Consents in the Medical Record for Human Research Protection

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Purpose

- To communicate to the staff caring for a patient that the patient is in a clinical research study that could have an effect on the clinical treatment.

- HRP guidance - HRP-803 Section 3.4
  - (next slide)

- JCAHO standards
  - Provision of Care
  - Communication
  - Safety
  - Medication management
IRB Guidance - HRP-803 Section 3.4

- The guidance allows the Principal Investigator to determine when the signed consent document should be placed in the medical record.
  - Suggestion for studies that meet the guidance “includes procedures which are or can affect clinical care”
    - FDA regulated studies including IND, IDE, biologic (BB)IND and any study investigating the safety and efficacy of the above that do not require an IND, IDE or BBIND.
    - Studies that include procedures that could place the patient at greater risk for harm.
    - Studies with procedures or drugs or devices that separately or in combination with patient clinical treatment could place the patient at greater risk for harm.
How does the Research Team place the consent in the Medical Record?

- **Research being done during inpatient stay**
  - Place a **Hard copy** of the signed consent form in the subject’s medical chart and also send a copy to Health Information Management (HIM).
  - **WHY DO BOTH?**
    - **Hard copy** allows for real time communication to staff providing *clinical care*.
      - After discharge, the hard copy will be scanned into Hyland On-Base as part of that episode of care.
      - Consent is retrievable but search can be tedious
    - Sending a **copy** to Health Information Management (HIM)
      - Allows HIM to scan consents into Allscripts (the outpatient, longitudinal record)
      - Consents are always available under the *Administrative Documents Tab* in a sub-folder labelled *Research Consents*.

- **Research being done in Ambulatory or other outpatient setting**
  - Provide a copy of signed consent to Health Information Management (HIM)
Methods to provide consent to HIM (in order of preference)

1. Email to HIM
   - Write the Medical Record Number (MR#) on the consent form to increase likelihood of consent being placed in the correct record.
   - Scan the consent form to create a PDF. Save the PDF with the following naming convention: First initial, last name and Medical Record Number (MR #).
   - Each subject’s consent should be converted to a PDF individually. Do not batch the consents into a single PDF.
   - When emailing the PDF, do not put PHI in the subject line. Subject line should read “Research Consent Form”.
   - Email to SoarianMedicalRecordNumberIssues@umassmemorial.org
Methods to provide consent to HIM (in order of preference) cont.

2. Ambulatory Clinic Scanning Bins.
   - Ambulatory clinics have scanning bins for hard copy documents that must be scanned into Allscripts.
   - Place consent in the scanning bin

3. Fax to HIM at 508-334-9777

4. Interoffice mail
Important

- The PI and/or delegated research team member is responsible for assuring the consent is in the medical record if it meets guidance in HRP-803 section 3.4.
  - Review Allscripts to assure consent is present after sending to HIM
  - Contact HIM if consent is not in Allscripts
- Always keep the *original signed consent form* in your research records.
Informed Consent FAQ

How long do you retain the informed consent and HIPAA documents?

Retain research records (including signed consent documents) for the greater of:

- Three years after completion of the research
- Maintain signed and dated consent documents for at least three years after completion of the research.
- Maintain signed and dated HIPAA authorizations and consent documents that include HIPAA authorizations for at least six years after completion of the research.

(HRP-800: Investigator Obligations)