate gloves, protective eyewear and laboratory coats will be provided. The employee will perform DOT shipping/receiving of hazardous biological or infectious materials. The employee will be required to walk to and from other campus building to obtain laboratory specimens and work some late hours.

Appendix B: Example SOP Management SOP

Title: SOP Management **Document #**				
Applies to:	Version number:		Supersedes:	Effective date:

	Name	Signature	Title	Date
Written by:				
Amended by:				
Approved by:				
Reviewed by:				
Reviewed by:				
Reviewed by:				
Reviewed by:				
Reviewed by:				
Reviewed by:				

Revision History

Revision	Date	Author	Change Reference	Reason for Change

Procedure

Creation of SOPs

1. A laboratory technician, supervisor, or manager drafts an SOP, using the manufacturer's insert.
2. The draft is checked by another technician, QA/QC supervisor, lab manager or designee.
3. The Lab Manager approves and signs all SOPs prior to their implementation.

FORMAT of SOPs

1. SOPs shall be written in the Clinical and Laboratory Standards Institute (CLSI) format.
2. The SOP cover page template is attached as appendix 1.
3. When the general format of the SOP is changed all new SOPs will be created using the new format and active SOPs will be re-formatted when reviewed or revisions are required.

MAKING CORRECTIONS TO SOPS

1. When errors are found in an SOP they will be brought to the departmental supervisor's attention.
2. The supervisor or tech who finds an error will make the correction on their copy of the SOP.
3. A copy of the page(s) with the correction(s) will be made and given to the Lab Manager/designee.
4. The lab manager/designee will document at the top of the page(s) "Changes made to SOP on dd/mmm/yy" and initial & date the comment.
5. A copy of this page will be attached to the front of each copy of the SOP.
6. Corrections will be incorporated into the next version of the SOP at the time of annual review.

Revision of the SOPs

1. A committee including the Lab Manager or Lab QA/QC Supervisor reviews the SOPs at least once a year.
2. The review committee identifies necessary changes and revises the SOP accordingly.

Distribution & destruction of SOPs

SOPs are distributed and destroyed per the Document Control SOP (QA/QC-14).

REFERENCES

None

Appendix C: Example Read and Understood Statement Template

Review of Standard Operating Procedure

For

Title:_____

SOP#: _____ **Version #:**_____

Effective Date:_____

By signing this form, I hereby state that I have read and understand the above Standard Operating Procedure. I will follow it to the best of my ability.

Date	Print Name	Position	Signature

Form [Version] [Date]

Appendix D: Example Document Control SOP Template

Standard Operating Procedure **[SOP #]**

Document Control **[Version]**

[Laboratory] **[Date]**

Approved by: _____ _____
Name/Title Date

_____ _____
Name/Title Date

ANNUAL REVIEW

Reviewed by:	Date	Reviewed by:	Date

Purpose

This document describes how the Johns Hopkins Project Laboratory controls the distribution of standard operating procedures.

References

None

Scope

This SOP applies to the following Johns Hopkins Project staff: Lab Manager, Lab QA/QC Supervisor, Lab Technicians, Field Director, Principle Investigators, Coordinators, Nurses, and Drivers.

Allowable Exceptions

This SOP is meant to be followed without deviation. However, it is an allowable exception to follow procedures specified in a protocol or Study Specific Procedure Manual (SSP) that may deviate from this SOP.

Procedures

I. SOP Distribution

A. Upon Completion and Approval of New SOPs, copies of the SOPs are made.

B. The number of copies made is dependent upon the subject of the SOP and the number of departments which will require the SOP. For example:

1. [SOP] is required in the [Department(s)] department and the training binder = [Number] copies.

C. The original SOP containing the original approval signatures is filed in the master SOP File in the Lab Manager's Office.

D. All copies are stamped 'COPY' and numbered sequentially.

E. Copies are distributed per the guidelines below:

1. COPY #1 goes to the primary department
2. COPY #2 goes to the Technical Staff Review Files (training file)
3. COPY #3 and higher go to subsequent departments for which the SOP is relevant.

F. Distribution of all copies is documented on the [location]. The following information is recorded in the record:

1. SOP Number
2. SOP Name
3. SOP version
4. Copy Number
5. Department receiving the SOP
6. Name of person in the department who received the SOP
7. Initials of person in the department who received the SOP
8. Receipt date
9. Initials of person from QA or Management distributing the SOP

G. When new versions of SOPs are distributed, Old versions are retrieved. All copies are destroyed, the original SOP with the approval signatures is stamped 'RETIRED' and placed in the "Retired SOP File'.

H. Documentation of retrieval and destruction of copies of old SOPs is also done on the [location]. The following information is recorded:

1. Retrieval date
2. Initials of person returning the old SOP
3. Initials of person from QA or management retrieving the SOP
4. Destroyed date

II. Appendix

A. [Lab Name] – Distribution Record

II. Authors:

A. [Name, Title]

B. [Name, Title]

Appendix E: Example Quality of Water Policy

Organization [City, State/Country]	[Department] POLICY AND PROCEDURE MANUAL
POLICY: QUALITY OF WATER Adopted: [Date]	

POLICY:

As water is the most utilized reagent in the laboratory, minimum standards have been established to ensure its purity and adequacy for the purposes of its use. Standards for laboratory water and recommended frequency of monitoring are defined for:

- Ionic impurities (Resistivity)
- Microbiological impurities (CFU)
- Organic impurities (Total organic carbon, TOC)
- Particulate content
- CO_2 content (as necessary)
- Total hardness (as necessary)
- Ammonia Nitrogen (as necessary)

All water used in the laboratory will meet the requirements specified for its use. Water utilized in performing assays will be Clinical Laboratory Reagent Water unless a specific procedure requires different water specifications, which will be followed in that case.

BACKGROUND:

CLSI has defined 6 grades of water:

1. Clinical Laboratory Reagent Water (CLRW) (replaces former Types I and II for most applications).

Defined by CLSI per table below.

Suitable for:

- Atomic absorption/Atomic Emission Photometry
- Ligand assays
- Trace metals
- Enzymatic procedures sensitive to trace metals
- Electrophoresis
- Chromatograhic procedures except mass spec
- Fluorometric procedures
- Buffer solutions
- Standard solutions
- General reagents with or without preservatives
- Microbiology systems
- Stains and dyes

2. Special Reagent Water (SRW). Meets minimum standards for CLRW, but may have more stringent and/or additional standards.

