

IRB Regulations 101

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Workshop objectives

- 1** Describe how federal regulations define human subject research
- 2** Identify what regulations require of researchers and IRBs
- 3** Discuss how to facilitate researcher-IRB communication

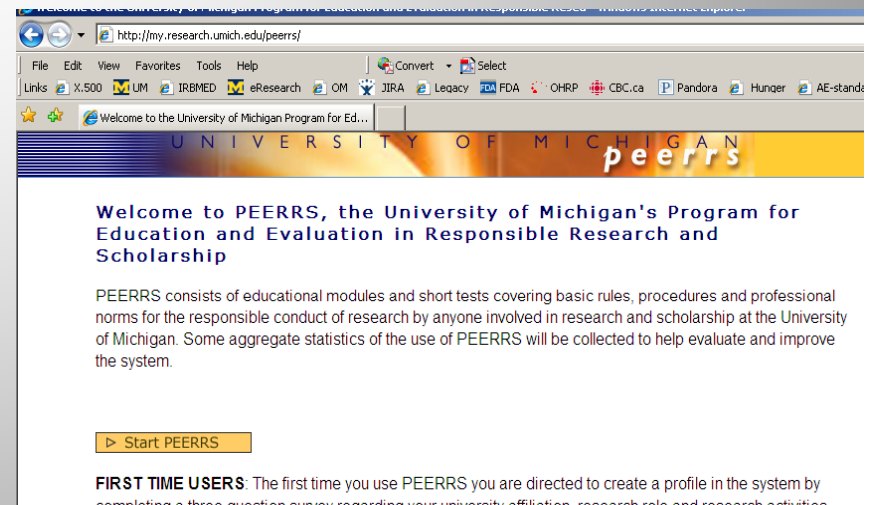
Regulations Regarding Human Subject Research

- Food and Drug Administration (FDA)
 - Part 21 of the Code of Federal Regulations (CFR), mainly sections 50, 56, 312, and 812
- Office of Human Research Protections (OHRP)
 - Part 45 of the CFR, section 46 (Common Rule and Subparts B, C, & D)
- Office of Civil Rights (OCR)
 - Part 45 of the CFR, section 164

UM Policies

- Anyone who has access to identifiable private information for research must complete the “PEERRS” human subjects module.
 - IRB approval is contingent upon *key personnel* completing the module.
 - The *principal investigator is responsible* for assuring all others to which the policy applies are compliant.

<http://my.research.umich.edu/peerrs/>



The screenshot shows a web browser window with the address bar displaying <http://my.research.umich.edu/peerrs/>. The browser's menu bar includes File, Edit, View, Favorites, Tools, and Help. The address bar also shows a search engine icon and a 'Convert' button. The browser's toolbar includes a search bar and several icons for links, including X.500, UM, IRBMED, eResearch, OM, JIRA, Legacy, FDA, OHRP, CBC.ca, Pandora, Hunger, and AE-stand. The main content area features a yellow banner with the text 'UNIVERSITY OF MICHIGAN' and 'peerrs' in a stylized font. Below the banner, the text reads: 'Welcome to PEERRS, the University of Michigan's Program for Education and Evaluation in Responsible Research and Scholarship'. A paragraph follows: 'PEERRS consists of educational modules and short tests covering basic rules, procedures and professional norms for the responsible conduct of research by anyone involved in research and scholarship at the University of Michigan. Some aggregate statistics of the use of PEERRS will be collected to help evaluate and improve the system.' At the bottom, there is a yellow button labeled 'Start PEERRS' and a section for 'FIRST TIME USERS' which states: 'The first time you use PEERRS you are directed to create a profile in the system by completing a three question survey regarding your university affiliation, research role and research activities.'

UM Policies

UM Human Research Protection Program *Operations Manual* <http://www.hrpp.umich.edu/om/>

The screenshot shows a Windows Internet Explorer browser window displaying the University of Michigan HRPP Operations Manual website. The browser's address bar shows the URL <http://www.hrpp.umich.edu/om/>. The website header features the University of Michigan logo and the text "RESEARCH". Below the header, the main content area is titled "Human Research Protection Program (HRPP)" and includes the text "Office of the Vice President for Research" and a link to the "Operations Manual (Link to Full Version)". A descriptive paragraph states: "The HRPP Operations Manual (OM) is designed to illuminate the system and its overarching governing rules and to serve as a reference for investigators, IRBs, administrators, and others." Below this, a section titled "Part 1: Introduction, Purpose and Ethical Principles" describes the mission of the HRPP and lists six items: I. Mission Statement and Organizational Summary, II. Scope of Human Research at the University (with sub-items A. Types of Human Research Conducted and B. Categories of Participants), III. Institutional Authority, IV. Limitation on Institutional Authority, V. Protection from Undue Influence, and VI. Ethical Principles. On the right side of the page, there are three sections: "QUICK LINKS" with links to HRPP Home, eResearch, OHRP, and FWA; "MAJOR COMPONENTS" with links to IRBs, IBC, COI-OVPR, COI-Med, RPC, IDS, UMCCC, GCRC, BEU, and TPS; and "OTHER KEY UNITS" with links to MICH and OHRCR. At the bottom of the right sidebar, there is a "POLICIES" section with links to the Operations Manual, Guidelines & Regulations, and Human Research SRG.

