


**RESEARCH  
Compliance  
Conference**

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**Quality Improvement or Human Subjects Research?  
A Glimpse at the Gray Areas**

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**I. Why Should I Care About The Gray Areas?**

Because the government does...

- Pay for performance
- Hospital Compare
- Quality Improvement Organizations
- “Never Events”

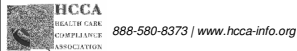
And because we are seeing a new climate of quality improvement and a desire and need to educate the healthcare community about these efforts.



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## II. The Johns Hopkins vs. OHRP Saga

- December 30, 2007: Op-ed appears in the NY Times criticizing the OHRP's decision to shut down a JHU checklist program implemented in Michigan that aimed to decrease the rates of hospital infection
  - Shut down after series of letters between OHRP and JHU in which JHU argued the program was exempt from IRB approval because it was a quality improvement (QI) initiative, rather than "research"
  - OHRP noted that quality improvement activities can also be "research," and cited a need for *IRB approval at every participating hospital and explicit written permission from every provider AND patient* to use checklist (July 19, 2007 & November 6, 2007 letters from OHRP)
  - November 6, 2007 letter went so far as to suggest QI studies that included retrospective reviews might be considered "research."



## The Johns Hopkins vs. OHRP Saga (cont'd)

- Upon hearing of this, many institutions stop QI initiatives or send them through the IRB approval process:
  - Atul Gawande, author of the NY Times article, describes a Nigerian physician learning statistics in a Harvard Public Health School class. "As a class project, he came to me for mentorship in looking at the patterns of his hospital's surgical death and complication rates... Given the ruling against Johns Hopkins, however, we were advised (when I stupidly inquired) that he could NOT do this research work without submission to an IRB – likely at both Harvard and at each institution. It's hard to see how this ruling could mean otherwise. But this is a 4-week class. The result: the project was dropped. That can't be good for patients."
- January 15, 2008: After numerous inquiries about the Op-Ed, OHRP releases a statement defending its decision:
  - *"As stated above, the regulations do not apply when institutions are only implementing practices to improve the quality of care. At the same time, if institutions are planning research activities examining the effectiveness of interventions to improve the quality of care, then the regulatory protections are important to protect the rights and welfare of human research subjects..."*



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*"The only solution I can see is to hold a series of long and costly hearings in order to put off finding a solution."*

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### The Johns Hopkins vs. OHRP Saga (cont'd)

- Grass roots opposition campaign from researchers, institutions, patients, etc. follows...
- February 15, 2008: OHRP reverses decision and releases statement that Michigan hospitals can continue implementing the checklist to reduce the rate of catheter-related infections in ICUs without falling under regulations governing human subjects research
  - **"We do not want to stand in the way of quality improvement activities that pose minimal risks to subjects,"** said Dr. Ivor Pritchard, acting director of OHRP. **"HHS regulations provide great flexibility and should not have inhibited this activity. The regulations are designed to protect human subjects."**

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### **Even Though OHRP Deemed The Program QI...**

OHRP mentions in its determination:

- We note that the human subjects research activities described in the initial grant and IRB applications, as well as similar activities, would likely have been eligible for review by the IRB in an expedited manner.
- We note that the human subjects research activities described in the initial grant and IRB applications, as well as similar activities, would likely have been eligible for waiver of informed consent.

### **III. Key Question**

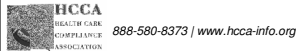
If studies geared toward the reduction of healthcare risks and the improvement of public health are undertaken, what parts, if any, involve human subject research?

## **IV. Regulation of Research**

### **A. Office for Human Research Protections (OHRP)**

- Conducts investigations
- Reviews assurances
- IRB registration and guidance

see [www.hhs.gov/ohrp](http://www.hhs.gov/ohrp)



## **Regulation of Research (cont'd)**

### **B. Research**

The systemic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

~ 45 C.F.R. § 46.102(d)



## Regulation of Research (cont'd)

### C. Human Subject

Living individual about whom an investigator (whether professional or student) conducting research obtains

- (1) data through intervention or interaction with the individual, or
- (2) identifiable private information.