Required for:

- LC/Mass Spectrometry
- Genetics Laboratory
- Molecular Biology applications (DNAse, RNAse free)

3. Instrument feed water (IFW), intended for internal rinsing, dilution and water bath functions of automated analyzers. In general, CLRW is more than adequate for IFW, but this definition allows manufactures to establish requirements for their instruments.

4. Water supplied by a manufacturer as a diluent or reagent for use in a particular analytic system, intended only for the uses stated in the manufacturer's labeling. Such water is useable only for the stated purposes and may not be used for other purposes, nor substituted by CLRW or SRW, without validation in the lab.
5. Commercially bottled, purified water. This must meet the required specifications for its intended use. Manufacturers' validation will be accepted, but the water must be transported, stored and handled in containers that protect it from external contamination and allow no unacceptable leaching from the container.
6. Autoclave Wash Water, intended for feed water in autoclaves and automatic laboratory glassware washers with heat drying cycles. There is no consensus specification for autoclave wash water. CMH has adopted the standard of previous Type III water (see table below).

PROCEDURE:

The primary source of CLRW, SRW, IFW and Autoclave wash water will be checked according to the schedule in the table below. Resistivity is monitored via in-line monitors at each water source. Microbial testing is performed by the Microbiology Laboratory on samples delivered in sterile containers. Chemical testing is performed by the Chemistry Laboratory or sent to appropriate reference laboratories per the Chemistry Water Testing manual.

Results of tests will be forwarded to the relevant laboratory and recorded there. Results exceeding acceptable limits will be brought immediately to the attention of the Laboratory Manager. All water test results will be reviewed by the Laboratory Director or an appropriate designee.

LABORATORY WATER STANDARDS:

Water standards for CMH Laboratories, and the recommended frequency of testing, are listed in the table below. Individual laboratories may define exceptions to this policy on a per case basis and note the exceptions in their local procedure manuals.

Type	Resistivity (MegΩ-cm)	Monitor Frequency	Microbial impurities	Monitor frequency	Organic impurities	Monitor frequency	Particulates	Silica ppb	Monitor frequency
Clinical laboratory reagent water (CLRW)	≥10 MΩ	Daily	<10 CFU/mL	Quarterly, or with filter change	TOC <500 ng/g	Annually	Filter 0.22µm	N/A	N/A
Special reagent water (SRW)	Criteria defined per application, appropriate for application (see below)								
Instrument feed water	≥10 MΩ	Per mfgr	<10 CFU/mL	Per mfgr	TOC < 500 ppb	Per mfgr	< 1 um	N/A	N/A
Autoclave wash water	≥0.25 MΩ	Installation	<1000 CFU/mL	Quarterly	TOC <1000 ng/g	Annually	N/A	N/A	N/A
Bottled water	Appropriate for use, qualified by manufacturer. Packaging and storage conditions must protect from contamination.								
Mfgr. - supplied water	Qualified by manufacturer. Must be used per manufacturer instructions.								
Special Reagent Water defined for CMH Laboratories									
HPLC/MS	≥18 MΩ	Daily	< 1 CFU/mL	Monthly, or with filter change	TOC < 2 ppb	Daily	0.05 µm	<10	Annually
Genetic	≥17 MΩ	Daily	<10 CFU/mL	Quarterly	TOC <500 ng/g	Annually	Filter ≥0.22µm	<100 CO_2<5ppm NH_3<.2ppm Hardness neg	Annually
Molecular Biology (Sigma-Aldrich or equivalent)	≥18 MΩ	Mfgr	<10 CFU/mL	Mfgr	DNAse, RNAse, nickase, protease free	Mfgr	0.1 um	N/A	N/A

Author:

Supercedes policy dated [Date]

	Date	Reviewed by
Adopted		

Appendix F: Example Laboratory Inventory

Location / Asset	Classification ID	Manufacturer Name	Model	Serial	Vicinity	Dpt. Name	Cust #	Responsibility Repair Name	Responsibility Safety Name	Responsibility PM Name
2331-437879	Hood, Fume	Fisher Hamilton	54L	24188	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437880	Centrifuge, General Purpose	N/A	TJ6RS	290348	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437881	Centrifuge, General Purpose	Beckman Instruments, Inc.	ALLEGRA X15R	31186	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437883	Pipetter	Drummond Scientific Co.	PIPET AID	P-54498	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437885	Scale, Laboratory	Ohaus Scale Corporation	HARVARD TRIP	AC5448	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437887	Scale, Laboratory	Mettler	H20	418379	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437888	General PM	Abbott Labs. Diag. Division	M2000SP	NA	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437889	Centrifuge, Refrigerated	Rupp & Bowman Co.	S103NAR	8709595	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437890	Mixer, Test Tube	American Hospital Supply Corp	S8223	G18344	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437891	Incubator, Small/Large	Abbott Labs. Diag. Division	COMMANDER	1N654010	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437893	Analyzer, Electrolyte	Abbott Labs. Diag. Division	Dual Wavelength	21001-96	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437894	General PM	Beckman Instruments, Inc.	MW 96/ 384	NA	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437895	General PM	Abbott Labs. Diag. Division	Quikwash	NA	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment
2331-437898	Hood, Fume	Labconco	3620302	164002	Super Lab	Super Dept.	101114	Super Equipment	Super Equipment	Super Equipment

Appendix G: Example Incident Report Form Template

Incident Report Form

Date: **Time of Incident:** **Location of Incident:**

Name: **Phone #:**

Person initiating call: **Phone #:**

Brief Characterization of Incident:

Describe the Incident:

Response Summary:

Recommended Corrective/Preventative Action:

Comments:

Responder:

Date/Time of Resolution:

Cc: Facility Manager

☐ **Check here if this requires further action by P.I.**

Signature of Person Filling Out Report:

Appendix H:
Example Laboratory Safety Annual Training Topics Template

[Institution or Laboratory Name]

Laboratory Safety Annual Refresher Training Topics

(Check off topics you cover during training, and send with sign in sheet to EH&S, [Mail Code or Fax Number]