Operations Manual - Windows Internet Explorer
http://www.hrpp.umich.edu/om/

File Edit View Favorites Tools Help
Links X.500 UM IRBMED eResearch OM JIRA Legacy FDA FDA OHRP CBC.ca Pandora Hunger AE-standard Dev Facebook CTools

Operations Manual

UNIVERSITY OF MICHIGAN
RESEARCH

Human Research Protection Program (HRPP)
Office of the Vice President for Research
Operations Manual
(Link to Full Version)

The HRPP Operations Manual (OM) is designed to illuminate the system and its overarching governing rules and to serve as a reference for investigators, IRBs, administrators, and others.

Part 1: Introduction, Purpose and Ethical Principles - describes the mission of the University of Michigan, the purpose of the University's Human Research Protection Program (HRPP) and authority under which it operates, and the scope of research conducted at the University. (PDF version)

- I. Mission Statement and Organizational Summary
- II. Scope of Human Research at the University
 - A. Types of Human Research Conducted
 - B. Categories of Participants
- III. Institutional Authority
- IV. Limitation on Institutional Authority
- V. Protection from Undue Influence
- VI. Ethical Principles

QUICK LINKS

- HRPP Home
- eResearch
- OHRP
- FWA

MAJOR COMPONENTS

- IRBs
- IBC
- COI-OVPR
- COI-Med
- RPC
- IDS
- UMCCC
- GCRC
- BEU
- TPS

OTHER KEY UNITS

- MICH
- OHRCR

POLICIES

- Operations Manual
- Guidelines & Regulations
- Human Research SRG

UM Policies

- IRBMED website has additional policies, informed consent & assent forms, and key information.
- Google “IRBMED” or type <http://www.med.umich.edu/irbmed/>

The screenshot displays the IRBMED website interface. At the top left is the University of Michigan Medical School logo. The main header features the text "IRBMED" and four small images of medical professionals. Below the header is a navigation bar with links: "UMMS Home | About UMMS | Education | Research | Patient Care | Community Service". A secondary navigation bar includes links: "eResearch | UM HRPP | Engage | Office of Research | iFeasible".

The main content area is titled "Institutional Review Boards of the University of Michigan Medical School". The text below the title reads: "The five Institutional Review Boards of the University of Michigan Medical School (IRBMED) are charged with the oversight of human subjects research conducted by medical school faculty, students, and staff at any University of Michigan Health System (UMHS) facility or site. The purpose of an IRB is to protect the rights and welfare of human subjects in research. Guiding this process is the application of federal and state laws, university policies, ethical principles; particularly those articulated in the Belmont Report." Below this, it states: "Investigators should not commence research involving human subjects until the IRBMED has approved the study or has determined it is exempt." The text continues with a definition of a "Human Subject" according to federal regulations.

On the left side, there is a vertical navigation menu with the following items: "IRB Home", "Forms", "Informed Consent & Assent Templates", "Guidance", "Education", "About IRB", "Resources", "AE/ORIO/Unanticipated Problems", "IRBMED Members", "Research Participants", "Feedback Form", and "IRBMED".

On the right side, there is a "News" section with two articles. The first article is titled "Fast Track Review of American Reinvestment and Recovery Act (ARRA) Submissions" and discusses IRBMED's response to the economic stimulus plan. The second article is titled "2009 Report on the UM IRBs including turnaround time for review of submissions is now available from the Office of the Vice President for Research. Click here".

What is an IRB?

- “Institutional Review Board”
- An ethical review board required by the federal government at institutions that conduct human subject research
- Minimum of 5 members
- Provides oversight of human subject research (regardless of funding)
- UM has 9 IRBs

IRB-BehavSci



IRB-Health



IRB-Flint



IRB-
Dearborn



Med School



IRBMED

Is this research?



- Standard treatment for a certain kind of benign tumor that's usually found in the femur is to remove the tumor, curette the area, then fill the hole with cement, or cement plus hardware
- An orthopedic surgeon plans to modify this last step with a significant change to the hardware on a patient she thinks might benefit from this innovative approach

Definitions of Research

- **OHRP:** A *systematic* investigation, including research development, testing and evaluation, designed to develop or contribute to *generalizable* knowledge. 45 CFR 46.102 (d)
- **FDA:** Any experiment that involves a test article and one or more human subjects or their specimens . . . the results of which are intended to be submitted to . . . FDA. 21 CFR 56.102 (c) & 21 CFR 812.3 (p)



Is this human subject research?



