

## Research and Medical Records – Where They Meet, Collide and Miss The Mark

### 2009 HCCA Compliance Institute

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## Overview

- Identify the issues
- Define the two records and their content
- Understand the regulatory environment and your organization
- Scope out a plan



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## Issues

- **Treatment** - Care-givers may lack awareness of patient's research participation
- **Confidentiality** - Obligation (sponsor and patient) to protect research results
- **Privacy** - Failure to clearly define and segregate the research data in the medical record could lead to release (third party payer requests, court orders and subpoenas)



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## Considerations

- Harmonization of varying requirements
- Overlap of medical and research records
- Need to notify clinicians of research participation
- Need to separate clinical and research participation

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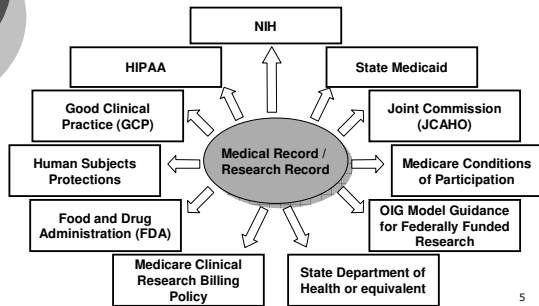
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## Regulatory Environment



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## Definitions

- Focus on the definition of the "medical record" and the "research record" in order to determine the broad parameters for the issue.
- If a definition is prescriptive, constraints are placed on decision-making. If a prescriptive definition is in regulation, then greater constraints are placed on the decision-making.

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## Definitions of Medical Record

- Regulatory
  - The hospital must maintain a medical record for each inpatient and outpatient. Medical records must be accurately written, promptly completed, properly filed and retained, and accessible. Medical records must be retained in their original or legally reproduced form for a period of at least 5 years. (Medicare Conditions of Participation 42 CFR §482.24(b)(1))
  - HIPAA defines "record" as "any item, collection, or grouping of information" containing PHI, that is "maintained, collected, used or disseminated by or for a covered entity." (45 CFR §164.501)

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## Definitions of Medical Record

- Guidance
  - AHIMA defines the legal health record as "generated at or for a healthcare organization as its business record and is the record that would be released upon request..." September 2005.

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## Contents of the Medical Record

- The contents of the medical record are equally important in setting parameters as we delve into the details of the scope and content of the research record. There will likely be overlap in the contents of these two records.
- Where there is overlap between the medical record and the research record, determinations about the location of original versus copies of documents should be made.

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**Contents of the Medical Record Regulatory**

- Medicare Conditions of Participation:
  - The medical record must contain information to justify admission and continued hospitalization, support the diagnosis, and describe the patient's progress and response to medications and services. (42 CFR §482.24(c))

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**Contents of the Medical Record Regulatory**

- Medicare Conditions of Participation:
  - All records must document the following as appropriate:
    - Evidence of physical examination
    - Admitting diagnosis
    - Results of consultative evaluations
    - Documentation of complications
    - Properly executed informed consent forms
    - Orders, discharge summary and final diagnosis

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**Contents of the Medical Record Regulatory**

- Medicare Claims Processing Manual:
  - The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review. (Chapter 32, § 69.3)

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## Contents of the Medical Record Guidance

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- Joint Commission:
  - The hospital has a complete and accurate medical record for patients assessed, cared for, treated, or served. (IM 6.10)
  - Records contain patient-specific information, as appropriate, to the care, treatment, and services provided. (IM 6.20)
  - For patients receiving continued ambulatory services, the medical record contains a summary list(s) of significant diagnoses, procedures, drug allergies, and medications. (IM 6.40)



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## Contents of the Research Record

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- The regulatory and guidance materials that outline contents of the research record are as important as the guidance for the contents of the medical record for similar reasons.
- In reviewing the varying directives, we must continually refer back to whether it is a must from a regulation, or a should/could from guidance.
- Current practice should advise decisions as the risk/benefit of requiring changes are weighed.