- ☐ **Identification of Hazards:** Review all potential radioactive, chemical and biological hazards used in the laboratory and the tasks performed by laboratory staff and their coworkers that may cause exposure to these agents. Include potential hazards in shared facilities.
- ☐ **General Epidemiology:** Explain the modes of transmission of hazardous agents.
- ☐ **Protective Measures:** Discuss the measures your staff can take to protect themselves from laboratory hazards, including appropriate work practices, personal protective equipment, and emergency procedures. *Suggestion: have staff find the nearest safety shower/eye wash while blindfolded, with or without the help of coworkers. Review PPE required in your lab (lab coat, gloves, safety glasses, full face mask).*
- ☐ **Material Safety Data Sheets:** Review the location and availability of reference materials on the hazards, safe handling, hazard classification, storage and disposal of hazardous materials in your laboratory. References must include, but are not limited to, Material Safety Data Sheets (MSDSs) received from chemical suppliers. MSDS On-line, at [url], provides manufacturer-specific MSDSs for chemicals at [Institution]. *Suggestion: ask a staff member to locate emergency information on a randomly chosen chemical in your lab. Discuss that chemical's hazards, recommended protective measures and appropriate emergency response.*
- ☐ **Exposure Control Plan:** Discuss the laboratory's *Exposure Control Plan*.
- ☐ **Written Protocols:** Review the need to follow and the location of written protocols, particularly for work related to research submitted to the various faculty oversight committees, e.g., Radiation Safety Committee (RSC), Institutional Biosafety Committee (IBC), Institutional Animal Care and Use Committee (IACUC), Institutional Review Board (IRB).
- ☐ **Carcinogen Use:** Discuss the properties and hazards of all carcinogens used in your laboratory, and review any tasks that may expose workers to carcinogenic materials. Discuss control measures, including the requirement to post usage and storage areas, and employee responsibility to follow safety practices. Contact EH&S at [Phone Number] if you would like personal exposure monitoring for a particular lab task or location.
- ☐ **Waste Disposal:** Review proper disposal procedures for hazardous wastes, including segregation of waste, use of appropriate containers, container placement, and record keeping procedures. EH&S reference site: [url].
- ☐ **Contamination Control:** Review the defined work areas for radioactive materials, carcinogens, toxins and select agents, selection of appropriate survey methods and instrumentation, and the need for frequent monitoring, prompt decontamination and documentation of spills, and visual indication of area boundaries.
- ☐ **Record Keeping Procedures:** Review record-keeping procedures, such as Select Agent Access Logs, Radioactive Material Usage Records, Disposal Record forms, Transfer of Radioactive Material forms, and Wipe Test results (if required).
- ☐ **Transfer of Radioactive Material:** Discuss that a transfer of radioactive material, either on campus or to another institution, requires prior written approval by Radiation Protection.
- ☐ **Ordering Radioactive Material and DOJ Chemical Precursors:** Review the procedures for ordering radioactive material. Procedures should include use of the Radiation Paperless Requisition Entry Process (WEBBA Budget Administration System) and the information necessary to complete an order, such as: permit holder, permit number, chemical form, and amount of activity ordered. All deliveries must be made to the Environmental Health & Safety Office, [Address]
- ☐ **Radioactive Material Inventory Control:** Discuss the specified locations and procedures for radioactive material use and storage, and the importance of making accurate entries with the Online Radioactive Protection system and placing the RMC number on all stock vials, tubes and other sources.

- ☐ **Changes on the Radioactive Material Use Permit:** Discuss any changes or amendments made on the Use Permit in the last 12 months (e.g., new approved research protocols, new authorized users, addition of new radionuclides, changes in possession and procedure limits, addition of new authorized locations).
- ☐ **Personal Dosimeters (if applicable):** Review with laboratory staff proper use and care of personal dosimeters (Whole Body & Ring badges), proper return of badges to Radiation Protection and reporting procedures for lost/damaged badges.
- ☐ **Security of Radioactive Material, Select Agents, and DOJ Chemical Precursors:** Discuss ways to assure that these materials are secure when stored and in use. Lock laboratory doors or storage areas when materials are unattended.
- ☐ **Proper Use of Portable Survey Instruments:** Review the proper use of portable survey instruments to detect possible contamination, and the need to monitor hands with disposable gloves before, during and after handling radioactive material.
- ☐ **Emergency Response and Notification:** Discuss procedures to report accidents and incidents that involve hazardous materials, and what to do following an exposure incident, including how and where to obtain medical attention, and what documentation is required.
- ☐ **Post-Exposure Follow Up:** Provide information on what to do in the event of an exposure, and the post-exposure evaluation and follow-up that will be provided following an exposure incident.
- ☐ **Engineered Sharps:** Use safety engineered sharps whenever possible, and review with your group to never recap needles, leave needles unattended, or place used needles in trash or biohazard bags.
- ☐ **No Food or Drink in Laboratories:** Assure that all staff members know that food for human consumption, including drinking water, is not allowed to be stored or eaten in any laboratory where hazardous materials may be present. An automatic suspension of the use of radioactive materials can be enforced if food or evidence of food is found in laboratories where radioactive materials are used. Water for research purposes should be labeled “Not For Human Consumption.”
- ☐ **Conduct Safety Meetings:** Review and discuss any hazards that were cited in safety audits of your laboratory. Set periodic meeting times throughout the year to discuss operating procedures and provide opportunity for your staff to discuss and resolve any safety concerns. Safety Fact Sheets distributed to Home Department Coordinators, and found at [url] are designed to provide topics for discussion during safety meetings. Document meeting attendance with a sign-in sheet that is retained in department files.
- ☐ **Evacuation plan:** Review and discuss the posted evacuation plan for the lab.

Appendix I: Example Bloodborne Annual Training Topics Template

Annual Bloodborne Pathogens Training Required Outline

(Cover all topics below during training. Send sign-in sheet to EH&S, ([Mail Code] or [Phone Number])

Principal Investigators may conduct this training in lieu of sending employees to refresher training classes provided by Environmental Health and Safety. (Send new employees to an EH&S class.)

The following training topics constitute the **minimum** required elements, and are taken directly from the Bloodborne Pathogens standard. View www.osha.gov/SLTC/bloodbornepathogens and

capsnet.usc.edu/LabSafety/BioSafety/BloodBornePathogensProgram for more information on the topics.