A retrospective chart review comparing the safety and complication rate of ipsilateral versus contralateral breast reconstruction.

Abstracted data to include:

- | | |
|---|--|
| <ul style="list-style-type: none">▪ County in which patients resides▪ Stage of breast disease▪ Adjuvant therapies▪ Body mass index▪ Tobacco use history | <ul style="list-style-type: none">▪ Other medical problems and surgical history▪ Complications:<ul style="list-style-type: none">■ partial or total flap loss■ hematoma■ Seroma■ abdominal wall herniation |
|---|--|

Definition of 'human subject'

- **FDA:** A human . . . on whose specimen an investigational device is used *or* an individual who is or becomes a participant in research, either as a recipient of the test article or as a control, the results of which are intended to be submitted to the FDA. ²¹

CFR 50.3 (g), 21 CFR 56.102 (e), 21 CFR 812.3 (p)



?

Definition of 'human subject'

- **OHRP:** A living individual about whom an investigator conducting research *obtains* (1) Data through intervention or interaction with the individual, OR (2) Identifiable private information. 45 CFR 46.102 (f)
- **'Obtaining'** includes research use, study, or analysis of identifiable private information or identifiable specimens *already in your possession*.

Definition of 'Identifiable Private Information'

This is data:

- about behavior that occurs when person reasonably expects that no observation or recording is taking place.

OR

- provided for specific purposes by an person which the person expects will not be made public.

AND

- the identity of the subject may readily be ascertained by the investigator.

Definition of 'Coded Information'

- Identifying information that would enable the investigator to ascertain the identity of the subjects has been replaced with a number, letter, or symbol

AND

- A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.

Definition of 'De-Identified Information'

- Identifying information that would enable you to ascertain the identity of the subjects has been replaced with a number, letter, or symbol

AND

- No key to decipher the code exists *or* you do not have access to the key. You cannot link the data with particular subjects.

So . . . is this human subjects research?



- | | |
|--|--|
| <ul style="list-style-type: none">▪ County in which patient resides▪ Stage of breast disease▪ Adjuvant therapies▪ Body mass index▪ Tobacco use history | <ul style="list-style-type: none">▪ Other medical problems and surgical history▪ Complications:<ul style="list-style-type: none">■ partial or total flap loss■ hematoma■ Seroma■ abdominal wall herniation |
|--|--|

It depends on what the data looked like the first time you see it.

What You See and Do	IRB Application
<ul style="list-style-type: none"> <input type="checkbox"/> You receive a coded or de-identified data set <input type="checkbox"/> You have an agreement with the supplier that they will not, under any circumstances, reveal the identity of the subjects to you. <p><i>Important exception:</i> If the supplier of the data is involved in the research, you must complete a Standard Application</p>	<p><i>Optional</i> Not Regulated Application</p>
<ul style="list-style-type: none"> <input type="checkbox"/> You collect <i>only</i> data that existed <i>before</i> receiving your IRB letter <input type="checkbox"/> You see names and/or ID numbers <input type="checkbox"/> You remove all identifiers <input type="checkbox"/> You DO NOT have key, or other means to determine the identity of the subjects 	<p>Exempt Application</p>
<ul style="list-style-type: none"> <input type="checkbox"/> You collect only data that existed <i>before</i> your IRB approval <input type="checkbox"/> You see names and/or ID numbers <input type="checkbox"/> You code the data <input type="checkbox"/> You keep a key to the code 	<p>Secondary Use Application</p>
<ul style="list-style-type: none"> <input type="checkbox"/> You will receive data that is collected <i>after</i> you receive IRB approval <ul style="list-style-type: none"> <input type="checkbox"/> Example: Patient information collected for clinical care <input type="checkbox"/> You see names and/or ID numbers <input type="checkbox"/> You code the data or you keep identifiers (securely maintained) <input type="checkbox"/> You keep a key to a code if you use one 	<p>Standard IRB Application</p>

Involvement of the Person(s) Providing You a Coded Data Set

Involvement includes, but is not limited to:

- Interpretation of data
- Analysis of the data resulting from the coded information or specimens
- Authorship of presentations
- Authorship of manuscripts related to the research.

Call us if you aren't sure!

Is this human subjects research?



Dr. U.M. Smith requests de-identified, to-be-discarded colon biopsy samples to isolate peptides. The purpose of the research is to develop a new diagnostic test for colon cancer.

FDA Definition of a Human Subject

A human . . . *on whose specimen an investigational device is used* or an individual who is or becomes a participant in research, either as a recipient of the test article or as a control, *the results of which are intended to be submitted to the FDA.*

So . . . Is this human subjects research?

Dr. U.M. Smith & her assay research.