~ 45 C.F.R. § 46.102(f)

## Regulation of Research (cont'd)

### D. "Research" Within HIPAA

- Defined as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (45 C.F.R. 164.501).
- Very similar to the Common Rule definition.
- Important because HIPAA requires
  - authorization from patients (45 C.F.R. 164.508) or
  - a waiver from the IRB/Privacy Board (See 45 CFR 164.512(i)(1)(i))

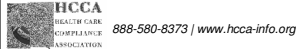
for uses and disclosures of protected health information (PHI) for "research" purposes

- Note: A covered entity may always use or disclose for research purposes health information which has been de-identified (in accordance with 45 CFR 164.502(d), and 164.514(a)-(c) of the Rule) without regard to the provisions above.

## Regulation of Research (cont'd)

### E. The Common Rule: 45 C.F.R. Part 46

- Applies to all research involving human subjects conducted or supported or otherwise subject to regulation by any federal department or agency.
- Requirements:
  - IRB review and oversight.
  - Informed consent.
  - Note: Even if privately funded, is there an Institutional Assurance or is the research subject to U.S. Food and Drug Administration requirements?
    - Institution may have agreed to comply with human subjects research regulations for ALL studies involving humans
    - Research may involve drug or device subject to clinical investigation requirements imposed by FDA regulations under the Federal Food, Drug, and Cosmetic Act.



## Regulation of Research (cont'd)

### F. IRB Oversight Functions

- Initial and continuing review of research at intervals appropriate to the degree of risk.
- Documentation of informed consent or waiver of documentation.
- Authority to review and approve or to require modifications in all research activities.
- Determining which projects require more than annual review and which projects need third party verification that no changes have occurred since last IRB review.
- Ensuring prompt reporting to IRB of changes in research activity.
- Ensuring that changes to approved research projects not be implemented without IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects.

~ 45 C.F.R. 46.109

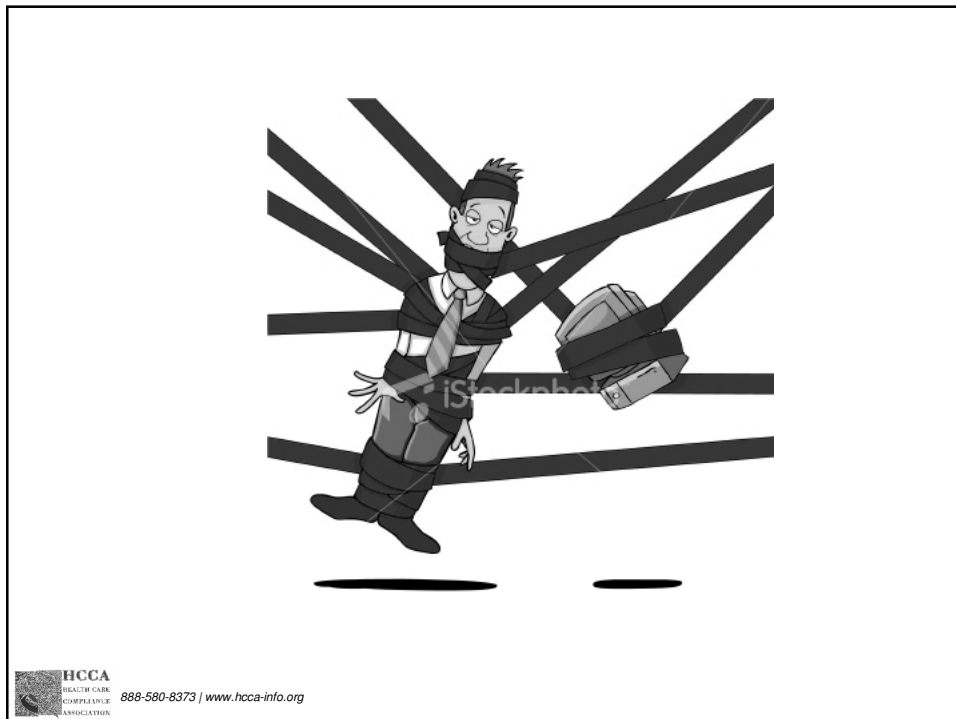


## Regulation of Research (cont'd)

### G. Expedited IRB Review

- Available if research involves no more than minimal risk, and for minor changes in previously approved research
  - Can obtain IRB approval more quickly than full review
  - Often used when the prospective collection of data is contemplated.