1. **An Accessible Copy of the Standard:** Inform laboratory staff where they can find the Cal/OSHA Bloodborne Pathogens Standard and an overall explanation of its contents. The standard can be accessed at www.dir.ca.gov/title8/5193.html.
2. **Epidemiology and Symptoms:** Explain the general epidemiology and symptoms of bloodborne pathogens.
3. **Modes of Transmission:** Explain the modes of transmission of bloodborne pathogens.
4. **Risk Identification:** Explain the appropriate methods for recognizing tasks and other activities that may involve exposure to blood and other potentially infectious materials (OPIM).
5. **Employer's Exposure Control Plan:** Explain your lab's Exposure Control Plan and how the employee(s) can obtain a copy of the written plan. Review what to do in case of exposure.
6. **Methods of Compliance:** Explain the use and limitations of methods that will prevent or reduce exposure, including appropriate engineering (engineered sharps, biosafety cabinets), administrative or work practice controls, and personal protective equipment (gloves, safety glasses).
7. **Decontamination and Disposal:** Review proper decontamination and disposal procedures.
8. **Personal Protective Equipment:** Discuss the basis for selection, proper use, location, removal, handling, decontamination and disposal of personal protective equipment for work in your lab.
9. **Hepatitis B Vaccination:** Remind staff members about the Hepatitis B vaccine, its efficacy, safety, benefits of being vaccinated, and that, when applicable, it is provided free of charge to employees through the Medical Surveillance Program at [phone number] or [email address].
10. **Emergencies:** Provide information on the appropriate actions to take and persons to contact in an emergency involving blood or OPIM.
11. **Exposure Incident, Post-Exposure Evaluation and Follow-Up:** Explain the procedures to follow if an exposure incident occurs, including how to report an incident, location of medical facilities, and that medical follow-up that will be made available. Note: Completion of the Sharps questions on the Supervisor's Report of Injury, if applicable, are required for OSHA recordkeeping.
12. **Signs and Labels:** Explain the signs and labels and/or color coding required in the lab.
13. **Interactive Questions and Answers:** Provide an opportunity for interactive questions and answers.

NOTE: Additional training is required for employees of HIV, HBV and HCV Research Laboratories. Contact EH&S at [email address] for additional information.

Appendix J: MSDS Fact Sheet

A Material Data Safety Sheet (MSDS) is a document that provides the end user critical information about a specific substance in terms of (a) potential hazards(health, fire, reactivity, and environmental), (b) toxicological properties, (c)safe use and handling, and (d) compatible storage. The OSHA Hazard Communication Standard (HCS) requires that chemical manufacturers provide MSDSs for each of their products according to the criteria described below:

1. Chemical name (IUPAC)
2. Physical Data (melting point, boiling point, flash point, appearance and odor, etc.)
3. Fire and Explosion Data (flashpoint, autoignition temperature, recommended extinguishing media, etc.)
4. Health Effects and First aid (specific organs or systems in the body affected by overexposure)
5. Reactivity Data (incompatibilities with other chemicals and conditions that may cause instability)
6. Personal Protective Equipment (PPE) and Emergency Procedures for Accidental Spill or Release

The MSDS can be obtained, downloaded, and printed

To Obtain an MSDS:

- Go to EH&S Website [url]
- Simply provide ***Product name*** and ***Manufacturer*** in order to acquire the MSDS of the specific chemical from the binder view.

If you do not find the MSDS you require from this binder view, you may perform one of the advanced search processes available to find MSDSs from the MSDS Online Public Database.

In the event that you cannot access the web during an emergency, [instructions for accessing MSDSs in an emergency].

Hard copy MSDSs are also recommended for the laboratory as a back-up resource in the event that electronic access is interrupted.

Appendix K: Example Dry Ice (Carbon dioxide, solid) Safe Handling Procedure Template

[Lab Name and Address]	Laboratory Policies and Procedures		Page	1	of	3
	Subject:	Dry Ice Safe Handling Procedure	Initial and Date:			
	Section:	Laboratory safety Procedures	Lab Manager Review:			
	Author:		Medical Director Review:			
	Adopted:	Revised:	Distributed:			

Purpose

The purpose of this procedure is to provide guidelines for the safe handling of dry ice.

Principle

There are inherent safety hazards associated with the handling of dry ice. Dry ice is solidified carbon dioxide (CO2) and is extremely cold, -79°C. Severe frostbite and eye damage may occur upon contact. Dry ice sublimates releasing CO2 which may cause asphyxiation. When handled properly dry ice is safe to use.

Potential Hazards

1. Contact. Dry ice is extremely cold, -79°C. Contact with skin may cause severe frostbite within seconds of direct contact.
2. Asphyxiation. Dry ice sublimates releasing CO2. In confined, poorly or non-ventilated room it can displace air, causing asphyxiation. Vapor may cause increase respiration and increased heart rate followed by headache, impaired hearing, symptoms of intoxication, choking, and unconsciousness. Vapor may also cause dizziness, drowsiness, and nervous system damage. Carbon dioxide vapor is substantially heavier than air, colorless, and the odor is none to pungent.
3. Explosion. Dry ice expands upon sublimation. Storage in a sealed container can result in a rupture or explosion of the container from over-pressurization.

Personal Protective Equipment

1. Lab coat. A lab coat is required to minimize skin contact. Also, trousers should be worn.
2. Closed-toe shoes (non-fabric) with non-slip soles.
3. Safety goggles (unvented). Required when performing any experiments.
4. Cryogloves. Insulating gloves should be loose fitting.

Engineering and Ventilation Controls

Adequate ventilation is essential when working with dry ice. Do not use in confined spaces due to the threat of asphyxiation. The sublimation of carbon dioxide can also displace oxygen in the room and cause asphyxiation without warning.

Training Requirements

- Employees must have XXX Laboratory documented training and approval prior to handling dry ice.
- Employees must read and sign XXX Lab Dry ice safety procedure including MSDS.
- Employee must attend University/Institution Lab Safety Class.
- Employee must attend Bloodborne Pathogen Class offered at University/Institution.
- Employee must attend annual lab safety and bloodborne pathogen refresher training.