Because this involves a device *and* the data will be submitted to the FDA, IRB review and approval is required.

What is an FDA Regulated Device?

Any instrument, apparatus, implement, machine, contrivance, implant, *in vitro reagent* intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.

Definition of Protected Health Information (PHI)

- Information about health that must be 'protected' by the 'covered entity' that collected it .
- Includes medical records AND health information you collect for research purposes.

What about HIPAA?

Does this study include regulated PHI?



- | | |
|--|---|
| <ul style="list-style-type: none">▪ general demographic data—county only▪ stage of breast disease▪ type of cancer▪ adjuvant therapies | <ul style="list-style-type: none">▪ body mass index▪ tobacco use history▪ other medical problems and surgical history▪ complications |
|--|---|



Data Element	De-Identified Data Set ¹	Limited Data Set
Names	Remove	Remove
Address, city and other geographic information smaller than state. <i>3-digit zip code may be included in a de-identified data set for an area where more than 20,000 people live; use "000" if fewer than 20,000 people live there.</i>	Remove	Remove postal address information other than city, town, state or zip code.
All elements of dates (except year); plus age and any date (including year) if age is over 89. <i>Examples: date of birth, date of death, date of admission, date of discharge, date of service.</i>	Remove	May be included.
Telephone, fax numbers; e-mail addresses, web URL addresses, IP addresses.	Remove	Remove
Social security number, medical record number, health plan beneficiary number, any account number, certificate or license number.	Remove	Remove
Vehicle identifiers and serial numbers, including license plate numbers.	Remove	Remove
Device identifiers and serial numbers.	Remove	Remove
Biometric identifiers (e.g., fingerprints; voice prints). <i>DNA is not considered a biometric identifier for purposes of HIPAA.</i>	Remove	Remove
Full-face photographs and any comparable images.	Remove	Remove
Any other unique identifying number, characteristic or code.	Remove ²	May be included. ²⁵

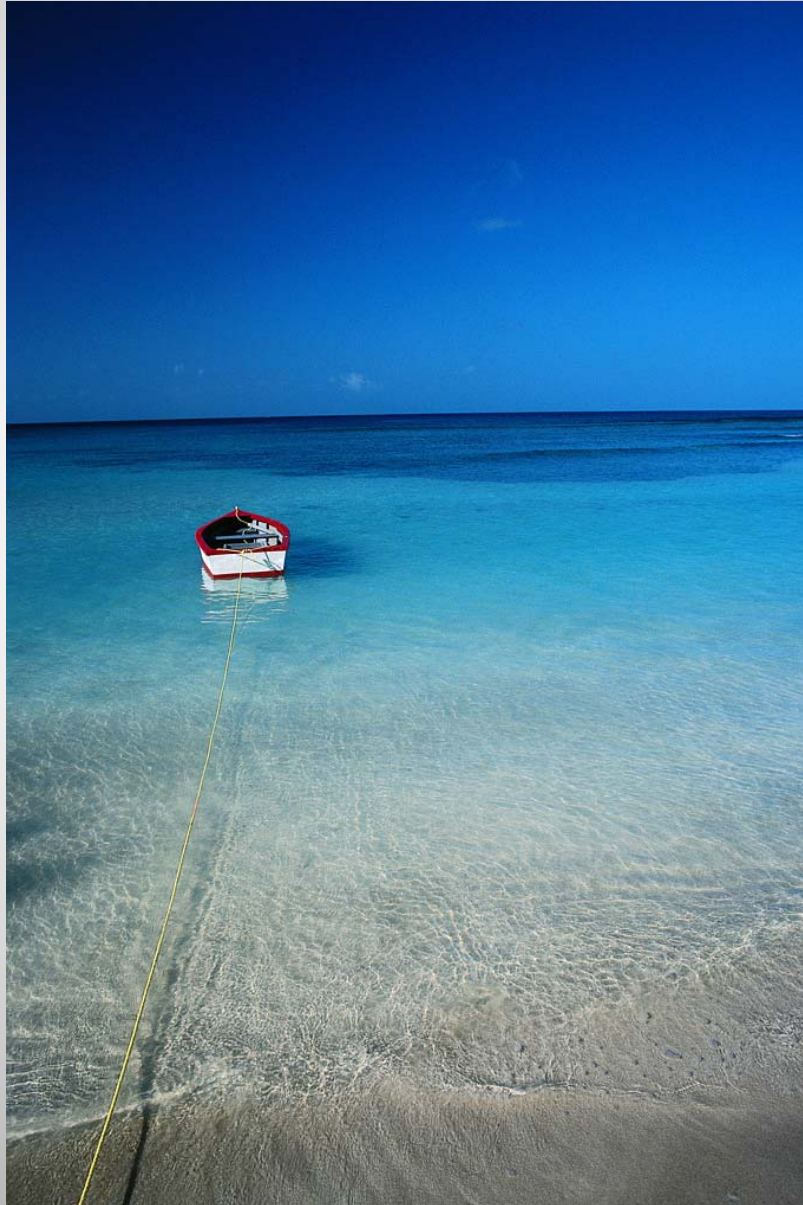


As defined under HIPAA



- *De-identified* data sets do **not** require oversight.
- *Limited data sets* require patient authorization or Privacy Board authorization through eResearch.
- If we added **patient age and dates** of diagnosis and treatment to the data set in the example we would have a 'Limited Data Set.'

