HEALTH INFORMATION MANAGEMENT DEPARTMENT

REGULATORY AUDIT GUIDE

INTRODUCTION

This informational guide was developed to explain the requirements for scheduling and conducting regulatory audits for interested NIH employees, NIH-contract employees and external auditors. If you have questions or comments please contact the Health Information Management Department (HIMD) in Building 10, Room B1L400, (301) 496-3331, 7:00 a.m. to 5:00 p.m., Monday through Friday (excluding Federal Holidays) for prompt assistance.

REGULATORY AUDIT

In the course of providing requested services to the National Institutes of Health (NIH), external auditing personnel (e.g., pharmaceutical company representatives, consultants, statistical analysts, etc.) may require access to review NIH patient medical records. As well, record access may be needed by NIH employees or contractors for purposes internal to the NIH. The Health Information Management Department is responsible for the coordination of both external and internal audits with a specific NIH "Point-of-Contact" employee. Regulatory audits by external audit personnel using any patient-specific medical record material may not be conducted in any location outside of the Health Information Management Department.

REGULATORY AUDIT REQUIREMENTS

1. An NIH Point-of-Contact employee, by the authority of the Principal Investigator(s) of the NIH protocols to be reviewed, must provide HIMD personnel with a memorandum requesting record access. The memorandum must identify the following required items:

    - Name of audit group
    - Date(s) of record review
    - NIH Institute
    - Protocol number(s)
    - Principal Investigator name(s)
    - Name(s) of the auditing personnel
    - Approximate number patient records needed
    - Whether Clinical Research Information System (CRIS) access will be required by auditors
    - Whether a Curriculum Vita (C.V.) has been provided to the Health Information Management Department personnel within the past year for each auditor

- Whether a NIH CC Confidentiality Agreement has been provided to the Health Information Management Department personnel within the past year for each auditor
- NIH point-of-contact (name, NIH phone number, NIH address, NIH e-mail address, signature) responsible for monitoring the performance of the auditing personnel, particularly as it pertains to the handling of confidential patient information, photocopying and abstracting of data

A template of this memo may be obtained on the NIH Intranet at: http://intranet.cc.nih.gov/medicalrecords/forms/pdf/RegulatoryAuditSchedulingForm.pdf. This completed memorandum must be submitted to HIMD personnel before audit space will be scheduled. Prior to submitting this memo, it is recommended that the NIH Point-of-Contact verify that audit space is available for the requested timeframe. To best ensure space availability, it is recommended that this memorandum be sent to HIMD personnel at least one month prior to the first day of the audit. The memorandum may be faxed, e-mailed or personally delivered to the HIMD.

2. The Chief of the Health Information Management Department, or designee, shall review any abstracting documents intended for use by an external auditor. Patient name, NIH number, or other unique patient identifiers, such as Social Security number, patient address or telephone number are not to be abstracted or otherwise collected by the external auditing personnel.

3. External auditors must wear an NIH visitor's badge on their outermost clothing at all times while on NIH property. HIMD personnel must view this badge prior to the commencement of each audit.

4. External auditors are required to submit a current Curriculum Vita (C.V) to HIMD personnel the Wednesday prior to the week the audit occurs. Curriculum Vitae are considered valid for one year and maintained on file in the Health Information Management Department. External auditors will not be permitted to review records without a current CV on file.

5. Internal auditors (NIH employees and NIH contractor employees) must wear their NIH identification badge on their outermost garment at all times and display it to HIMD personnel on the first day of each audit.

6. As a courtesy to other requesters, notification regarding cancellation of scheduled audits to HIMD personnel by the Point-of-Contact is required in writing (via delivery, e-mail or facsimile machine) as soon as possible. Failure to notify HIMD personnel of

a canceled audit more than three times in one month will result in the cancellation of any future audits for that particular auditor until a meeting can be scheduled with HIMD personnel to discuss the circumstances and strategies to prevent recurrences.

7. To ensure availability of audit space to all interested parties and to minimize cancellations and "no shows", audits may be booked no more than six months in advance.

8. Photocopying/printing of medical record documentation is not permitted by external auditors. If use of the Health Information Management Department photocopier is needed by auditors for information other than medical record documentation, auditors must yield use of the copier to all HIMD customers and may resume photocopying once customers have finished. Auditors should expect HIMD personnel to examine photocopies to ensure NIH patient medical documentation is not being photocopied.

9. All auditors are required to sign-in at the audit front desk each day that they present to audit.

10. In an effort to not disrupt others and maintain confidentiality, meetings should not be held within the Regulatory Audit room within the Health Information Management Department. If meeting space is needed, please request this in advance (at least one business day). Meeting space is subject to availability.

11. No verbal cell phone use is allowed within the Health Information Management Department.

12. No cellular hot spots are allowed to be used within the Regulatory Audit room within the Health Information Management Department. These devices cause interference with NIH wireless systems. Guest wireless networks are available for auditor use.

REGULATORY AUDIT MEDICAL RECORD REVIEW

1. A list of requested patient medical records must be received by HIMD personnel no later than the Wednesday prior to the week of the audit. A template of a record list may be obtained from HIMD personnel. If a record list is not received by the Tuesday prior to the week of the audit, the NIH Point-of-Contact will be contacted by HIMD personnel. If the NIH Point-of-Contact fails to respond or provide a list of needed

records by the Wednesday prior to the week of the audit, the reservation for audit space will be released.

Records shall be requested as follows:

a. Via a list submitted to HIMD personnel, Building 10, Room B1L400 in typewritten form indicating each of the following items:

- Name of the auditing group
- Name and NIH address, telephone number and e-mail address of the Point-of-Contact
- Date(s) of the audit
- Each patient name and medical record number.

Lists should be submitted via encrypted email to HIMD personnel and/or the CC-HIMD Regulatory Audit email group.

RESEARCH FILES

Any hard copy research files may be brought down to the Health Information Management Department for review. All binder and/or folders must be collected by the NIH point-of-contact no later than 4:00PM each Friday. Auditor access to electronic research files shall be coordinated through the Health Information Management Department via a secure folder location on an NIH server. NIH point-of-contacts will be given access to the folder in order to place files for auditors to review. All files must be password protected. We recommend using the Principal Investigator's last name as the password. All files will be removed by HIMD personnel at the conclusion of the audit. For access to the secure folder, please contact Health Information Management Department personnel.