# Storage of Research Data and Informed Consent Documents

## Policy

- Storage requirements for research data and informed consent documents must be determined for each research protocol.
  - **For research that involves the care, diagnosis, or treatment of a patient**, the original or a copy of the informed consent must be placed in the medical record. If the original is placed in the medical record, a copy should always be maintained in the research record as well. In addition, the investigator is to specify those test and other research results that are to be included in the medical record.
  - **For research that does not involve procedures, interventions, treatments that are part of a subject's care, diagnosis, or treatment**, the investigator may choose to store the informed consent document and associated research data in his or her research files and **not** in the medical record.

## Purpose

To outline for investigators where research data and informed consent documents are to be stored.

## Procedure

Investigators are to identify where research study data from tests and assessments, and informed consent documents, are to be recorded and stored. For some research, particularly studies that implicate present or contemplated clinical care, or that produce clinically relevant and reliable results, it is important that a subject's participation in the research, and certain results, be reflected in the medical record. At other times, a subject's participation and results should not to be included in the medical record (e.g., in order to protect confidentiality; because lab results are not from a CLIA-certified laboratory or otherwise deemed clinically reliable; because the research, and its results, are not pertinent to clinical care). These determinations are to be made on a protocol-by-protocol basis by the investigator initially, and are subject to review and approval by the Institutional Review Board (IRB).

Informed consent documents must be readily accessible at all times. Therefore, where the research is pertinent to clinical care by Boston Children's Hospital or Boston Children's Hospital physicians, investigators must maintain copies or the original informed consent document in research records as well as the medical record. In the event commercial sponsors require the original informed consent document to be filed with a research binder, the Medical Records Department will accept a copy of the subject's signed informed consent in lieu of the original. In order to determine the manner of storage, it is important to understand sponsor requirements prior to initiating a study. Please also take into

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consideration the possibility that a consent document could be misplaced and not make its way to the medical record. For that reason an investigator may choose to always store the original consent in their research records.

The following IRB guidelines are provided to assist investigators in considering the appropriate manner of storage for research informed consent documents and research data. Sample template language for informed consents is also provided.

**For research that involves the care, diagnosis, or treatment of a patient**, the original or a copy of the informed consent must be placed in the medical record. Either the original or a copy must also be maintained with the research records. In addition, the investigator is to specify those tests and other research results that are to be included in the medical record, using his or her discretion informed by the factors outlined above. Examples include:

- For research undertaken at Boston Children's Hospital for the intervention, treatment, or diagnosis of a disease, disorder, or condition (e.g., drug and device trials; comparison of psychological interventions; testing new diagnostic techniques), either the original or a copy of the informed consent form is to be stored in the medical record, as are any reports and results that bear on the care of the patient, including the proper interpretation of unrelated clinical tests that would otherwise be anomalous. In addition the original or a copy should be maintained in the research record at all times.
- For research that involves any procedure(s) for which medical care or support is required and provided by Boston Children's Hospital, the research results applicable to a particular patient, except in rare instances, are to be reported and included in the medical record just as they are when the care or support is provided for non-research purposes.
- For research that <u>does not</u> involve procedures, interventions, treatments that are part of a subject's care, diagnosis, or treatment, the investigator may consider storing the informed consent document and associated research data in his or her research files only and not in the medical record. Examples of such research include: studies that involve genetic testing (except where clinically indicated, and the patient anticipates and agrees to the placement of consent and data documents in the medical record); behavioral assessments not intended for clinical use; and completion of questionnaires on sensitive issues.
- For either category of research described above, the investigator is responsible for including a statement in the informed consent document that specifies where copies of the informed consent document and research data are to be maintained. Because each protocol represents a unique set of circumstances, it is important that these determinations be made on a protocol-by-protocol basis. Investigators are to indicate on the protocol application where the informed consent document is to be stored and where the results of research tests are to be recorded. The IRB reviews this information during the review process and informs investigators of any required changes.

## Suggested Informed Consent Statements

**<u>If consent form will be placed in medical record</u>**

*A copy of this consent form will be placed in your medical record. If you do not have a medical record at Boston Children's Hospital, one will be created for you.*

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**If consent form will NOT be placed in medical record**

*A copy of this consent form will not be placed in your medical record.*

**If research data will be placed in medical record:**

*Information collected during this research will become part of your medical record, if the information is related to the care you receive at Boston Children's Hospital. Medical records are considered permanent records; therefore, information cannot be deleted from the record. Medical records are available to health care professionals at Boston Children's Hospital and may be reviewed by Hospital staff when carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your medical record may not be given to anyone unaffiliated with Boston Children's Hospital in a way that could identify you without written consent, except as required or permitted by law.*

**If research data will not be placed in medical record;**

*The results of the tests performed for research purposes will not be placed in your medical record. Because of this, it is unlikely that others within the hospital, an insurance company, or employer would ever learn of such results.*

# Related Content

***1. Document Retention and Destruction: Clinical Research, Investigator Files; pgs. 12 – 15. (CH Compliance Manual, ELibrary)***

# Document Attributes

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