Break Time



Communicating with the IRB

Things to think about before you start your IRB Application

- What is your plan or hypothesis?
- What do you need to do to test it?
- Who are the potential subjects?
- How will you recruit subjects?
- What risks are involved?
- Is the research sufficiently funded to reach its goals?
- Do you need permission from the FDA?
- Who will be responsible for what?

How to facilitate your IRB review

1. Show that risks to subjects are minimized “to the extent possible.”

- Identify the risks of the research itself
 - Include risks of all procedures that would *not* be done if the subjects were not in the study.
- If possible, use clinical procedures that would have been done even if the subject wasn't in your study.
- Have a data and safety monitoring plan even for non-high risk studies.
- Document those “of course I would do that” protections.

Case Study #1

How can you show the IRB you will minimize risks 'to the extent possible'?

- You need 1 tube of fresh blood from patients with kidney disease to test your hypothesis.
- You plan to get the blood from patients the day they come to the Taubman Center for a routine visit.

Case Study #2

How can you show the IRB you will minimize risks 'to the extent possible'?

- You plan a 3-arm anti-depression drug study:
 - 1 Depressed subjects on Prozac
 - 2 Depressed subjects on New Drug
 - 3 Depressed subjects on Placebo
- Study requires that all subjects have not taken any anti-depressant within 8 weeks of randomization.

How to facilitate your IRB review

2. Demonstrate that the “risks of the study are reasonable in relationship to the benefits.”

- Identify the benefits without hyperbole
- If your study has more than one arm, assess what the risks and benefits are in each.
- Understand that this regulation requires the IRB to do a scientific review.

Case Study #2

Can you convince the IRB that the risks are reasonable in relation to the benefits?

- You plan a 3-arm anti-depression drug study:
 - 1 Depressed subjects on Prozac
 - 2 Depressed subjects on New Drug
 - 3 Depressed subjects on Placebo
- Study requires that all subjects have not taken any anti-depressant within 8 weeks of randomization.

Case Study #2 continued

Can you convince the IRB that the risks are reasonable in relation to the benefits?

- **Provide justification for withholding, postponing, or altering treatment with proven therapies.**
 - Reviewer & Government FAQ
 - Don't assume it is obvious to those outside of your project

How to facilitate your IRB review

If your research includes “vulnerable populations” learn the additional regulatory requirements.



How to facilitate your IRB review

Learn Regulatory Terminology

- **Interaction** (includes but is not limited to):
 - Sending email
 - Using a website to gather information
 - Surveys
 - Focus groups
 - Asking for informed consent to use medical records or other reasons

How to facilitate your IRB review

Learn Regulatory Terminology

- **Intervention** (includes but is not limited to):
 - Collecting urine
 - Collecting blood
 - Conducting an MRI
 - Counseling
 - Randomizing patients to different treatments
 - Surgery
 - Administering drugs
 - Administering devices

How to facilitate your IRB review

Learn Regulatory Terminology

- Data Safety Monitoring Plan (DSMP)
(includes but is not limited to):
 - How you will minimize risks
 - Data you collect to assure subjects are safe
 - Methods of ensuring data security
 - Methods of ensuring data integrity
 - How often the study team meets
 - What will be done in an emergency
 - How, and to whom, adverse events will be reported.

eResearch Tip—Answer YES to question 7-1.10

How to facilitate your IRB review

Learn Regulatory Terminology

- Possible “Harms” (includes but is not limited to):
 - Side effects of the research procedures
 - Side effects of investigational agents
 - Emotional upset caused by the research
 - Social trauma caused by the research
 - Financial loss caused by the research

Review Tip—Use your DSMP to demonstrate to the IRB you have carefully considered all type of harms.

How to facilitate your IRB review

Learn Regulatory Terminology

- Possible Harms continued
 - What could happen if research records were revealed?
 - What would embarrass or harm a potential subject?
 - Explain your steps to protect privacy and confidentiality
 - Where records will be stored
 - Who will have access to records

Case Study #3

What would you put in your DSMP?

- You want to study risk-seeking behavior in teens
 - You plan to recruit teens in the emergency room, either as patients or with a patient
 - Research involves a 3-page survey and a 5 minute interview
 - Subjects are questioned about various risks from skateboarding, sky-diving, sex, selling and using drugs, cheating in school, etc.