Special Handling Procedures

1. Never allow any unprotected part of the body to touch dry ice. Skin coming into contact may suffer frostbite.
2. Never handle dry ice with bare hands. Cryogenic gloves and/or scoops/tongs must be used to handle dry ice.
3. Do not place dry ice in your mouth or ingest dry ice. If dry ice is accidentally ingested, it can cause severe internal injury.
4. Obtain dry ice in the form and size in which it will be used. Never saw a block of dry ice.
5. Do not store dry ice in glass or any container with a tight fitting lid. A tightly sealed container will build up pressure as the dry ice sublimates and may explode. Use only approved unsealed containers.
6. Use dry ice only in well ventilated places. Dry ice releases heavy carbon dioxide vapor that can cause rapid suffocation.
7. Do not store dry ice directly on countertops. The cold temperature could cause the countertop to crack.
8. Do not attempt to dump unused dry ice. Allow the dry ice to sublimate to the atmosphere in a well-ventilated area where no buildup of carbon dioxide vapor can occur.
9. Never dispose of dry ice by pouring it into a sink, sewer, or toilet. The extreme cold will harm sink disposals, toilet parts, and pipes.
10. Do not dispose of dry ice in garbage receptacles or garbage chutes.
11. Do not dispose of dry ice in areas accessible to the general public.
12. If transporting dry ice in a vehicle, transport in trunk or truck bed. Leave windows open for fresh circulation.
13. If shipping with dry ice, it is considered a miscellaneous hazard (Class 9) by U.S. Department of Transportation (DOT) and International Air Transport Association (IATA). Hazard Class 9 is assigned to materials which present a hazard during transportation, but which do not meet the definition of any other hazard class. UN1845 is the United Nations identification number specifically for Dry ice. All shipping regulations must be followed and are addressed in a separate shipping instructions document.
14. Exercise caution when adding dry ice to a dewar of liquid at room temperature. It will cause the liquid to boil and splash vigorously.
15. Notify supervisor of all irregularities.

Storage and Labeling Requirements

1. Containers must be labeled with the name of Dry ice and appropriate hazmat labels: Health 3, Flammability 0, Physical hazard 0.
2. Storage areas must be labeled appropriately by placards.

First Aid

Obtain medical attention in all cases of frostbite, eye contact, ingestion, and inhalation exposure. Contact XXX and request emergency medical assistance.

Recovery from frostbite may be complete if only the skin and underlying tissues are damaged. If blood vessels are damaged, gangrene may ensue which may require amputation of the affected area.

If medical assistance is not immediately available, re-warming first aid may be given:

1. Remove or loosen clothing that may constrict blood circulation in the frozen area.
2. Immerse the affected area(s) in warm water (never HOT) water, or apply warm cloths repeatedly for 20 to 30 minutes. The recommended water temperature is 104 to 108ºF. Keep circulating the water to aid the warming process. Severe burning pain, swelling, and color change may occur during warming. Warming is complete when the skin is soft and sensation returns. Do not rub the affected area before or after warming.
3. Apply dry, sterile dressing to the frostbitten areas. Put dressings between frostbitten fingers or toes to keep them separated.
4. Move thawed area as little as possible.

5. If there is eye contact with the dry ice, immediately flush eyes with warm water for 15 minutes. Hold the eyelids open and away from the eyeballs to ensure that all surfaces are flushed thoroughly.
6. If dry ice ingested, seek immediate medical attention.
7. For inhalation exposure, remove to fresh air. Assistant respirant & supplemental oxygen should be given if not breathing.

Spill and Accident Procedures

1. Leave the area immediately if you start to pant or have difficulty catching your breath. This is a sign that you have breathed in too much carbon dioxide gas.
2. Contact emergency contacts at your university or institution in the case of an explosion.

References

1. International Chemical Safety Card, http://www.cdc.gov.niosh/ipcsneng0021.html
2. Praxair Material Safety Data Sheet, Praxair Canada, Inc.
3. MSDS Dry Ice, NSN: 685000F002383, http://avogadro.chem.iastate.edu/MSDS/carbon_dioxide_solid.htm

Appendix L: Example Policies and Procedures for Use of Liquid Nitrogen Template

[Laboratory Name and Address]	Laboratory Policies and Procedures		Page		of	
	Subject:		Initial and Date:			
	Section:		Lab Manager Review:			
	Author:		Medical Director Review:			
	Adopted:	Revised:	Distributed			

Liquid Nitrogen Safety

Purpose

The purpose of this standard is to provide guidelines for the safe handling of liquid nitrogen.

Principle

There are inherent safety hazards associated with the handling of liquid nitrogen, a cryogenic liquid. The extremely low temperature of liquid nitrogen (-196ºC at atmospheric pressure) can cause severe frostbite or eye damage upon contact. Items in contact with liquid nitrogen become extremely cold. Touching these items may result in damage to the skin.

Potential Hazards

1. Contact /Absorption. Cryogenic liquids are extremely cold at atmospheric pressure. Contact with skin may lead to burns and/or severe frostbite.
2. Explosion. A cryogenic liquid expands by orders of magnitude upon vaporization. One liter of liquid nitrogen becomes 24.6 cubic feet of nitrogen gas.
3. Asphyxiation. A poorly or non-ventilated room will be quickly enveloped by the expanding gas off a cryogenic liquid such as nitrogen. Inhalation may cause respiratory tract discomfort or irritation. Prolonged exposure may lead to asphyxiation/suffocation without warning.
4. Fire. The use of cryogenic liquids such as nitrogen will condense oxygen from the atmosphere. Exposure of combustible materials to oxygen-enriched cryogenic liquids enhances the combustibility of the material. Because the boiling point of oxygen is above that of nitrogen, oxygen can condense from the air into the liquid nitrogen. If dewars and insulated flasks containing liquid nitrogen are left uncovered for an extended period of time, liquid oxygen can build up to levels which may cause violent reactions with organic materials (i.e. a severe clothing fire could result).

Personal Protective Equipment

1. Lab coat. A lab coat is required to minimize skin contact. Also, trousers should be worn on the outside of boots or work shoes to prevent shoes from filling in the event of a spillage.
2. Closed-toe shoes (non-fabric) with non-slip soles.
3. Safety goggles (unvented). Required at all times.
4. Full face shield. Required when pouring or filling.
5. Cryogloves. Insulating gloves should be loose fitting, so they can be thrown off if liquid pours inside them, or they should be elastic cuff insulated gloves.

Engineering and Ventilation Controls

Adequate ventilation is essential when working with liquid nitrogen because a small amount of liquid can rapidly convert to a large volume of gas. Do not use in confined spaces due to the threat of asphyxiation. On vaporization it expands by a factor of 700; one liter of liquid nitrogen becomes 24.6 cubic feet of

nitrogen gas. This can cause explosion of a sealed container. This release of nitrogen can also displace oxygen in the room and cause asphyxiation without warning.

