Family Medicine and Community Health – Monthly Research Forum

To IRB or Not to IRB

Or…

The Institutional Review Board (IRB): Everything You Wanted to Know But Were Afraid to Ask

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September 15, 2017

Workshop Objectives

- Review basic guidelines regarding the ethical conduct of research
- Review the history of human subject protection
- Discuss issues of informed consent
- Discuss the ethics of and use of incentives for recruitment and participation of human subjects in research studies
- **Discuss QI vs Evaluation vs Human Subjects Research**
- **Review IRB processes at UMMS and FMCH Guidelines**
- **Questions and Answers**

Direct and Indirect Needs for Human Subjects Protection

- There are a number of challenges to ethical conduct in research!
- Whether conducted in an academic setting or a healthcare institution/agency/organization, research involving human subjects often raises ethical concerns as study participants may experience risks and inconveniences primarily to benefit others by advancing knowledge.
- Ethical questions may arise at any time during the research process – from the design phase to subject recruitment to data collection to analyses and dissemination of study results.

Direct and Indirect Needs for Human Subjects Protection

- Institutions engaged in research using human subjects are required to provide written assurance of compliance with regulations (including documentation that the IRB reviewed the research project) to funding sources.
- There may be times when multiple IRBs must approve the study (e.g., for multi-center trials, for collaborative projects between two agencies, etc.). Studies conducted at multiple sites may pose additional IRB concerns (e.g., maintaining confidentiality of data held at multiple sites; insuring consistency of protocols between sites, etc).

The History of the Human Subjects Protection System

- The modern story of human subjects protections began with the *Nuremberg Code* (of 1947), developed for the Nuremberg Military Tribunal as the standard by which to judge the human experimentation conducted by the Germans.
- The Code captures many of what are now taken to be the basic principles governing the ethical conduct of research involving human subjects.
- The first provision of the Code states that "*the voluntary consent of the human subject is absolutely essential*."
- Freely given consent to participation in research is the *cornerstone* of ethical experimentation involving human subjects.

The History of the Human Subjects Protection System

- The Code provides details implied by such a requirement:
  - capacity to consent;
  - freedom from coercion; and
  - comprehension of the risks and benefits involved.
- Other provisions require:
  - the minimization of risk and harm;
  - a favorable risk / benefit ratio;
  - qualified investigators using appropriate research designs; and
  - freedom for the subject to withdraw at any time.

The History of the Human Subjects Protection System

- Similar recommendations were made by the World Medical Association in its *Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects* – first adopted in 1964.
- In the U.S., regulations protecting human subjects first became effective in 1974. The regulations established the IRB as one mechanism through which human subjects would be protected.

The History of the Human Subjects Protection System

- The National Research Act, passed in 1974, led to the issuance of reports and recommendations identifying the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and recommending guidelines to ensure that research is conducted in accordance with those principles – known as *The Belmont Report (submitted in 1978 by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research – the commission established by the National Research Act)*.

The History of the Human Subjects Protection System

- The Belmont Report set forth the basic ethical principles of respect for persons, beneficence, and justice – *the quintessential requirements for the ethical conduct of research involving human subjects*.
- Respect for persons involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle underlies the need to obtain *informed consent*.

The History of the Human Subjects Protection System

- Beneficence entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle underlies the need to engage in a risk / benefit analysis and to *minimize risks*.
- Justice requires that the benefits and burdens of research be distributed fairly. This principle requires that subjects be *fairly selected*.