How to facilitate your IRB review

Learn Regulatory Terminology

- Informed Consent
 - Consent is an on-going process, not just a form
 - Federal regulations have specific requirements about what must be in the consent document
 - Aim for a 6th grade reading level
 - Conduct *no* research procedures prior to obtaining consent from the subject or a waiver from the IRB
 - Not even getting weight or blood pressure

How to facilitate your IRB review

Learn Regulatory Terminology

■ Waiver of Informed Consent

- You don't ask subjects if they want to participate (or you can't because you don't know who they are yet)
 - Instead, you ask the IRB for a waiver
- Research must be not more than minimal risk
- It is not practical to get consent
- Subjects' rights and welfare would not be adversely affected
- If appropriate, you will provide subjects with pertinent information

How to facilitate your IRB review

Learn Regulatory Terminology

- No more than minimal risk:
 - The **probability** and **magnitude** of harm or discomfort anticipated as a result of participation in the research are **not greater** in and of themselves than those ordinarily encountered in **daily life** or during the performance of **routine** physical or psychological examination or **tests**. 45 CFR 46.102 (i)
- “Encountered in daily life” means the daily life of the average, healthy, person or child.

How to facilitate your IRB review

Learn Regulatory Terminology

- Waiver of HIPAA authorization
 - You don't ask subjects if you can use their protected health information (or you can't because you don't know who they are yet)
 - Instead, you ask the IRB for a waiver
 - Risks to privacy must be not more than minimal risk
 - It is not practical to get authorization
 - You couldn't do the research without the PHI
 - You will protect the PHI and destroy identifiers at the earliest opportunity.

How to facilitate your IRB review

Learn Regulatory Terminology

- Lots more information about consent and waivers is available in Informed Consent 101 and 201.

How to facilitate your IRB review

Good Writing and Organization

- The Project Summary:
 - Write it like an abstract for an article
 - Spell check, grammar check, friend check
 - The primary reviewer describes her interpretation of your study to the committee but . . . EVERYONE sees your summary
 - Your words are prominently displayed during IRB discussion
 - EVERYONE sees your summary, forever

How to facilitate your IRB review

Good Writing and Organization

- Explain the goals and significance of the research as clearly, completely AND concisely as possible.
 - Reviewer FAQ
 - Put the answer at their fingertips
 - Good answers go along way

How to facilitate your IRB review

Good Writing and Organization

- Provide the IRB with all needed documents
 - Protocol
 - Data collection tool (for retrospective data reviews)
 - Informed consent documents
 - Investigators' Brochure
- Be sure the IRB can tell which document is which, and which is the most current.

How to maintain good relations with your IRB

- Apply for IRB approval BEFORE implementing changes in a protocol or consent
- EXAMPLES:
 - Eligibility criteria
 - Number of subjects to be recruited
 - Adding or deleting a procedure or analysis
 - Adding or changing a recruitment method (letters, flyers, fairs)
 - Change in investigators or facilities

How to maintain good relations with your IRB

- Apply for IRB approval before implementing changes EXCEPT when **safety protections** are "necessary to eliminate apparent immediate hazards to the subject."
 - Implement a safety change and report IMMEDIATELY to IRB.

What to Tell the IRB about Your Research After Initial Approval

- If a potential subject is a prisoner, or when an 'active' subject becomes incarcerated—contact the IRB
- Audit/Inspection reports
- Renewal application (submitted before a project expires) or a termination application when complete
- Information that may affect subjects willingness to participate

How to maintain good relations with your IRB

Learn what you need to report after approval

- Unanticipated Problems
- Unexpected and expected Adverse Events
- Protocol and consent deviations
- See the IRB website for full details
- Attend Applications 201 and 202 for more details.

Use eResearch to Submit New Studies for to IRB Review

eResearch - Windows Internet Explorer

http://eresearch.umich.edu/

View Favorites Tools Help

X.500 M UM IRBMED eResearch OM FDA FDA OHRP AE-standard CBC.ca Legacy Pandora Hunger Dev Face

Select

MAIS eResearch

eResearch **M**

Regulatory Management
(IRB, IBC, etc.)
LOGIN ►

Proposal Management
LOGIN ►



Welcome to eResearch

[Regulatory Management \(IRB, IBC, etc.\)](#)

Used for the review and approval process for Human Subjects Research Applications and IBC Biosafety Registrations. [Learn more...](#)

To begin a new IRB application or IBC rDNA registration, [login](#) to eResearch Regulatory Management.

