

FAQs

How to Store Signed Research Consent and Assent Forms in Medical Records

QUESTION: Where do I store signed research consents/assents for my study?

ANSWER:

- Principal Investigator: *always* keep the original signed consent in a secure research file
- Research Subject/Family: *always* give a signed copy for their records
- Medical Records (Powerchart): *only when* required by IRB, copy of signed consent should be added

QUESTION: When should a copy of a subject's signed consent form(s) be filed in their BCH medical record (PowerChart)?

ANSWER: When required by the IRB as specified at time of IRB final approval.

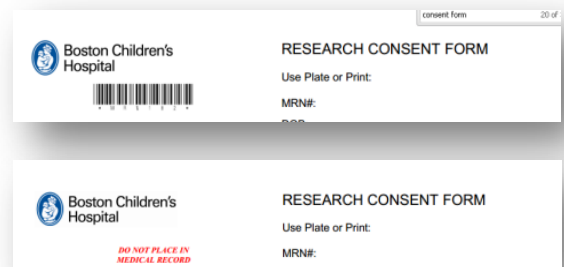
All of the following will indicate whether the consent should be filed in subject's medical record.

↳ Ensure all determinations are consistent. If not, contact the IRB to clarify at x5-7052:

IRB Final Approval Letter: will include a statement specifying if copies of signed consent forms should be filed in the subject's medical record.

IRB Approved Consent Forms:

- If the approval letter specifies a signed copy should be filed in the medical records, there will be a **barcode*** in the top left hand corner of the approved consent form.
- If not required, there will be a stamp **"DO NOT PLACE IN MEDICAL RECORD"**.
- In the section *"Who May See, Use or Share Your Health Information?"* there will be a statement specifying whether the consent *"WILL or WILL NOT* be placed in the subjects clinical medical record."



ChERP Protocol SmartForm: in *"Research Data, Documents, Subject Reports & Consent/Assent Forms Storage: Where will the signed informed consent and assent be stored? Check all that apply."*

QUESTION: How do I add the signed consent to the medical record (PowerChart)?

ANSWER: Send signed copy of consent to Health Information Management (HIM) who will upload to the appropriate location in PowerChart (only HIM can upload consents).

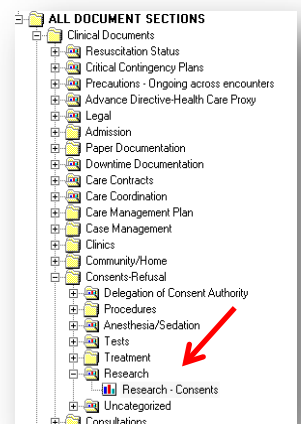
You can send copy of signed consents/assents to HIM using either of the following methods:

Ricoh Copier: Scan and send copy to medrecupload@childrens.harvard.edu.

↳ Note: you may only scan and send one consent form at a time.

Interoffice mail: address interoffice envelope to 'HIM/Medical Records'

↳ Note: first page must be an original printout or include a printed bar code sticker to ensure bar code is readable (for more info on bar code stickers, see [June 2016 IRB newsletter](#))



QUESTION: Where will the consents be saved in PowerChart?

ANSWER: The consents will be saved to a Documents folder titled **"Consents-Refusal: Research: Research- Consents"**