

# OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

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## A MESSAGE FROM THE DIRECTOR OF THE OFFICE FOR THE PROTECTION OF RESEARCH SUBJECTS

As summer nears its end, OPRS continues to work toward the AAHRPP application submission and accreditation. "Still?" you ask. Yes! As OPRS is comprised of many levels and layers, all these elements are under scrutiny and open to change. New policies mean new procedures. New procedures mean training for IRB members, OPRS staff and Investigators.



James H. Fischer  
Director, OPRS

Eventually, when it comes down to the AAHRPP site visit, any UIC investigator or coordinator could be called for an interview. To help make those interviews successful, Charles Hoehne has taken on the role of Assistant Director of Education and Training. He will be rolling out training programs in September in anticipation of the accreditation site visits in the Fall at JBVAMC and Winter at UIC.

Our policies and forms are being updated. Within the year, our manual will be replaced by an on-line manual that is searchable for quick reference.

OPRS is currently testing software for on-line submissions. Testing is a lengthy process, but the outcome of on-line submissions will be worth the effort.

In our further efforts to streamline submissions, Medical Record Reviews may now be submitted for exempt review when identifiers will not be recorded: see page 3.

Please know that your feedback is always welcomed and appreciated.

Sincerely,

Jim Fischer  
Director

### OPRS Newsletter Publication Schedule:

Oct/Nov    Dec/Jan    Feb/March



## NEWS FOR INVESTIGATORS

### IMPORTANT DATE FOR CLINICAL TRIALS

September 27, 2008 is the deadline imposed by the FDA Amendments Act of 2007 for two important requirements.

#### What are the requirements?

1) Sponsors or designated responsible parties are required to submit information into the results database of ClinicalTrials.gov within one year of study completion or within 30 days of FDA product approval. This requirement applies to affected trials that were on-going as of September 27, 2007 or started after that date. [Please note: phase 1 trials and small feasibility studies of devices are excluded from this requirement.]

2) Sponsors or designated responsible parties are required to register trials that were ongoing as of 9/27/2007 and **do not** involve a serious or life threatening disease or condition.

#### Who does this apply to?

This requirement applies to trials that were on-going as of September 27, 2007 or that have started after the date. Phase I trials and small feasibility studies of devices are excluded from this requirement.

#### When must a trial be registered?

The OVCR previously notified investigators about the need to register clinical trials initiated after September 27, 2007, or that **are** ongoing as of December 26, 2007 by the later of December 26, 2007 or 21 days after the first patient is enrolled. Existing ICMJE policy requires that the Principal Investigator register the trial before beginning new subject enrollment.

The new deadline of September 27, 2008 is for trials that **were** ongoing as of September 27, 2007 and do **not** involve a serious or life threatening disease or condition.

#### Who does this NOT apply to?

Trials that **were** ongoing as of September 27, 2007, involved a serious or life threatening disease or condition, and were completed by December 26, 2007, are not subject to the FDAAA requirements, though they are subject to pre-existing FDAMA requirements. Ongoing in this context means a trial had one or more subjects enrolled, but had not examined the final subject or provided the final subject an intervention for the purposes of final collection of data for the primary outcome as of September 27, 2007.

For trials already registered in compliance with ICMJE policy, minimal additional data is required to meet the FDA Amendments Act of 2007 requirements. Additionally, once registered, the data should be updated during the course of the trial. The UIC Principal Investigator should work collaboratively with sponsors of multi-site trials to avoid duplication of efforts.

*Remember, September 27, 2008 is the deadline imposed by the FDA Amendments Act of 2007 for two important requirements.*

## IMPORTANT DATE FOR CLINICAL TRIALS CONTINUED FROM PAGE 2

For additional information related to clinical registration requirements and whether you should register your clinical research study, please refer to UIC guidance on this topic - <http://tigger.uic.edu/depts/ovcr/research/protocolreview/irb/policies/0268.pdf> or contact Dr. Clyde Wheeler, Associate Director for Research Compliance at [cwheeler@uic.edu](mailto:cwheeler@uic.edu) or 312-355-0159.

For further information regarding this requirement, please refer to the ClinicalTrials.gov registration process system website - <http://prsinfo.clinicaltrials.gov/>.