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## Definitions of the Research Record

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- Three sets of criteria:
  - DHHS regulations
  - FDA regulations
    - Includes drug and device regulations that differ
  - ICH-GCP
- Each has different applicability (definition of what is "human research")
- Each has different requirements
  - For clinical trials combining requirements makes sense



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### Important notes about ICH-GCP

- o "International Conference on Harmonisation – Good Clinical Practice – E6"
- o International standard
- o Required for most European and Asian approvals
- o Applies only to clinical trials
- o Not the same as GCP defined by FDA
- o Not a US requirement
- o Clinical trial contracts usually say the organization and investigator will abide by ICH-GCP
  - You may be unknowingly committed to ICH-GCP

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### DHHS Applicability

- o Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. (45 CFR §46.102(d))
- o Human subject means a living individual about whom an investigator (whether professional or student) conducting research obtains: (45 CFR §46.102(f))

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### DHHS Research Record: Signed Consent Documents

- o The records required by this policy shall be retained for at least 3 years, and records relating to research which is conducted shall be retained for at least 3 years after completion of the research. (45 CFR §46.115(b))
- o OHRP interprets signed consent document as "records required by this policy" and requires these documents to be part of the research record.

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**Research Record:  
FDA Applicability**

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- Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be later submitted to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit. The terms research, clinical research, clinical study, study, and clinical investigation are deemed to be synonymous for purposes of this part. (21 CFR §56.102)

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**Research Record:  
FDA Applicability**

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- Plain language (21 CFR §56.102)
  - Any use of an unapproved drug in humans
  - Any use of a marketed drug in humans outside medical practice
  - Any use of a device in a human or a human specimen to evaluate safety or effectiveness.
  - Use of humans as controls for the above
  - Collecting data to submit to or hold for inspection by FDA

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**FDA Research Record:  
Overview**

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- Electronic Records
- Signed Consent Documents
- Control of Test Articles
- Case Histories
- Investigator Reports

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### FDA Research Record: Electronic

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- o Electronic record means any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. (21 CFR §11.3)
- o FDA has extensive regulations that apply to electronic records that need to be implemented during the design of an electronic system.

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### FDA Research Record: Signed consent documents

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- o The records required by this regulation shall be retained for at least 3 years after completion of the research. (21 CFR §56.115(b))
- o FDA interprets signed consent document as "records required by this regulation" and requires these documents to be part of the research record.

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### FDA Research Record: Control of Test Articles

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- o **Drugs:** An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. (21 CFR §312.62 (a))
- o **Devices:** A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation ... [including] records of receipt, use or disposition of a device that relate to ... (21 CFR §812.140(a)(2))

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### FDA Research Record: Case Histories

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- **Drugs:** An investigator is required to prepare and maintain adequate and accurate case histories that record all observations and other data pertinent to the investigation on each individual. (21 CFR §312.62(b))
- **Devices:** A participating investigator shall maintain the following accurate, complete, and current records relating to the investigator's participation in an investigation ... records of each subject's case history and exposure to the device. 21 CFR §812.140(a)(3))

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### FDA Research Record: Case Histories

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- **Drugs:** Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes. The case history for each individual shall document that informed consent was obtained prior to participation in the study. (21 CFR §312.62(b))
- **Devices:** Case histories include the case report forms and supporting data including, for example, signed and dated consent forms and medical records including, for example, progress notes of the physician, the individual's hospital chart(s), and the nurses' notes.

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### FDA Research Record: Investigator Reports

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- **Drugs:** (21 CFR §312.64)
  - Progress reports
  - Safety reports
  - Final report
- **Devices:** (21 CFR §812.150)
  - Unanticipated adverse device effects
  - Withdrawal of IRB approval
  - Progress reports
  - Deviations from the investigational plan
  - Informed consent
  - Final report
  - Other reports

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## ICH-GCP General

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- 4.9.4 The investigator/institution should maintain the trial documents as specified in Essential Documents for the Conduct of a Clinical Trial (see 8.) and as required by the applicable regulatory requirement(s). The investigator/institution should take measures to prevent accidental or premature destruction of these documents