Training Requirements

1. Employees must have XXX Laboratory documented training and approval prior to handling liquid nitrogen.
2. Employees must read and sign XXX Lab Liquid Nitrogen Safety procedure.
3. Employee must attend University/Institution Lab Safety Class.
4. Employee must attend Bloodborne Pathogen Class offered at University/Institution.
5. Employee must attend annual lab safety and bloodborne pathogen refresher training.

Special Handling Procedures

1. Never allow any unprotected part of the body to touch exposed pipes/vessels containing liquid nitrogen. Skin coming in contact with the cold metal may adhere to it and tear when attempting to withdraw.
2. Exercise caution when adding liquid nitrogen to a dewar at room temperature or an object at room temperature to liquid nitrogen. Both will cause the liquid to boil and splash vigorously.
3. Keep ignition sources away when handling cryogenic liquids.
4. Only use containers or equipment specified for cryogenic use.
5. Do not store liquid nitrogen in any container with a tight fitting lid. A tightly sealed container will build up pressure as the liquid boils and may explode after a short time. Use only approved unsealed containers. Do not store liquid nitrogen for long periods in an uncovered container. Use only fittings that have been designed specifically for use with cryogenic liquids as non-specialized equipment may crack or fail. Cover them when not in use to prevent an accumulation of moisture and ice.
6. Inspect pressure relief valves on equipment for ice build-up.
7. Use liquid nitrogen only in well ventilated places. Never dispose of liquid nitrogen by pouring it on the floor. It could displace enough oxygen to cause suffocation. Nitrogen is colorless and odorless – the cloud that forms when you pour liquid nitrogen is condensed water vapor from the air, not nitrogen gas.
8. Do not touch any item that has been immersed in liquid nitrogen until it has warmed to room temperature. Do not transport liquid nitrogen in wide-mouthed glass dewars.
9. Never dip a hollow tube into liquid nitrogen; it may spurt liquid.
10. Never ride in an elevator with liquid nitrogen.
11. Always fill warm dewars slowly to reduce temperature shock effects and to minimize splashing.
12. Do not fill cylinders and dewars to more than 80% of capacity, since expansion of gases during warming may cause excessive pressure buildup.
13. Notify supervisor of irregularities in tanks or hoses. Any leaking LN2 tank should also be reported directly to the vendor.
14. In case of immediate danger or explosion, notify occupants of building and vacate.

Storage and Labeling Requirements

1. Containers must be labeled with the name of Liquid nitrogen and appropriate hazmat labels.
2. Storage areas must be labeled appropriately as well.
3. Liquid nitrogen containers must be stored in dry, ventilated area.

First Aid

Recovery from frostbite may be complete if only the skin and underlying tissues are damaged. If blood vessels are damaged, gangrene may ensue which may require amputation of the affected area. Contact XXX and request emergency medical assistance.

If medical assistance is not immediately available, re-warming first aid may be given:

1. Remove or loosen clothing that may constrict blood circulation in the frozen area.
2. Immerse the affected area(s) in warm water (never HOT) water, or apply warm cloths repeatedly for 20 to 30 minutes. The recommended water temperature is 104 to 108ºF. Keep circulating the

water to aid the warming process. Severe burning pain, swelling, and color change may occur during warming. Warming is complete when the skin is soft and sensation returns. Do not rub the affected area before or after warming.

3. Apply dry, sterile dressing to the frostbitten areas. Put dressings between frostbitten fingers or toes to keep them separated.
4. Move thawed area as little as possible.

Spill and Accident Procedures

1. For a small spill, evacuation may not be necessary if the spill is in a well ventilated area.
2. For large spills, notify others in the immediate and surrounding work area. Evacuate the spill area; assemble outside the building. Deny entry into the spill area. Contact emergency contacts at your university or institution.

Appendix M: Biological/Medical Waste Fact Sheet

Biological /Medical waste is carefully monitored and regulated by state and federal laws because it contains virulent pathogens that may cause infectious disease if exposed to it. The following types of biological/ medical waste maybe encountered in a laboratory setting: solids, sharps, liquid, outdated or chemotherapeutic/pharmaceutical, pathological, and glass.

Solids

Examples: Biological solid waste material must be disposed of into red biohazard bags within rigid, leak-resistant containers with lids. All containers and bags must be labeled “Biohazardous Waste" and the universal biohazard symbol. The biological /medical waste barrel must be kept covered at all times and not overfilled. Red Biohazard Bags must be replaced weekly when anything is placed inside.

Sharps

Examples: Needles, razor blades, scalpels, contaminated microscope slides, glass pipettes and pipette tips, glass Pasteur pipettes, glass Vacutainer tubes, and dental wires. Sharps must be disposed of into a rigid puncture resistant sharps container that is leak resistant, tightly covered, and labeled with the universal biohazard symbol. Items are not allowed to rest on or protrude from the baffle. Sharps containers must be disposed of within a week after the lid is closed.

Liquid

This includes blood and body fluids, and fluids containing fibrin, which may be disposed of through the conventional sanitary sewage system after they have been deactivated with 10% solution bleach and copious amounts of water. Only non-clotted blood or body fluids may be disposed of in this manner.

Chemotherapeutic/ Pharmaceutical

This includes all outdated pharmaceuticals, empty vials, and broken ampoules which must be disposed of in a securely sealed pharmaceutical waste container. All chemotherapeutic waste (including PPE) must be disposed of in a yellow waste container and sealed securely. Place this box on top of the biohazardous barrel until pick-up for disposal or call the Biological Safety Specialist for instructions.

Pathological

Examples: Organs, tissues, body parts, and fluids which have been removed by trauma, surgery, autopsy, or other medical procedure. Human or animal tissues injected with a human pathogen are potentially infectious. Pathological waste must only be placed in a white container, and must be immediately disposed of when generated. Animal carcasses injected with a retroviral vector or carcinogen must be placed in a labeled biohazardous Ziploc bag and frozen until pick-up.

Glass

Examples: Broken glassware that is visibly contaminated with biological materials which must be disposed of in the appropriate sharps container. Broken or intact laboratory glassware must be decontaminated before disposal. Non-contaminated glassware may be disposed of in a heavy, puncture resistant cardboard or metal container lined with plastic. Seal the container and label with “CLEAN GLASS: REGULAR WASTE DISPOSAL.” These may be disposed of as regular trash.