Please be reminded that the deadline for two requirements of the FDA Amendments Act of 2007 is September 27, 2008.

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## New Forms and Policies for Researchers

### EXPANSION IN TYPES OF RESEARCH ELIGIBLE FOR A CLAIM OF EXEMPTION

Previous to the implementation of the Health Insurance Portability and Accountability Act (HIPAA) of 1996, an investigator could submit research involving the retrospective analysis of health (i.e., medical) records for exempt review. After HIPAA, this was no longer true.

OPRS has now revised the Exemption Policy and through this revision Retrospective Chart Reviews are eligible with some restrictions for review as research in exempt category 4.

If the individuals completing the chart review are not recording any of the 18 HIPAA identifiers (dates of service and geographic codes less specific than street address are allowable), the research may qualify for exempt review. A request for a waiver of HIPAA authorization is still needed as PHI is being accessed. However, this request can now be done directly on the Claim of Exemption application, and there is no need to submit a separate appendix.

Excerpt from the OPRS revised policy on Exempt Research:

Category 4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, provided:

1. These sources are publicly available, or
2. The information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects. [45 CFR 46.101(b)(4), 38 CFR 16.102(b)(4)]

Continued on page 4

## EXPANSION IN TYPES OF RESEARCH ELIGIBLE FOR A CLAIM OF EXEMPTION CONTINUED FROM PAGE 3

### 3. Additional guidance:

- a. Publicly available means that the general public can obtain the data/biological specimens. Sources are not considered publicly available if access to the data/specimens is limited to researchers.
- b. All material that will be used to conduct the research must exist at the time the research is proposed; no on-going or prospective collection of material is allowed.
- c. Under this exemption, an investigator may review identifiable records, but must record information in the research record in a non-identifiable manner. Moreover, the data must be permanently and completely de-linked at the time of extraction (that is, the investigator will not have any further access to the identifiable records).
- d. Exemption from IRB review does not also represent an exemption from HIPAA requirements for authorization or waiver of authorization when the research involves the use or access of PHI.
- e. Research involving the retrospective analysis of medical records qualifies for exemption category 4 when the information extracted from the chart and recorded in the research record does not contain any identifiers, including most of the 18 HIPAA elements (dates of service and geographic codes less specific than street address are allowable), codes derived from any of the HIPAA elements or codes linked to identifiers. The investigator must also receive a waiver of HIPAA authorization from the IRB, as looking at medical records is considered accessing PHI regardless of whether or not identifiers are being recorded.

Research involving the analysis of medical record data does not qualify for a claim of exemption if:

- prospective rather retrospective data is collected,
- any of the 18 HIPAA elements, except dates of service and geographic codes less specific than street address, or combinations of the elements are entered into the research records, or
- data contained in the research records are linkable in any way to the identity of the subjects.