~ 45 C.F.R. 46.101



## V. “Quality Improvement” Activities

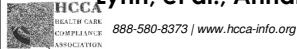
### A. Overview

*“[A] systematic pattern of actions that is constantly optimizing productivity, communication, and value within an organization in order to achieve the aim of measuring the attributes, properties, and characteristics of a product/service in the context of the expectations and needs of customers and users of that product.”*

~ Institute of Medicine

*“The group defined QI as the systematic, data-guided activities designed to bring about immediate improvements in health care delivery in a particular setting.”*

~ The Ethics of Using Quality Improvement Methods in Health Care,  
Lynn, et al., *Annals*, May 2007, Vol. 146, No. 9, 666-674.



## “Quality Improvement” Activities (cont’d)

### B. Quality Improvement Within HIPAA

- Defined as part of “Health Care Operations.”
- “Conducting quality assessment and improvement activities, including outcomes evaluation and development of clinical guidelines, provided that the obtaining of generalizable knowledge is not the primary purpose of any studies resulting from such activities; population-based activities relating to improving health or reducing health care costs, protocol development, case management and care coordination, contacting of health care providers and patients with information about treatment alternatives; and related functions that do not include treatment;” (45 C.F.R. 164.501).
- Important because HIPAA requires no permission from patients for uses and disclosures of protected health information (PHI) for “treatment, payment or health care operations (TPO)” (45 C.F.R. 164.502(a)(ii)), *so entity need not obtain authorization from patients for information used in QI activities under this law!*



## “Quality Improvement” Activities (cont’d)

### C. QI Purposes

- Improve quality.
- Usually for internal auditing purpose only.
- No infringement on patient privacy.
- Little to no risk to subjects/participants.
- Little to no risk to faculty or staff
  - But...what if results are published?

## “Quality Improvement” Activities (cont’d)

### D. Quality Improvement vs. Research

- Issue is regularly debated due to little guidance available.
- Recent OHRP decision may help, but there are still gray areas
  - Why is the program being implemented?
  - What is the level of risk to patients?
  - Who are the subjects? Are they identifiable?
  - Where is information being disseminated?
- Note: IRBs may claim oversight of any QI with intent to publish.
- What happens when a program may be *both* QI and Research?

## QI vs. Research: The Differences

|                        | Quality Improvement   | Research  |
|------------------------|---|---|
| <b>Goal</b>            | Improve patient care, clinical program or service: identify specific services, protocols, clinical practices, or clinical processes/ outcomes for improvement                           | Advance general knowledge in academic, scientific or professional community: generate, evaluate or confirm explanatory theory or conclusion and invite critical appraisal by peers through presentation/debate in public forums |
| <b>Lit Review</b>      | Available literature and comparative data, or clinical programs, practices or protocol at other institutions to design improvement plan; do not plan full scientific literature reviews | Organized review of relevant literature   |
| <b>Research design</b> | Established quality improvement methods aimed at producing change.  | Leads to scientifically valid findings (controlled clinical study, including a valid protocol and statistical analyses)   |
| <b>Benefit</b>         | Most patients who participate are expected to benefit from the knowledge gained   | Many patients/subjects will NOT benefit from the knowledge gained   |
| <b>Risk</b>            | Imposes very little or no risk or burden on patients  | May impose risk or burden on patients   |

## The Confusion Is In The Similarities...

### **Both:**

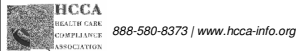
- Involve human participants.
- Are concerned with investigation and examination.
- Are processes in which inquiry generates questions that data collection are designed to answer.
- Propose a set of acceptance criteria and outcome measures that will support proposal.
- Involve study solutions.
- Require critical evaluation of data.
- Synthesize data into a well-structured document.

## **VI. So Who Should Determine Whether IRB Approval Is Required?**

### **A. There is no consistent approach. Institutions may:**

- Have a QI registration site; surveillance by IRB or others.
- Have a Quality Improvement or Quality Improvement Research Committee that routinely kicks the program back to IRB for review.
- Requires an IRB to approve all studies, regardless.
- Allow researchers to conduct QI without any oversight based on:
  - Institutional P&Ps currently in place
  - Colleague's experiences
  - Own past experiences with QI and/or the IRB.

