



## 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 Committee on Clinical Investigation (CCI).

Informed consent documents must be readily accessible at all times. Therefore, where the research is pertinent to clinical care by Children's Hospital or 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 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 CCI 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 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 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 nonresearch purposes.
- For research that does not 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 CCI reviews this information during the review process and informs investigators of any required changes.

## Suggested Informed Consent Statements

### **Suggested wording if you do place research data and informed consent documents in the medical record:**

Medical information collected during this study will become part of your/your child's hospital record if the information is determined to be pertinent to the care you/your child receive/s at Children's Hospital, [including the following information:\_\_\_\_\_]. In addition, a copy of this informed consent document will be filed in your medical record. Medical records are considered permanent records; therefore, materials cannot be deleted from the record. Medical records are available to health care professionals at Children's Hospital and may be reviewed by Hospital staff in the course of carrying out their responsibilities; however, they are required to maintain confidentiality in accordance with applicable laws and Hospital policies. Information contained in your/your child's medical record may not be given to anyone unaffiliated with Children's Hospital in a manner that could identify you/your child without written consent, except as required or permitted by law. Information collected during the study that does not become part of your/your child's medical record will be stored in separate research files maintained by the investigator. These research records will not be made available to any individuals who are not part of the research team unless you so request or as required by law. If you/your child withdraw from the research study, information that has already been collected will become part of the research data; however, you/your child will not be identified.

### **Suggested wording if you do not place research data and informed consent documents in the medical record:**

The results of the tests performed for research Purposes and a copy of this informed consent will not be placed in your/your child's medical record. A copy of this form and the results of the research will be kept in a separate research file maintained by the primary investigator. In this manner it is unlikely that others at the Hospital, an insurance company, or an employer will 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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