[Proposal Management](#)

Used for the electronic routing, approval, and submission of proposals to external sponsors, including Grants.gov. [Learn more...](#)

To begin a new proposal, [login](#) to eResearch Proposal Management.



eResearch News

Regulatory Management

System Upgrade was completed on 11/15/09. [Learn about system changes...](#)

Education opportunities offered by IRBMED and IRB-HSBS

Verify Your IRB Approval

Current State

Approved

[View Study](#)

[Printer-Friendly Version](#)

[Submission Summary](#)

My Activities

- [CORS Assign Owner](#)
- [CORS Record Elements of Discussion](#)
- [CORS Update Meeting History](#)
- [CORS Finalize Documents](#)
- [CORS Prepare Letter](#)
- [CORS Edit Contingencies](#)
- [CORS Manage Documents](#)
- [CORS Edit Agenda Information](#)
- [CORA Voluntary Hold](#)
- [CORS Administrative Withdrawal and Termination](#)
- [CORA Suspend](#)
- [Post Correspondence](#)

Study Name

[Pre-Submission](#) [Cancer Review](#) [Ancillary Review](#) [GCR](#)

Study Team Member	Study Team Role	Department
William Hasler	PI	Int Med-Gastroen
Radoslav Coleski	Co-Investigator	Int Med-Gastroen

Approval Date: 1/5/2006
Expiration Date: 1/4/2007
Staff Owner: Rosalind Fantone
GCRC ID: 2176
GCRC Study Type: A

[Correspondence](#) [Documents](#) [Amendments](#) [C](#)

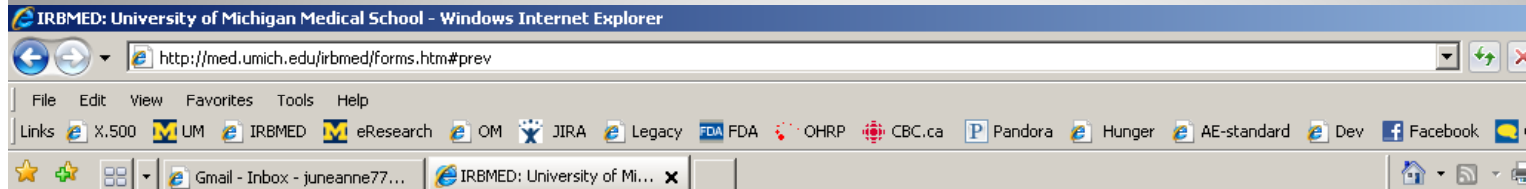
Study Team Correspondence

Activity

- [CORS Approved](#)
 - See Approval Letter
- [PI Submitted Contingencies](#)
 - We have addressed all of the concerns of the
- [Posted Correspondence](#)
 - We have made the requested changes in the
- [CORS Approved with Contingencies](#)



