

Johns Hopkins Bayview Medical Center

CLINICAL RESEARCH UNIT

Research Record Handling and Storage

Policy No. 143
Original Date: 07/11/2002
Reviewed Date: 4/11/2008

Purpose: To establish a procedure for the retention and maintenance of subject/participant medical records, which assures continuity of the information contained as well as confidentiality as required by the Code of Federal Regulations and the Maryland law.

Policy:

1. It is the responsibility of the Research Team / Primary Investigator to maintain the original Research Record on every subject/participant enrolled in a research study. This original research record may be temporarily housed at the CRU during open activity of the study or housed with the coordinator and brought to the CRU for study visit(s). The original Research Records will be maintained in compliance with appropriate Regulatory Agencies and the National Center for Research Resources.
2. The contents of the Inpatient Medical Record for every subject/participant's original research record will contain the following:
 - a. A copy of consent forms signed by the subject/participant.
 - b. Physician orders
 - c. All records of drugs administered to the subject/participant with, if applicable, investigational drug information form.
 - d. All records of any applicable history and physical examinations performed on the subject/participant.
 - e. All records of vital signs, weight, and any other physician ordered measurements taken of bodily functions, which are related to the research protocol and performed by the CRU Staff.
 - f. All progress notes, nursing protocol sheets and regulatory documents.
 - g. All records of laboratory tests performed on the subject/participant, including the results and interpretations of those tests.
 - h. All records of any clinical radiology/imaging procedures performed on the subject/participant, including the results and any interpretations of those tests.
 - i. Any adverse event records and actions taken.
 - j. Discharge summary.
3. The contents of the Outpatient Research Record for every subject/participant's original medical record will contain the following:
 - a. A copy of the consent forms signed by the subject/participant.
 - b. Physician orders.
 - c. All records of drugs administered to the subject/participant with, if applicable, investigational drug information form.
 - d. All records of any applicable history and physical examinations performed on the subject/participant.
 - e. All records of vital signs, weight, and any other physician ordered measurements taken of bodily functions, which are related to the research protocol and performed by the CRU Staff.
 - f. All progress notes, nursing protocol sheets and regulatory documents.
 - g. All records of laboratory tests performed on the subject/participant, including the results and y interpretations of those tests.

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- h. All records of any clinical radiology/imaging procedures performed on the subject/participant, including the results and any interpretations of those tests.
 - i. Any adverse event records and actions taken
 - j. Subject completion note.
4. Coordinator, Primary Investigators and CRU Staff will follow any applicable Federal and State Laws for any requests for copies of subject/participant's research records.

Procedure:

1. A subject/participant will have a research record initiated on the first CRU visit in which the subject/participant consents to be a part of the research protocol. The subject/participant's consent form for participation in the research protocol will immediately be copied and placed in the research record.
2. Should a request for the subject's research records arise it is the responsibility of the requestor to contact the subject/participant and have the subject/participant sign the appropriate documents. Once the Principle Investigator or coordinator is presented with the appropriate documentation the requested research records will be released.
3. Once initiated, the subject/participant research record will contain the documents listed in detail at the beginning of this Policy.
 - a. No document may be removed from any subject/participant's research record.
 - b. No information within the subject/participant's research record may be destroyed, obliterated, or otherwise made illegible. All entries in the research record will be in black ink.
 - c. No document within the subject/participant's research record may be released without the written approval of the subject/participant. Such written authorization must be kept in the research record.
4. All information concerning the subject/participant's participation in a research protocol is confidential in nature and therefore adhere to State and Federal confidentiality policies as apply.
5. Access to information is limited.
 - a. During the research protocol, the subject/participant's outpatient research chart may be kept by the coordinator and brought to the CRU on the date of the subject/participant's visit or the research chart may reside on the CRU for the duration of the study. The inpatient research chart will be kept on the CRU until subject/participant is discharged. Research records are for access by the principle investigator, research team, CRU Staff and any regulatory agency.

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- b. Access to these files will be limited to CRU Staff who are working on the research protocol. No copies of the subject/participant's research record for non-research activities may be made without the consent of the subject/participant and the principal investigator.
6. After research protocol is completed.
- a. It is the responsibility of the research team to collect the subject/participant's inpatient research record from the CRU upon inpatient discharge and to store and maintain files within regulatory requirements.
 - b. It is the responsibility of the research team to collect the subject/participant's outpatient research records from the CRU upon completion of a protocol and to store and maintain files within regulatory requirements.
 - c. The CRU Staff will maintain a log regarding removal of charts from the CRU Unit.

Reviewers: CRU Patient Care Manager
CRU Program Director
CRU Unit Services Coordinator

Pamela Ouyang, MBBS
Program Director, JHBMC

John Preto, RN, MSN
Director of Maternal Nursing

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Research Record Handling and Storage

Consent to Release Research Protocol Records

I _____ am over 18 years of age and competent to consent.

I am enrolling as a subject/participant in the

_____ Research protocol.

I understand that medical records, which reveal my participation in this protocol, will be created.

I agree that the medical records created during my participation in this research protocol may be co-mingled (mixed) with my non-research protocol medical records.

I agree that the medical records created during my participation in this research protocol may be released to a third party who presents a release, signed by my legally authorized representative or me or by subpoena (unless this protocol has special confidentiality protection through the Principal Investigator).

I agree to hold the staff, physicians, and employees of the Johns Hopkins Bayview Medical Center harmless for the release of the medical records created as part of my participation in this research protocol.

I have read the above statements, understand the meaning of these statements and agree to each of them.

Signature of subject/participant

Date

Witness

Date

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Research Record Handling and Storage

Refusal to Release Medical Records Created During Research Protocol

I _____ am over 18 years of age and competent to consent.

I am enrolling as a subject/participant in the

_____ Research protocol.

I understand that medical records, which reveal my participation in this protocol, will be created.

I DO NOT CONSENT to have the medical records created during my participation in this research protocol being co-mingled (mixed) with my non-research protocol medical records.

I DO NOT CONSENT to have the release of the medical records created during my participation in this research protocol to any third party, unless the release, signed by my legally authorized representative, or me specifically states the name of this research protocol.

Signature of subject/participant

Date

Witness

Date

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Research Medical Record

Do not release any copies or parts of this record to any Third Party. This record may be under protection by a Certificate of Confidentiality or other legal binding requirements.

The Patient Care Manager of the JHBMC Clinical Research Unit must give approval for record review. Please call 0-1850 to **obtain permission**.