Historical Consequences of Not Having IRB Oversight

- Tuskegee Study of untreated syphilis in African American men, 1932-1972
- Walter E. Fernald State School, 1946-1953
- Thalidomide, 1957-1961
- Jewish Chronic Disease Hospital, 1963
- Willowbrook Hepatitis Study, 1963-1966
- Holmesburg Prison, 1964-1968
- Stanford Prison Experiment, 1971
- Johns Hopkins Study of Lead Paint Hazards, 1990s - 2001

Institutional Review Board (IRB)

- The goal of the Institutional Review Board (IRB) (AKA: Human Subjects Committee or Committee for the Protection of Human Subjects Research) process is **to protect the rights and welfare of those individuals who contribute to the research process by participating as subjects**. In protecting the rights of subjects, the IRB also **protects the institution and the researcher from the potential consequences of an inadequate consent process or the exposure of the subject to a negative risk**.
- "The ultimate responsibility for protecting human subjects must be borne by the institutions that perform the research." (Shalala, D. Protecting research subjects - what must be done. New Engl J Med 2000;343:808-10)

Informed Consent

- Informed consent requires documentation ensuring that research subjects have voluntarily accepted to participate in the research and have been properly informed of each step in the research process.
- Informed consent should include: an invitation to participate in the research study; the purpose of the research; the selection criteria; the research procedures; the description of the benefits and risks; an alternative treatment if an experimental procedure is offered; the possibility to have questions answered by the study team; and an assurance of confidentiality.

Informed Consent

- Informed consent ensures the privacy (and sometimes the anonymity) of research subjects.
- Issues of informed consent are particularly important for vulnerable populations (e.g., the disabled, inmates, those with cognitive impairments or mental illness, children, pregnant women, and the elderly) where comprehending information and making voluntary choices isn't always possible.

Informed Consent

- Under federal guidelines, there are 2 circumstances in which informed consent is not required:
  - when the research is exempt from the regulations; and
  - when consent may be waived (see IRB checklist).
- Research involving surveys, interviews, or observation of pubic behavior, and research using existing records *may* be exempt from the federal regulations provided that data are recorded in such a way that the human subjects cannot be identified either directly or through linked identifiers.

Informed Consent

- Retrospective chart reviews (e.g., medical/school records) *may* also be conducted without individual consent, provided that identifying information is not recorded, directly or through identifiers linked to the subject.
- HOWEVER, individual IRBs may be more strict than federal regulations and may require IRB review and subsequent study subject consent.

Informed Consent

- Additionally, IRBs may no longer consider collection of some data (such as dates) as exempt if it includes any of the 18 identifiers specified in the federal privacy regulations mandated by the Health Insurance Portability and Accountability Act (HIPAA).
- Research that poses minimal risk but does not qualify as exempt may be eligible for review under the expedited process.

HIPAA

- HIPAA is the **Health Insurance Portability and Accountability Act**.
- It is a complex regulation that affects many researchers at all universities.
- HIPAA was designed to protect the use and disclosure of **Protected Health Information** (**PHI**).
- This regulation is applicable if your research study uses or will use PHI belonging to a provider/insurer of health services.

HIPAA

- The following 18 identifiers are considered Protected Health Information (PHI):
  - Names
  - Geographic subdivisions smaller than a state (addresses, zip codes, etc.)
  - Telephone numbers
  - Fax numbers
  - Email addresses
  - Social security numbers
  - Medical record numbers
  - Health plan beneficiary numbers
  - Account numbers
  - Certificate/license numbers
  - Vehicle identifiers and serial numbers (including license plate numbers)
  - Device identifiers and serial numbers
  - Web URLs
  - Internet protocol (IP) address numbers
  - Biometric identifiers (finger and voice prints)
  - Full face photographic images
  - Any other unique identifying number, characteristic or code

Incentives for Participation

- With many, many research projects, study subjects are often ‘paid’ for participating in research funded by federal bureaus, state agencies, private institutions, etc.
- Gone are the days when internal incentives – i.e., ‘wanting to help’, were sufficient to recruit subjects.
- In some cases, incentives are monetary.
- In other cases, ‘rewards’ are offered in lieu of money (e.g., free medical care, free medications, gift certificates to local stores, movie tickets, raffle ‘tickets’ – a chance to win a bigger prize, offers to donate money to a local charity, etc.).