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## Before the Trial Commences ICH-GCP 8.2

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<ul style="list-style-type: none"> <li>○ Investigator's brochure</li> <li>○ Signed protocol and amendments, if any, and sample case report form</li> <li>○ Information given to trial subject           <ul style="list-style-type: none"> <li>● Informed consent form</li> <li>● Any other written information</li> <li>● Advertisement for subject</li> <li>● Recruitment (if used)</li> </ul> </li> <li>○ Financial aspects of the trial</li> <li>○ Insurance statement</li> </ul>	<ul style="list-style-type: none"> <li>○ Signed agreement between involved parties</li> <li>○ Dated, documented approval/favorable opinion of the IRB</li> <li>○ IRB composition</li> <li>○ Regulatory authority(ies) authorisation/approval/notification of protocol</li> <li>○ Curriculum vitae and/or other relevant documents evidencing qualifications of investigator(s) and sub-investigator(s)</li> </ul>
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## Before the Trial Commences ICH-GCP 8.2 (continued)

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- Normal value(s)/range(s) for medical/laboratory/technical procedure(s) and/or test(s) included in the protocol
- Medical/laboratory/technical procedures /tests
- Instructions for handling of investigational product(s) and trial-related materials
- Shipping records for investigational product(s) and trial-related materials
- Decoding procedures for blinded trials
- Trial initiation monitoring report

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### During the Trial ICH-GCP 8.3

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- Investigator's brochure updates
- Any revision to: protocol/amendment(s) and CRF; informed consent form; any other written information provided to subjects; advertisement for subject recruitment (if used)
- Dated, documented approval/favourable opinion of IRB
- Regulatory authority(ies) authorisations/approvals/notifications where required for:
- Curriculum vitae for new investigator(s) and/or subinvestigator(s)
- Updates to normal value(s)/range(s) for medical/laboratory/ technical procedure(s)/test(s) included in the protocol
- Updates of medical/laboratory/technical procedures/tests
- Documentation of investigational product(s) and trial-related materials shipment
- Monitoring visit reports
- Relevant communications other than site visits
- Signed informed consent forms source documents
- Signed, dated and completed case report forms

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### During the Trial ICH-GCP 8.3 (continued)

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- Documentation of CRF corrections
- Notification by originating investigator to sponsor of serious adverse events and related reports
- Notification by sponsor and/or investigator, where applicable, to regulatory authority(ies) and IRB(s) of unexpected serious adverse drug reactions and of other safety information
- Notification by sponsor to investigators of safety information
- Interim or annual reports to IRB and authority(ies)
- Subject screening log
- Subject identification code list
- Subject enrolment log
- Investigational products accountability at the site
- Signature sheet
- Record of retained body fluids/
- Tissue samples (if any)

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### After Trial Completion ICH-GCP 8.4

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- Investigational product(s) accountability at site
- Documentation of investigational product destruction
- Completed subject identification code list
- Final report by investigator to IRB where required, and where applicable, to the regulatory authority(ies)
- Clinical study report

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**Areas where medical and research records may overlap**

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- Informed consent
- Records of use of test articles
- Case histories
  - Clinical observations
  - Medical care provided
  - Treatment of research-related injury
- Investigator reports
  - Adverse events
  - Reports of individual subjects

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**Recommended Approach**

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- Review of Relevant Regulation
  - What must you do?
- Review of Relevant Guidance
  - What should or could you do?
- Review of Current Practice
  - What are you doing now?

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**Overview of Approach**

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- Outline the parameters of the medical record and research record to guide your decision-making.
- Determine what the contents of the research record must and should be.

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## Overview of the Approach Roadmap to a Record

- Look at each document separately to ask:
  - Where should various documents be maintained (medical record, research record, both)?
  - For overlapping documents, what form should the document take for each record(original, copy)?
- Considerations
  - What is the document?
  - What mechanisms will optimize patient care?
  - Is there a regulatory requirement directing a certain result?
  - Is there guidance suggesting a certain result?
  - What is the preference of the institution?
  - What are the pros/cons to different results?