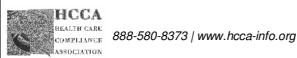
### **B. Consider establishing a QI Committee with real authority.**



## **So Who Should Determine Whether IRB Approval Is Required? (cont'd)**

### **C. Roles of the QI Committee May Include:**

- Assuring that the data obtained through QI activities are analyzed, recommendations made, and appropriate follow up of problem resolution is done;
- Incorporating internal and external sources of benchmarking data and JCAHO's 2003 National Patient Safety Goals;
- Reporting on ongoing findings, studies, recommendations, and trends to the Governing Board and Medical Staff at appropriate intervals; and reporting to hospital staff as appropriate;



### So Who Should Determine Whether IRB Approval Is Required? (cont'd)

- Identifying educational needs and assuring that staff education for quality improvement takes place;
- Appointing subcommittees or teams to work on specific issues, as necessary;
- Assuring that the necessary resources are available;
- Coordinating activities with third parties.

### VII. QI Research May Be Exempt From IRB Review

- Research conducted in established or commonly accepted educational settings, involving normal educational practice, such as
  - ✓ Research on regular and special education instruction strategies, or
  - ✓ Research on the effectiveness or **comparison among instructional techniques**, curricula or classroom management.

~ 45 C.F.R. 46.110

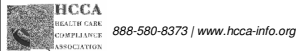
## QI Research May Be Exempt From IRB Review (cont'd)

- Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior, **unless information obtained is recorded in such a manner that human subjects can be identified.**

~ 45 C.F.R. 46.101(b)(2)

- Research involving the collection or study of existing data, documents, records . . . **If these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified.**

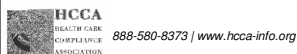
~ 45 C.F.R. 46.101(b)(4)



## *HYPOTHETICAL*

### **Oversight of Physician Care for Diabetic Patients**

- Purpose of the study is to assess effectiveness of educational interventions and identify future needs.
- Hospital wants to improve physicians' care of diabetic patients by measuring practice performance against national standard protocols.



- Hospital conducts grand rounds session on national guidelines for diabetic care/measurements.
- To determine the effectiveness of the training, the hospital:
  - ▣ Reviews charts for patients pre- and post-training
  - ▣ No identifiers in the charts.

### **Is It QI Or Research Or Both?**

Back to our definitions:

“... some data collection and analysis activities in health services area are not intended to generate scientific knowledge, but rather are used as a management tool to improve the provision of services to a specific health care population. ...”

~ **National Bioethics Advisory Commission (NBAC) (Dec. 2000)**

**OR**

The systemic investigation, including development and/or evaluation, designed to develop or contribute to generalizable knowledge.

~ **45 C.F.R. § 46.102(d)**

## Considerations

### Use of Patient Information

#### HIPAA

- No PHI removed from site.
- Or only de-identified information used.

#### Is it research?

- Plans to publish? What if no initial plans to publish and this changes later?
- If it is research, who are human subjects? Patient? Doctor? Doctor's office staff who implement program?

## Process

- Does IRB require review regardless of investigator's categorization?
- Is there a QI Committee in existence to review?
- If QI, then....
- If Research, then....
  - ▣ Can IRB Expedite?
  - ▣ Is it exempt under 45 CFR 46.101(b)(1), (b)(2), or (b)(4)?
  - ▣ If exempt, are there other requirements? (e.g. institution may require approval/agreement).

## Other Considerations

What do your policies and procedures for IRBs state?

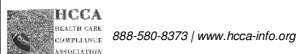
- Must IRB review and agree that project is QI/exempt?
- Note: IRBs may insist on review given regulatory oversight of the OHRP, especially absent any other system(s) of ethical oversight (e.g. a QI Committee).



## ***IRB Review / Now What?***

If IRB review deemed necessary

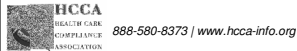
- Request expedited review – 46 C.F.R. § 110
- Be sure to inform IRB when project is completed
- HIPAA?
  - Authorization from Human Subject – the physician/patient information as well
  - Privacy Board Waiver for Authorization (See, 45 C.F.R. § 164.512).



### ***Deemed QI / Now What?***

If QI Committee / IRB / QI Process determines that the project constitutes QI, then pay particular attention to:

- Collection of data
- Subjects
- Dissemination of data
- Any expansion of the project.



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