Incentives for Participation

- Regardless of the external incentive, IRBs must consider whether 'paid' (i.e., reimbursed) participants in research are recruited fairly, informed adequately, and reimbursed appropriately.
- Taking into consideration the subjects' medical, employment, educational status, and their financial, emotional and community resources, the IRB must determine whether the incentives offered for participation in research constitute *undue inducements* or *coercion*.
- Federal regulations governing research with human subjects contain no specific guidance for IRB review of payment practices.

Incentives for Participation

- One of the primary responsibilities of the IRB is to ensure that a subject's decision to participate in research is truly *voluntary*.
- Clear cases of coercion may seem obvious, but 'undue inducement' is sometimes more difficult to recognize.
- Undue inducements may be problematic because:
  - Offers that are too attractive may blind prospective subjects to the risks or impair their ability to exercise proper judgment; and
  - They may prompt subjects to lie or conceal information that, if known, would disqualify them from enrolling – or continuing – as participants in the research project.

The IRB Process

- The purpose of the IRB is to *review research and determine if the rights and welfare of human subjects involved in research are adequately protected*.
- It has the authority to approve, require modification, or disapprove all human subjects research activities.
- Research approved by the IRB may be subject to review/ approval or disapproval by officials of the institution.

The IRB Process

- Office for Human Research Protections (OHRP), overseen by the U.S. Department of Health and Human Services, oversees all IRB functions at academic institutions and performs periodic audits of these institutions and the IRB applications approved.
- **OHRP can halt ALL HUMAN SUBJECT RESEARCH at an institution found not to be in compliance.**

The IRB Process

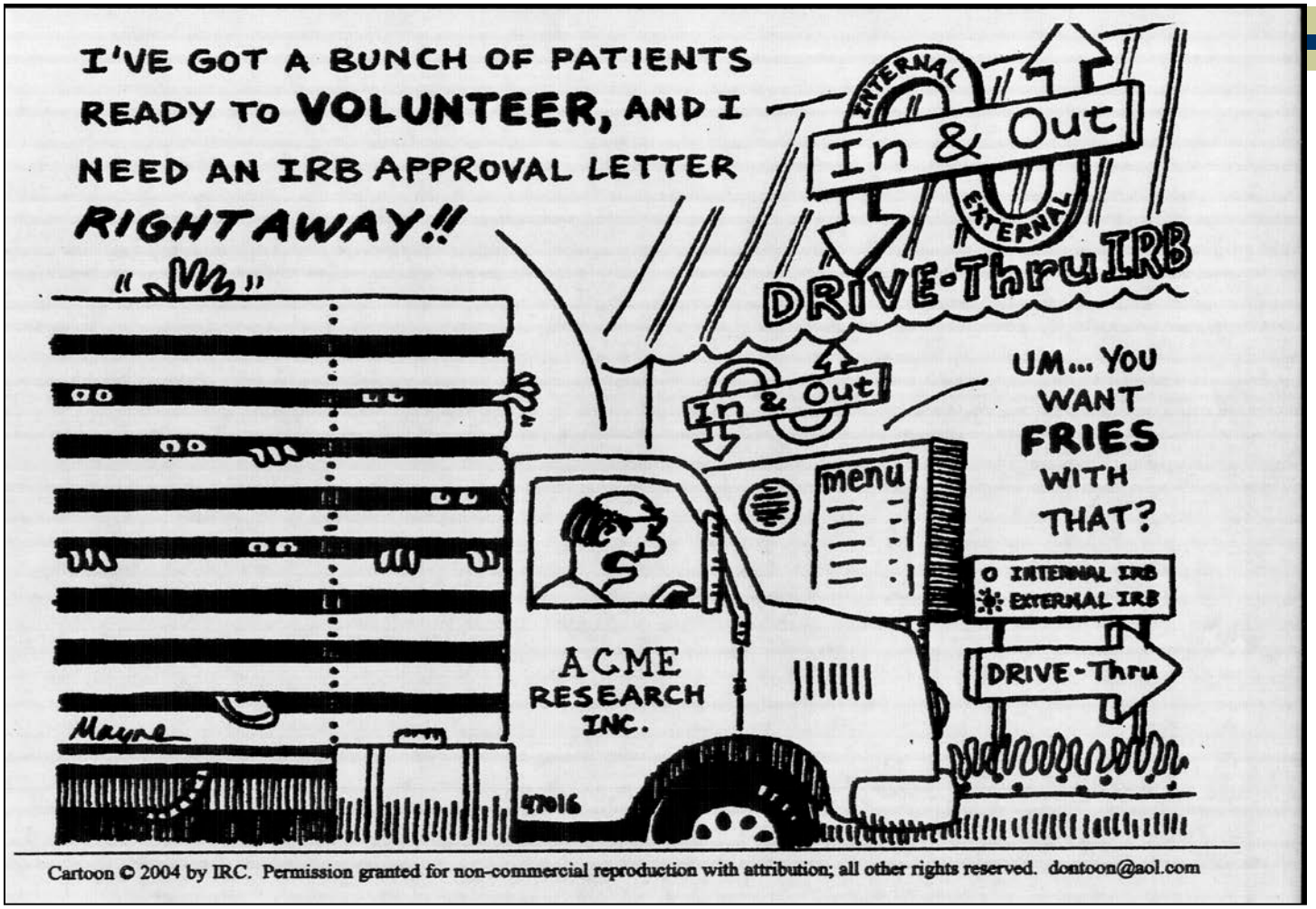
- The type of IRB review that is required typically depends on the **level of risk** presented by the study. The primary focus of this review is on the safety and well-being of research participants.
- The IRB office is typically a valuable resource in determining whether a research project requires a full or expedited review or whether the project may be exempt from review. The IRB office is open to calls and emails to discuss a possible study!