Appendix N: Example Chemical Waste Management Fact Sheet Template

Chemicals are classified as hazardous waste when they are no longer needed or wanted by the user. They have the potential to be harmful to human health or the environment if they are not managed or disposed of properly.

Chemical waste is normally segregated into the following waste streams:

1. Flammable/combustible solvents e.g. acetone, xylene, methanol;
2. Halogenated solvents e.g. chloroform, methylene chloride;
3. Nitrogenous hydrocarbon e.g. trimethylamine, diisopropylamine;
4. Sulfurous hydrocarbon e.g. dimethylsulfoxide, dimethylsulfate;
5. Corrosives. A separate stream must be started for each of the following:
   a. Mineral acids e.g. hydrochloric acid, sulfuric acid
   b. Organic acids e.g. trichloroacetic acid, formic acid
   c. Bases e.g. calcium oxide, sodium hydroxide
6. Aqueous solutions (e.g. metal salts, ethidium bromide; and Oils e.g. vacuum pump oil, motor oil.)

Do not mix dissimilar chemical wastes or waste streams.

Selecting the Appropriate Container

Waste is to be collected in a container that does not leak and is compatible with the waste. The following may be used to select the appropriate container:

Flammable Liquids

Glass bottles, steel cans, high density plastic containers (EH&S will provide a safety can for the recycling of flammable and halogenated solvents.)

Concentrated Acids and Bases

2.5 Liter corrosive glass bottle (Note: one gallon glass bottles are not acceptable for acids and bases since the high specific gravity of the material and the thinness of the one gallon container increases the likelihood of breakage.) Never mix acids and bases in the same container.

Aqueous Solutions

Glass bottles, plastic bottles, plastic cans

Broken Mercury Thermometers

No Free Flowing Hg: Double-bagged. Free Flowing Hg: Contained in a sealed glass or plastic bottle.

Management and Disposal

The lid should be a screw-on cap and compatible with the waste; corks, stoppers, and parafilm are not acceptable. “Headspace” should be no less than 1.5 inch from the top of the container to the top of the waste material. Liquid containers should not be filled to more than 80% capacity.

Keep containers capped and stored in a safe location. The use of secondary containment is recommended to prevent spillage and ensure a secured storage until disposal. Collection containers must be submitted for disposal within 90 days of the label start date regardless of whether or not they have been filled to capacity. Complete the hazardous waste label and chemical waste disposal form before container is picked up for disposal. Waste labels are available at the EH&S office; the chemical waste disposal form at: [url].

Go to [url] to request a hazmat pickup.

If you have any questions you can contact Chemical Safety at [phone number].

Appendix O: PPE Gloves and Lab Coats Fact Sheet

Door handles and telephones are frequent sites of contamination found during EH&S laboratory inspections. You can help minimize contamination from hazardous materials by following these guidelines.

1. Remove your gloves before touching common surfaces.

Before you touch the telephone, computer, microscope, faucet, drawer handles or other common use surface in your laboratory, remove your glove from the hand you will use. Before you enter common-use areas such as hallways or elevators, REMOVE YOUR GLOVES and WASH YOUR HANDS.

Hundreds of people use door knobs and elevator buttons daily without wearing a glove. Be mindful of the concerns of others.

Use a single glove or an appropriate secondary container when you transport materials through common use areas. Use your free ungloved hand to open door knobs or push bars. If you wear gloves just to "protect your sample from you," others do not know this and will properly be concerned about items you may contaminate with your gloves. Carry gloves with you to don as needed.

2. Remove your lab coat before leaving your lab.

Lab coats are intended to protect you from contamination, or to protect your work from being contaminated. Either way, they should be left in the lab except when you may need protection during transport. If you work in multiple labs or buildings, either keep a lab coat in each location or carry one with you. Do not wear lab coats in dining facilities.

3. As always, encourage those around you to work safely.

Appendix P: Example of Primary Specimens Received Report

Primary Specimens Received

Searched on: Received Date = 13/Apr/2010

Specimen ID	Group/Prot	PID/ID1	Global Spec ID	VID	Clinic	Spec Date	Rec Date	Prim	Add	Cond	Volume	Other Spec ID
001V10001115	Triad	3044	A01090NT-00	0.00 Ent		12/Apr/2010	13/Apr/2010	BLD	EDT	SAT	10.00 ML	
001V10001117	XMRV XMRV	741	C01090NW-00			13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	20.00 ML	
001V10001120	XMRV XMRV	743	H01090P1-00			13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	20.00 ML	
001V10001123	XMRV XMRV	744	E01090P6-00			13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	10.00 ML	
001V10001126	ACTG/IMPAACT	A52570014662G	J01090PC-00	0.00 Ent	107	13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	4.00 ML	
001V10001126	ACTG/IMPAACT	A52570014662G	E01090PF-00	0.00 Ent	107	13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	40.00 ML	
001V10001131	ACTG/IMPAACT	A50010014601C	E01090PZ-00	208.00 Wk	107	13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	4.00 ML	
001V10001131	ACTG/IMPAACT	A50010014601C	K01090Q1-00	208.00 Wk	107	13/Apr/2010	13/Apr/2010	BLD	EDT	SAT	10.00 ML	

Total Primaries 8

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Appendix Q: Example of Shipped Specimen Report

Shipped Specimen Report - Detail

Searched on: ACTG Protocol = A5269

Shipment Batch No: 4782 **Ship Date:** 08/Feb/2010 **Lab shipped to:** U.OF ALA. AT BIRMINGHAM ADULT VIR. ATL

Clinic	Spec ID	Other Spec ID	Group/Prot	Global Spec ID	PID/ID1	VID	Spec Date	Spec time	Prim	Add	Der	Sub A/D	Volume	Cond
101	001V10000367		ACTG/IMPAACT A5269	A0108YLK-01	0014970D	0.00 Scr	03/Feb/2010	10:00	BLD	EDT	PL2	N/A	1.00 ML	SAT
101	001V10000367		ACTG/IMPAACT A5269	A0108YLK-02	0014970D	0.00 Scr	03/Feb/2010	10:00	BLD	EDT	PL2	N/A	1.00 ML	SAT

Batch Total 2

Shipment Batch No: 4797 **Ship Date:** 10/Mar/2010 **Lab shipped to:** BIOMEDICAL RESEARCH INSTITUTE. (BRI)

