# Consents in the Medical Record for Human Research Protection

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# Purpose

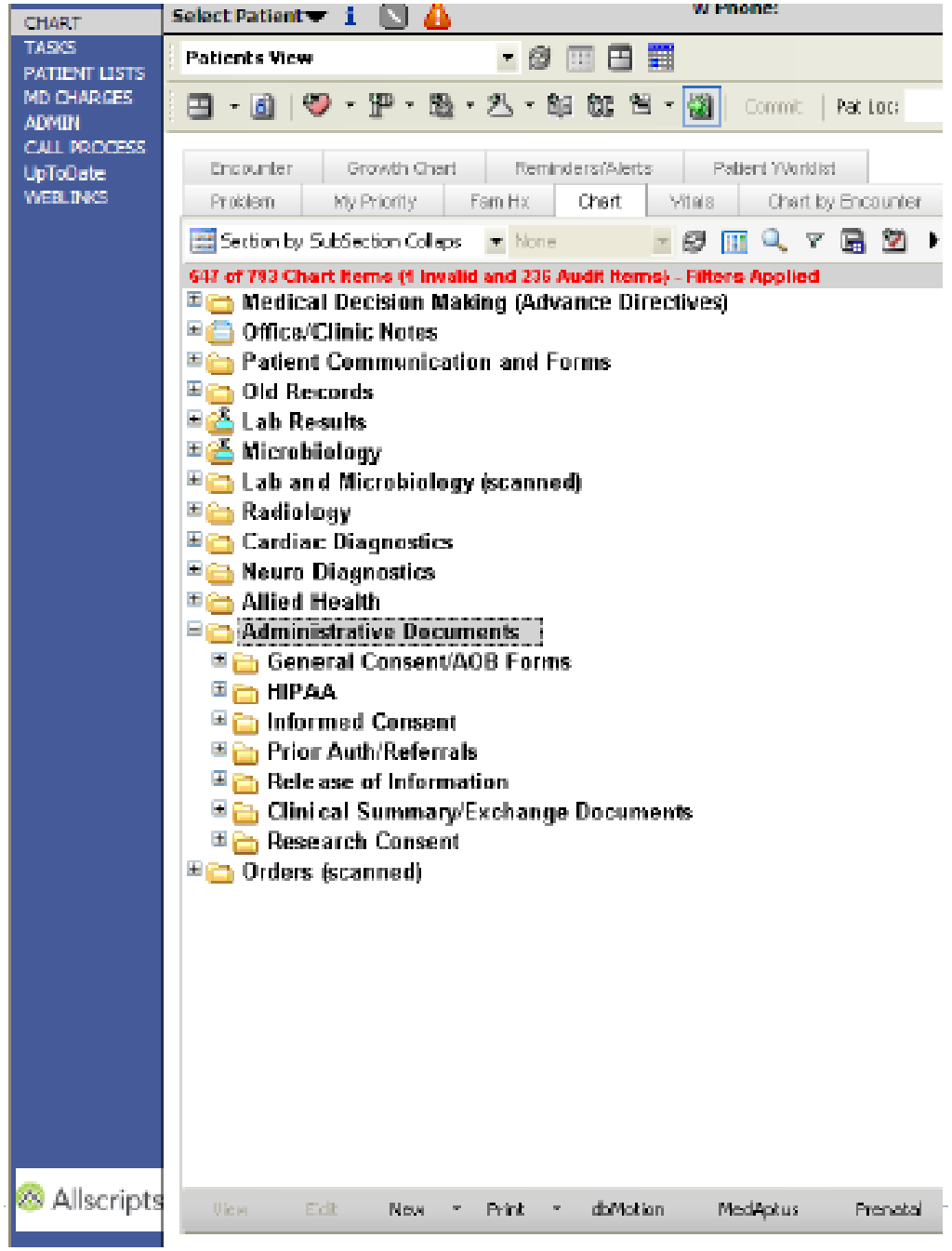
- To communicate to the staff caring for a patient that the patient is in a clinical research study that could have an effect on the clinical treatment.
  - HRP guidance- HRP-803 Section 3.4
    - (next slide)
  - JCAHO standards
    - Provision of Care
    - Communication
    - Safety
    - Medication 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)



CHART
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Reminders/Alerts
Patient Worklist
Problem
My Priority
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Chart
Vitals
Chart by Encounter
Section by SubSection Collaps
None
647 of 793 Chart Items (1 Invalid and 236 Audit Items) - Filters Applied
Medical Decision Making (Advance Directives)
Office/Clinic Notes
Patient Communication and Forms
Old Records
Lab Results
Microbiology
Lab and Microbiology (scanned)
Radiology
Cardiac Diagnostics
Neuro Diagnostics
Allied Health
Administrative Documents
General Consent/AOB Forms
HIPAA
Informed Consent
Prior Auth/Referrals
Release of Information
Clinical Summary/Exchange Documents
Research Consent
Orders (scanned)
Allscripts
View
Edit
New
Print
doMotion
MedAptus
Prenatal

# 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)