Types of Human Subject Reviews

- IRB reviews are qualified as one of three types: full, expedited, or exempt. The IRB office determines which level of review is needed.

- Full IRB Reviews:
  - Studies that include drug and device trials, vulnerable populations (children, prisoners, pregnant women), and high risk studies.

Expedited Reviews – Not…



Types of Human Subject Reviews

- Expedited Reviews:
  - Expedited review does not mean “fast”. It means that the study qualifies as minimal risk and does not need the approval of the entire review board.
  - Research involving data, documents, records or specimens that have been collected or will be collected solely for **nonresearch** purposes (e.g., medical/school record reviews, discarded tissue from surgical/pathology procedure, registry studies).

Types of Human Subject Reviews

- Expedited Reviews (continued):
  - Research on individual or group characteristics and behavior or research using surveys, interviews, focus groups, program evaluations, and quality assurance methodologies (see additional handouts on QI projects and program evaluations).
  - Collection of data through noninvasive procedures routinely employed in the clinical practice, excluding procedures involving x-rays (e.g., sensors attached to the skin, body composition assessment, moderate exercise).

Types of Human Subject Reviews

- Reviews receiving Exempt status:
  - Research involving prisoners does not qualify for exemption, nor can a project be exempt if the funding agency prohibits this.
  - Research conducted in an established or commonly accepted educational setting, involving normal education practices such as instructional strategies, research on effectiveness, or comparison among instructional techniques, curricula or classroom management.

Types of Human Subject Reviews

- Reviews receiving Exempt status (continued):
  - Research involving the use of educational tests, survey procedures, interview procedures or observation of public behavior as long as the information obtained is recorded in such a manner that the human subject cannot be identified directly or through identifiers linked to the subjects.
  - However, if there is a possibility that any disclosure of the human subjects' responses outside of the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects financial standing, employability, or reputation, the study will not qualify for exemption status.