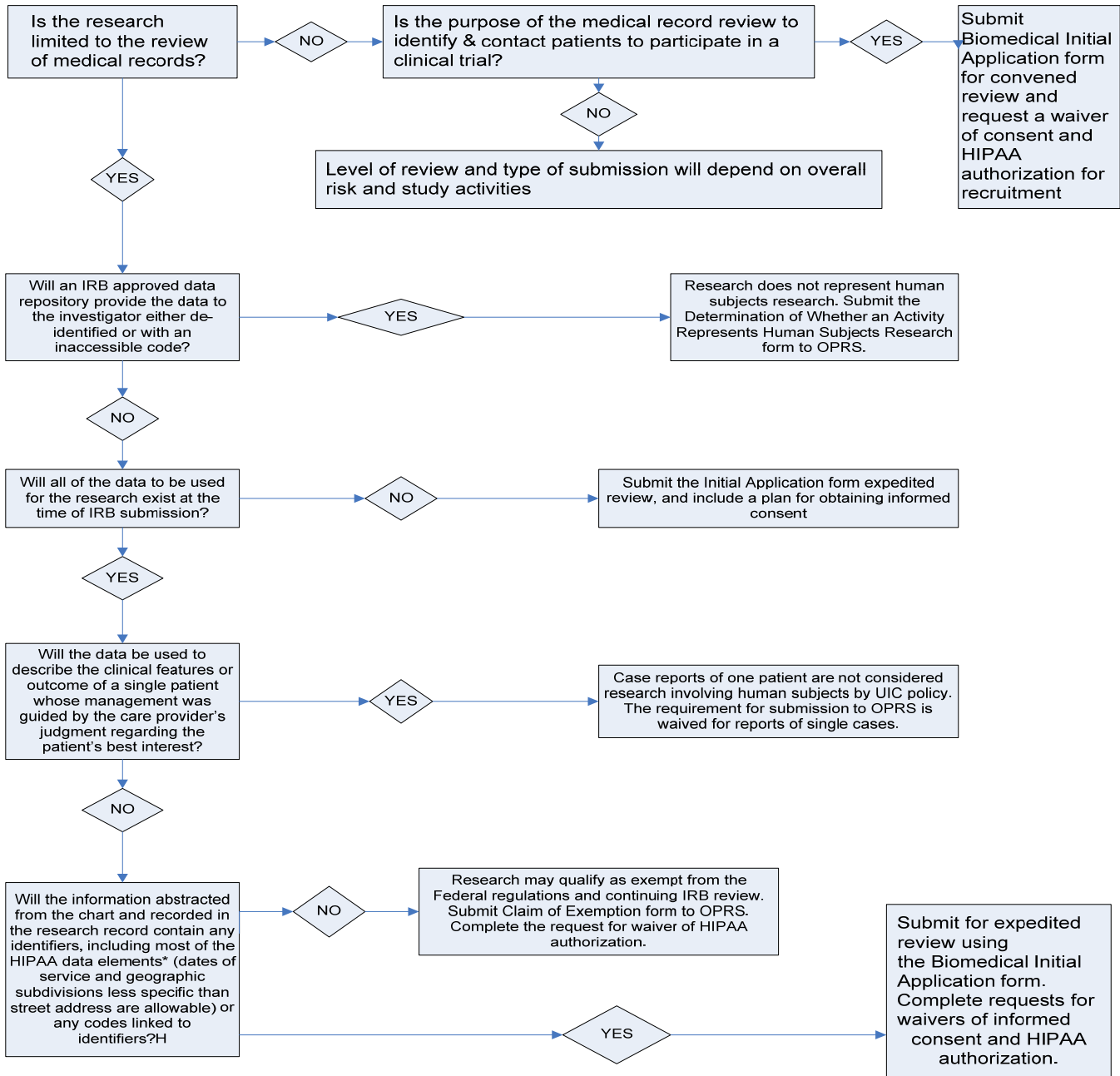
Use of the exemption process for research involving the retrospective analyses of health (medical) records data offers several advantages including a more concise application form, shorter turn around times for review and no requirement for annual continuing review.

For more information/clarification, please see the Decision Tree for Submitting Medical Record Review Research to UIC OPRS/IRB located on page 5 of this newsletter.

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**DECISION TREE FOR SUBMITTING MEDICAL RECORD REVIEW RESEARCH TO UIC OPRS/IRB**