Application for Legacy Amendments, Renewals, Reports



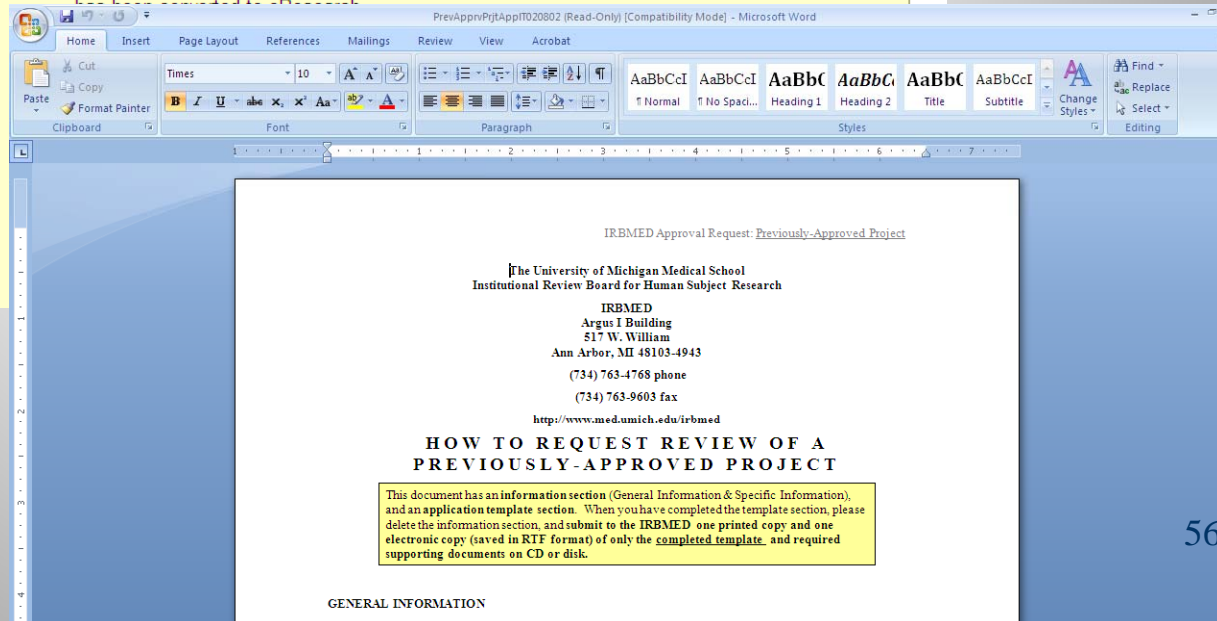
Previously Approved Projects

Note: When submitting the renewal application it is helpful to check if the informed consent template has been changed in a manner that impacts your study. See the [What's New: Informed Consent Templates](#) page. **REMINDER--Update to the new IRBMED Informed Consent Document Template** required on new studies, a subset of renewals (eResearch studies must update via an amendment application) and informed consent amendments **submitted after 11/1/2007**

Projects Approved in the Legacy (paper-based) system

- [Previously Approved Application](#)

Projects approved in the legacy system must use legacy to report adverse events, ORIOs, amendments, scheduled-continuation review (SCR), and termination until notified that the study has been converted to Research.



GENERAL INFORMATION

See <http://www.med.umich.edu/irbmed/forms/updates.htm> for a summary of IRBMED Application Form changes

Verify Your IRB Approval



The University of Michigan Medical School
Institutional Review Board for Human Subject Research (IRBMED)
 4558 Kresge Medical Research Building 1; 200 Zina Pitcher Place; Ann Arbor, Michigan 48109-0570
 Telephone: 734 763 4768 • Telefacsimile: 734 763 9603 •
 Electronic Mail: irbmed@umich.edu • Internet Web Location: <http://www.med.umich.edu/irbmed>

NOTICE OF OUTCOME OF REVIEW OF HUMAN SUBJECT RESEARCH

FAX TO: 7-####

Guy, Newbie (Principal Investigator) • IRBMED #: 2002-30802

Project Title: Quality of Food and Diet in the UMHS Hospital Unit

Sponsor & Its Identifier Code: Nabisco 362 • **Local Identifier Code:** QA 0000

Submit Date: 02/26/2003 • **Receipt Date:** 02/27/2003

Previously Approved: Direct involvement of human subjects (prospective): Research groups, observations, or other similar methods.

Supporting Documents: Informed Consent, HIPAA Consen.

Application Type: Amendment: HIPAA

FDA-Regulated Test Articles: No test article used.

Vulnerable Subjects: Children, Mentally Disabled Persons, Pregnant Woman with Child Bearing potential

Informed Consent Process: Assent, Comprehensive written

HIPAA Compliant: Yes

Initial Risk Level: No More Than Minimal • **Submission Risk Level:** No Increase

Outcome: Approved • **Decision Date:** 03/20/2003

Approval Date of Most Recent Version of Consent Document: 03/20/2003

Expiration Date of Project Approval: 01/22/2004

Information on the project and the outcome of the review by the IRBMED are provided in the descriptive paragraph above. The content of the submitted material conforms to relevant regulations of the United States Government. If the descriptive paragraph indicates that a "Comprehensive Informed Consent Process" was used, all copies of the consent document are required to display the following information: [1] Most Recent Version of Consent Document. [2] Approval Date of Consent Document. [3] Expiration Date of Project Approval. [4] If the project has been terminated, all activity involving the project will have been approved by the IRBMED as a new or extension of the project.

The investigators are required to report to the IRBMED any planned changes in a study, and do not implement any change without receiving approval, except to eliminate an immediate hazard to subjects, [1] for unexpected adverse events, and [3] any new information on the project that may adversely affect the risk/benefit ratio.

The investigators are responsible for applying for a Scheduled-Continuation Review and Approval of the project about eight weeks prior to the "Expiration Date of Project Approval" shown in the descriptive paragraph. In case IRBMED approval is not secured prior to Expiration Date, subject recruitment activity will cease, and no research interventions will be administered to the research subjects except to eliminate immediate hazard.

A list of IRBMED members is available at the IRBMED Internet web site ("Membership Roster (IRBMED)"). This Notice of Outcome of Review of Human Subject Research is provided to the sponsor of the project.

CORRELATE WITH YOUR COPY OF THE APPLICATION

DOUBLE CHECK FOR ACCURACY

RECORD OUTCOME, DATE AND ANY RISK CHANGE

RECORD IN MULTIPLE PLACES & WITH MULTIPLE PEOPLE

ALSO UPDATE CONSENT DOC IF NEEDED

We're here for you!

- Assistance is available during business hours:
 - Technical Help Desk: 936-7000
 - Application Assistance: 763-4768 and say you have a question about eResearch
 - Regulatory Assistance: 763-4768 and say you have a question about eResearch
- Also, "STARS" -- Speak To A Regulatory Specialist, 763-4768 and ask for STARS.
 - **Tues-10 a.m. to Noon, Weds-1 to 3 p.m.**

Questions?