Types of Human Subject Reviews

- Reviews receiving Exempt status (continued):
  - Research that involves only the collection or study of **existing** data, documents, records, pathological specimens, or diagnostic specimens. Existing means existing before the research is proposed or initiated; existing at the time of request. The data, documents, records, etc., to be used must be publicly available OR recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.

Types of Human Subject Reviews

- Reviews receiving Exempt status (continued):
  - Exemption from regulations does not necessarily mean that there is no IRB oversight. Many IRBs do not allow investigators to determine exempt status themselves; rather, there is a formal process for making such a determination (through submitting an ISP – Investigator's Study Plan).
  - Because journals are increasingly requiring evidence of IRB approval, it would be wise to consult with the IRB about exempt status, even if the project does not require formal review.

The IRB CITI Process

- The Collaborative IRB Training Initiative (CITI) program is the vehicle for ensuring comprehensive education in bioethics and human subjects protection.
- The CITI program is a 13-module program created by 'IRB experts' and is used by many academic health centers across the country. Certification via the CITI exam can easily be transferred to other academic institutions.
- The complete set of modules may take up to 4 hours to complete, but they *do not* have to be completed at one sitting. Recertification is required every three (3) years.

Is IRB Oversight Required?

- In order for a project to require IRB review, it must involve human subjects and qualify as research.
- A *Human Subject* is defined as "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, subpart A, section 46.102)

Is IRB Oversight Required?

- *Research* is defined as “a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46, subpart A, section 46.102)
- **NOTE**: Intent to publish, by itself, is not a reason to go to the IRB for review/oversight. It must be human subjects research (HSR) at the start of the study.
- **NOTE**: IRB now has a new form where you can request a determination be made regarding human subjects research or not. It’s much easier to use than completing an ISP to get the same determination.

Is IRB Oversight Required?

The IRB asks: Is it HSR?

If yes, does it meet any of the exemption categories?

If no, does it meet any of the expedited review categories?

If no, requires full Committee review

Is IRB Oversight Required?

- Quality Improvement Activities FAQs: http://answers.hhs.gov/ohrp/categories/1569
  - What is the purpose of the activity? Is it research?
  - Are you using QI data to answer a research question?
  - Remember: Intent to publish isn't, by itself, a rationale for IRB review – it must be human subjects research at the start of the study.
- Recent article: How to Distinguish Research from Quality Improvement; J of Empirical Research on Human Research Ethics 2015;19(2):209-201

Is IRB Oversight Required?

- Program Evaluations:
  - http://oregonstate.edu/research/irb/does-evaluation-require-irb-review
    - When does evaluation require IRB review?
  - https://compliance.vpr.okstate.edu/IRB/documents/IRB_toolbox/Program_Evaluation.pdf
    - Program Evaluation: When is it Research?

www.umassmed.edu/research

www.umassmed.edu/ccts/human-research

UMASS

CENTER FOR CLINICAL AND TRANSLATIONAL SCIENCE

UMASS MEDICAL SCHOOL

ABOUT | HUMAN RESEARCH PROTECTION PROGRAM | COMMUNITY | EDUCATION | FUNDING OPPORTUNITIES | RESOURCES

Center for Clinical and Translational Science > Human Research Protection Program

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

- IRB Home
- Ancillary Reviews
- Checklist for New Researchers
- Clinical Data Portal
- Clinical Research at UMMS
- Clinical Research Agreements
- Clinical Research Resources & Fees
- Conflict of Interest
- Community Engagement and Participation Outreach
- HRPP QA/QI and Education
- Information for Industry Collaborators
- OnCore
- Policies and Procedures
- Privacy and Security (HIPAA)
- Research Integrity Office

Human Research Protection Program (HRPP)

Mission Statement

The mission of the University of Massachusetts Medical School **Human Research Protection Program (HRPP)** is to facilitate excellence in human research by:

- Safeguarding and promoting the health and welfare of human research participants by ensuring that their rights, safety, and well-being are protected;
- Educating our community about research and the rights and responsibilities of research participants;
- Providing timely and high quality review and monitoring of human research studies.