**Decision Tree for Submitting Medical Record Review Research to UIC OPRS/IRB**

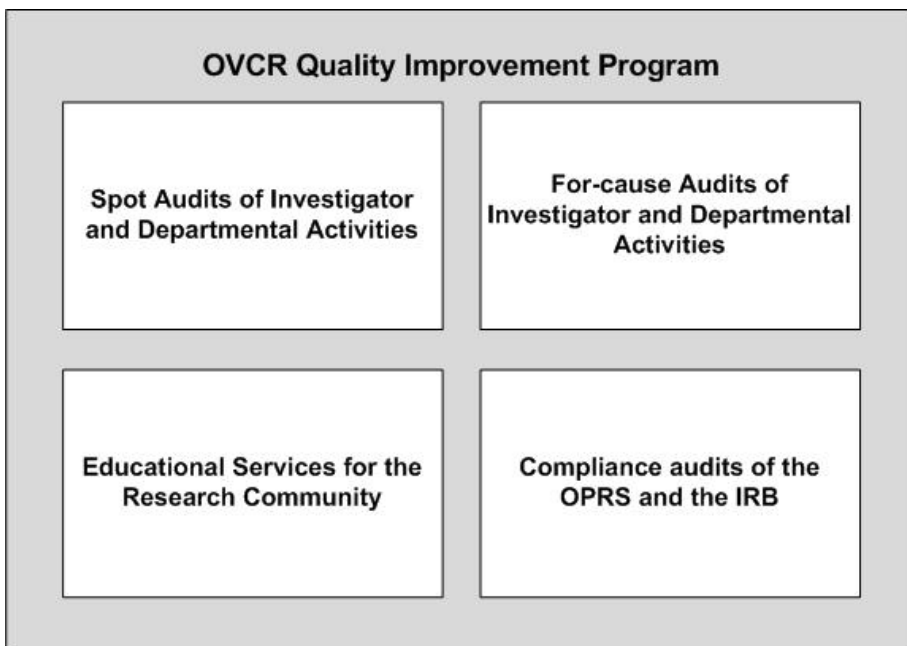


\* 1). names, 2). geographic subdivisions as specific as street address, 3). birth date and date of death, 4). telephone numbers, 5). fax numbers, 6). vehicle identifiers and serial numbers, including license plate #, 7). electronic mail addresses, 8). device identifiers and serial numbers, 9). social security numbers, 10). web Universal Resource Locators (URLs), 11). medical record numbers, 12). Internet Protocol (IP) address numbers, 13). health plan beneficiary numbers, 14). biometric identifiers, including finger and voice prints, 15). account number, 16). full face photographic images and any comparable images, 17). certificate/license numbers, or 18). any other unique identifying number, characteristic, or code.  
 H This question refers only to what is being recorded in the research record. Receiving and viewing medical record data with identifiers, including PHI, or preparing a list of records for retrieving information is acceptable; however, the information retained in the permanent research record must be de-identified. Investigator must be a part of the covered entity.

## New Forms and Policies for Researchers

### OVCR QUALITY IMPROVEMENT PROGRAM (QIP)

The OVCR has implemented a plan to assess and improve the quality, effectiveness, and compliance within the Human Subject Protections Program (HSPP). As part of its mission, the OVCR Quality Improvement Program (QIP) has developed a four-pronged approach to monitor and promote protections of human subjects and compliance with institutional policies, federal regulations, accreditation requirements, and applicable policies and directives governing human subjects research.



*Improving the quality, effectiveness, and compliance within the Human Subjects Protections Program.*

The OVCR QIP is overseen by Dr. Clyde Wheeler, Associate Director for Research Compliance, the former Associate Director of OPRS. Ms. Patricia Fischer, RN, CCRP, will assist in the educational and auditing activities. For more information on the QIP, please review the HSPP policy [OVCR \*Quality Improvement Program - Monitoring and Auditing\*](#) or contact Dr. Wheeler at [cwheeler@uic.edu](mailto:cwheeler@uic.edu).





## CONTINUING EDUCATION OPPORTUNITIES FOR INVESTIGATORS

OPRS requires that investigators and key research personnel take initial training before conducting research. Training also needs to be updated every two years with two Continuing Education credits.

### Need CE Credit?

- Does your department hold lectures that would be appropriate for Human Subjects Research Education credit?
- Have you heard of a program that you would like to see offered for Human Subjects Research Education credit?
- Will you be attending a conference that would apply to Human Subjects Research?

### Upcoming Department Lecture Available for HSPP Credit:

#### Breaking the Wall of Science: How Disclosure of Medical Mistakes Can Change the Culture of Medical Care and Improve Patient Safety

Speaker: Rosemary Gibson, MSc  
Senior Program Officer, Robert Wood Johnson Foundation

August 12 th  
12:00–1:00 p.m.  
1740 W. Taylor, Room 1130/1135  
1 credit

## INITIAL TRAINING IN HUMAN SUBJECTS PROTECTION

Offered throughout the year, Investigator 101 covers the history of research ethics, ethical principles and The Belmont Report, development and application of the federal regulations for human subject protections, UIC's Federal-wide assurance and policies, criteria for review of research, informed consent process, research protocol review processes, and the application of the ethical principles and regulatory requirements.

### UIC Investigator 101 Training Calendar

Friday, August 22, 2008	1:00 PM - 4:00 PM	SCE, Room 713
Tuesday, September 9, 2008	1:00 PM - 4:00 PM	MBRB Auditorium
Tuesday, November 18, 2008	1:00 PM - 4:00 PM	MBRB Auditorium

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