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## Example Informed Consent

- Regulation
  - 21 CFR §50.27 (human subject protection regulations) specifically requires documentation of the subject's consent and that a copy of such documentation be provided to the subject.
  - However, this regulation does not specifically require that the original informed consent form be maintained in any particular record.

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## Example Informed Consent

- Guidance
  - GCP §4.8 (Informed Consent of Trial Subjects) requires consent of the research subject (or legally authorized representative).
  - GCP §4.9 (Records and Reports) Investigator should maintain the trial documents as specified in "Essential Documents for the Conduct of a Clinical Trial"
  - GCP §8.2 (Essential Documents for the Conduct of a Clinical Trial) requires that information given to the trial subject be located in the files of the Investigator/Institution as well as the files of the Sponsor.
  - While informed consent is clearly required and should be documented for liability purposes, there is no clear requirement to have the original in any particular record.

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## Example Informed Consent

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- Guidance
  - Joint Commission Standards
    - RI.2.40 Informed consent is obtained.
    - RI.2.180 The hospital protects research subjects and respects their rights during research, investigation, and clinical trials involving human subjects.
    - IM.6.20 Medical records contain, as applicable, the following information: evidence of informed consent when required by hospital policy. (Elements of Performance (3))
- It appears that this standard applies to the informed consent obtained from patients for services performed at the health system, not the research informed consent form approved by the IRB.

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## Other Documents to Consider

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- Test Results
- Progress Notes
- Drug Data (amount, frequency, administration method, etc.)
- Device Data
- Adverse Event Reports/Data
- Should there be a rule that CRFs are not to be used as source documents?

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## Electronic Environment

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- As more and more institutions transition to electronic formats for their research and medical records, there should be a coordinated approach to contents of these records to ensure that the organization is attending to its most significant concerns.
- The electronic environment presents greater efficiencies, but also higher expectations.

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**Notification of research participation**

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- In most clinical trials, clinicians not involved in the research should know about research participation
  - Awareness of potential side effects
  - Drug interactions
  - Where to call for more information

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**Non-notification of research participation**

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- In some clinical trials, clinicians should not know about research participation
  - Trials related to specific sensitive or protected topics (e.g., psychiatric treatment)
  - Risks of not knowing are outweighed by risk of confidentiality issues

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**Recommended practice**

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- Have a process to identify subjects in a clinical trial on a routine basis
  - E.g., similar system to electronic alert or paper alerts for medication allergies
- Have a process to determine whether for specific clinical trials the alert system should not be used
- Look at systems used in Veteran Affairs hospitals for an example

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## Developing a Project

- Organize a Steering Committee to include representative stake holders and decision-makers.
- Prepare an overview of the regulatory requirements and the various guidance requirements for each record (e.g., Medicare Conditions of Participation for medical record and Good Clinical Practice standards for research record) to provide both a framework and the leeway available for decisions.
- Interview appropriate decision-makers to provide input.
- Facilitate a debriefing session with recommendations that considers the needs of the patients, the researchers, the care-givers, and the institutions.
- Develop a work plan



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## Benefits

- **Benefits for Research Operations**
  - Establish clarity and conformity throughout the research community.
  - Ensure privacy for the research subject, research sponsor, and research staff
- **Benefits for Clinical Operations**
  - Patient Safety and Risk Management
  - Defined process for location of research information that affects treatment.
- **Compliance & Operations**
  - Consistent and clear standards for regulatory compliance.
  - Increased efficiency in Health Information Management Departments.
- **Benefits for Subjects and Patients**
  - Enhanced availability of medical information.
  - Enhances communication between investigators and non-investigators.



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## What Can We Take Home?

- Good custodial practices must be in place regardless.
- There is considerable flexibility in the current regulatory environment that allows determinations that are in the best interests of the constituents (patients, researchers, clinicians, administrators).
- In a flexible environment, work to ensure that uncertainty does not breed chaos.
- Have a roadmap to guide your decision-making that considers the various constituents.



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**Follow Up**

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