Infectious Diseases Laboratory Policies

Confidentiality

1. Patient Health Information
   1.1. All patient health information (PHI) will be maintained in the strictest confidentiality with access permitted only to technicians entering results, laboratory supervisors, the laboratory director and his designees according to the Health Insurance Portability and Accountability Act of 1996 (HIPAA).
   1.2. No patient information will be released to any individual except the patient's physician or clinicians directly responsible to the physician.
   1.3. One copy of the requisition will be kept on file in a secure location for at least 7 years. In the event that the laboratory ceases operation, all records including patient requisitions, original analyzer runs sheets, QC and QI records, and any accreditation records will be retained for a period of 7 years within the Division of Infectious Diseases or Department of Medicine.
2. Proprietary Information
   2.1. All proprietary information (e.g., information about instruments or assays in development, research protocols, etc) will be kept in secure areas and will be available only to authorized personnel.
   2.2. Information about one sponsor's instrument or assay should never be discussed with representatives of another sponsor unless the other instrument or assay is being used in a comparison study; that is, both instruments or assays are being used in the same protocol.

Partial or waived payments: Partial payment would be considered in situations where there was an interruption in the funding mechanism. The investigator, sponsor, and lab would work together to bring the scope of work and budgetary limitations into alignment. In general, direct expenses (e.g., the cost of reagents or assay kits already used) would be recovered before other costs (e.g., personnel time). Payments might even be waived in certain cases, but these would need to be individually negotiated.

Prioritization of work

1. In general, work for research projects will be done on a first come, first served basis
2. If an investigator needs results sooner than the routine work flow will allow, he/she can request priority service from the laboratory director or associate director and provide justification for the request.
3. If the priority request is denied, the investigator can request a review of the decision by the chair of the core advisory committee. The chair of the core advisory committee has the option of calling an ad hoc meeting of the core advisory committee if a satisfactory solution cannot be negotiated.
4. Guidelines for these decisions (both by the director/associate director and the advisory committee) are as follows:
   a. NIH-funded studies (especially PDT-funded studies) take precedence over studies funded from other sources.
   b. Studies with finite time lines (e.g., developmental studies generating data for grant applications with restricted deadlines) may be given special consideration, regardless of funding source.
   c. The above considerations notwithstanding, all patient specimens for clinical care must be processed and completed within the guidelines specified in the QA/QC plan for the laboratory.

Publication and authorship expectations: Laboratory personnel (including the director an associate director) will not be included as authors on any publication using data generated by the laboratory unless they meet the ICJME guidelines for authorship (http://www.icmje.org/ethical_1author.html). Simply performing an established assay should not be considered a "substantial contribution" to data acquisition unless the assay was one that was developed or significantly modified by the laboratory and that assay is not generally available elsewhere.

Conflict resolution. (Scheduling, technical issues, quality, authorship, etc.): As noted in the policy for prioritizing work, any disputes can be taken to the chair of the core advisory committee who can then convene a meeting of the core advisory committee, if needed. The ruling of the core advisory committee will be considered final (although other avenues of appeal within the academic hierarchy will still be available, if needed).