Clinic	Spec ID	Other Spec ID	Group/Prot	Global Spec ID	PID/ID1	VID	Spec Date	Spec time	Prim	Add	Der	Sub A/D	Volume	Cond
101	001V10000675		ACTG/IMPAACT A5269	K0108ZLJ-11	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	EDT	CEL	DMS	5e^6 CEL	SAT
101	001V10000675		ACTG/IMPAACT A5269	K0108ZLJ-12	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	EDT	CEL	DMS	5e^6 CEL	SAT
101	001V10000675		ACTG/IMPAACT A5269	K0108ZLJ-13	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	EDT	CEL	DMS	5e^6 CEL	SAT
101	001V10000675		ACTG/IMPAACT A5269	K0108ZLJ-14	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	EDT	CEL	DMS	5e^6 CEL	SAT

Batch Total 4

Shipment Batch No: 4800 **Ship Date:** 18/Mar/2010 **Lab shipped to:** U.OF ALA. AT BIRMINGHAM ADULT VIR. ATL

Clinic	Spec ID	Other Spec ID	Group/Prot	Global Spec ID	PID/ID1	VID	Spec Date	Spec time	Prim	Add	Der	Sub A/D	Volume	Cond
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-09	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-10	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-11	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-12	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-13	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-14	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-15	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT
101	001V10000673		ACTG/IMPAACT A5269	H0108ZKZ-16	0014970D	0.00 Ent	04/Mar/2010	10:30	BLD	SST	SER	N/A	1.00 ML	SAT

Batch Total 8

Shipd.rpt Created on 15/Apr/2010 at 2:56:19PM Page 1 of 2

Shipped Specimen Report - Detail

Searched on: ACTG Protocol = A5269

Shipment Batch No: 4809 **Ship Date:** 07/Apr/2010 **Lab shipped to:** BIOMEDICAL RESEARCH INSTITUTE. (BRI)

Clinic	Spec ID	Other Spec ID	Group/Prot	Global Spec ID	PID/ID1	VID	Spec Date	Spec time	Prim	Add	Der	Sub A/D	Volume	Cond
101	001V10000978		ACTG/IMPAACT A5269	G01090CD-11	0014970D	4.00 Wk	31/Mar/2010	10:45	BLD	EDT	CEL	DMS	5e^6 CEL	SAT
101	001V10000978		ACTG/IMPAACT A5269	G01090CD-12	0014970D	4.00 Wk	31/Mar/2010	10:45	BLD	EDT	CEL	DMS	5e^6 CEL	SAT
101	001V10000978		ACTG/IMPAACT A5269	G01090CD-13	0014970D	4.00 Wk	31/Mar/2010	10:45	BLD	EDT	CEL	DMS	5e^6 CEL	SAT
101	001V10000978		ACTG/IMPAACT A5269	G01090CD-14	0014970D	4.00 Wk	31/Mar/2010	10:45	BLD	EDT	CEL	DMS	5e^6 CEL	SAT

Batch Total 4
Specimen Grand Total 18

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Appendix R: Example of Storage Detail Report

Storage Detail Report

Searched on: ACTG Protocol = A5256

REVCO FREEZER 1 / STORE IN CAMBRIDGE / BRI CELLS OVERDUE

Specimen ID	Global Spec ID	Grp/Prot	PID/ID 1	VID/Unit	Prim	Add	Der	Sub A/D	Volume	Ship	Storage Date	Spec Date	Time	Clinic	Pos	Other Spec ID
001V10000140	G0108XW4-06	ACTG/IMPAACT A5256	0014639G	46.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	10:45	107	A,001	
001V10000140	G0108XW4-07	ACTG/IMPAACT A5256	0014639G	46.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	10:45	107	A,002	
001V10000140	G0108XW4-08	ACTG/IMPAACT A5256	0014639G	46.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	10:45	107	A,003	
001V10000122	E0108XSY-06	ACTG/IMPAACT A5256	0014511E	36.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	12:00	107	A,004	
001V10000122	E0108XSY-07	ACTG/IMPAACT A5256	0014511E	36.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	12:00	107	A,005	
001V10000131	C0108XV1-06	ACTG/IMPAACT A5256	0012793B	46.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	12:00	104	A,006	
001V10000131	C0108XV1-07	ACTG/IMPAACT A5256	0012793B	46.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	12:00	104	A,007	
001V10000131	C0108XV1-08	ACTG/IMPAACT A5256	0012793B	46.00 Wk	BLD	EDT	CEL	DMS	10e^6 CEL	No	09/Feb/2010	11/Jan/2010	12:00	104	A,008	

StorageA.rpt Created on 15/Apr/2010 at 2:52:36PM Page 1 of 1

Appendix S: Example LDMS Back-Up Log Template

Laboratory Data Management System (LDMS)

Back Up Log

Note: The LDMS manual must be available in the laboratory. It can be accessed with the following link (FSTRF password required) **https://www.fstrf.org/apps/cfmx/apps/common/Portal/index.cfm**

The LDMS back-up disks must be stored in a different location than the LDMS computer.

Week of	Name	Storage Location

Comments:

Appendix T: Example Chain of Custody Template

Insert the information below at the bottom of your lab requisition forms:

CLINIC STAFF

# of blood tubes for transport: _____ Initials/Date: _____

COURIER

# of blood tubes received for transport: _____ Time Received: _____ Initials/Date: _____

LAB STAFF

# of blood tubes received: _____ Time Received: _____ Initials/Date: _____

Appendix U: Example Label Template

See next page.

Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]
Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]
Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]
Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]
Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]
Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]
Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]	Frit Lot # 076K4379 Histopaque Lot # 038K6170 Exp: [Date]

Appendix V: Example BSC Check Log Template

[Lab Name] Laboratory BioSafety Cabinet Daily Cleaning and Air Check

Month: Cabinet Serial Number:

Room:

Date	Checked Air Flow	Cleaned Before Start	Cleaned When Finished	Comments
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

N/A: Not Applicable due to unit not in use due to malfunction or not needed for workload

Appendix W: Example Mr. Frosty Change Chart Template

Mr. Frosty Change Chart

NOTE: The isopropyl alcohol in Mr. Frosty needs to be changed *after* each 5th use.

Date of Use	Isopropanol change (Y/N)	Initials

Date of Use	Isopropanol change (Y/N)	Initials

Reviewed by: ______________________________ Date: ______________________________

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