This Organization's Human Research Protection Program is a comprehensive system to ensure the protection of the rights and welfare of subjects in Human Research. We operate under the principles first established by the Belmont report (http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html) namely standards of honesty, justice, integrity, respect and a sense of responsibility to others. The HRPP adheres to federal regulations and laws, state law, as well as UMass Medical School policies that govern human participant research programs and ensuring the right of every human being to voluntary, informed consent. The framework of protection for both research participants and our researchers is comprised of the Institutional Review Board (IRB), which works together with

UMASS MEDICAL SCHOOL

Human Subjects Institutional Review Board

ABOUT | HUMAN RESEARCH PROTECTION PROGRAM | COMMUNITY | EDUCATION | FUNDING OPPORTUNITIES | RESOURCES

- IRB Home
- Getting started with UMMS IRB
- Policies/SOPs & Checklists/Worksheets
- Privacy and Security (HIPAA)
- Investigator Manual
- Investigator Guidance
- Forms and Templates
- IRB Job Aids
- eIRB Data Request
- CITI & GCP Training
- Education and Training
- IRB Meetings
- External IRBs
- Contact Us
- Additional Resources

Investigator's Manual

Submit a Question

eIRB Login

Welcome to UMass Medical School Institutional Review Board

If you plan to conduct research involving human subjects, the research study must be reviewed and approved by the UMass Institutional Review Board before the study begins. Constituted as the Committee for the Protection of Human Subjects in Research, the UMass IRB serves as IRB of record for all human research conducted by UMass faculty and investigators at the Medical School or at associated research locations, including the campuses of UMass Memorial Medical Center and the member hospitals of UMass Memorial Health Care.

Detailed instructions on how to submit a research study to the IRB can be found in the ***Investigator's Manual.*** Additional help is always available at the IRB Office at 508-856-4261 or email: IRB@umassmed.edu. We look forward to assisting you!

Visiting the IRB in-person?
Use the back elevators (past Conquering Diseases on the left and passing through the double set of doors at the end of the long hallway) to reach the 7th floor of the ACC. Badge access is required.
The 7th floor VA clinic has opened, and the IRB is no longer readily accessible from the main ACC elevators.

Click here to see the presentation slides on "**HIPAA and Research**"

News

News and Announcements

9/5/2017: Closed Labor Day 9/4/17

****Tip of the month****

September 2017

Remember to check the blue box in eIRB for the status of your study or follow-on submission. If the blue box in the upper left hand corner says **Pre-Submission** or **Pre-Review Clarifications Requested**, it's under your control and is not in the IRB office. See the job aids for step-by-step instructions for how to submit or respond to clarifications requested: https://www.umassmed.edu/ccts/irb/job-aids-ii/

Tips for 2017

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

- eIRB Job Aids
- eIRB Data Request
- CITI & GCP Training
- Education and Training
- IRB Meetings
- External IRBs
- Contact Us
- Additional Resources

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Tips for 2017

Investigator's Manual

Submit a Question

eIRB Login

Click here to see the presentation slides on "**HIPAA and Research**"

News and Announcements

9/3/2017: Closed Labor Day 9/4/17

8/8/2017: Revised Investigator Study Plan

8/7/2017: "Ask an Expert" Drop-In Sessions, 2nd & 4th Thursdays of each month

8/7/2017: "Ask an Expert" Drop in Thursday, 8/10, 1-2:30, Library computer classroom

7/27/2017: FDA Guidance Document on IRB WAIVER OR ALTERATION OF INFORMED CONSENT

7/24/2017: IRB drop in session THURSDAY 7/27/17 2:30~4:00

7/10/2017: (Revised, see announcement for 8/7/17) IRB drop in sessions held in Goff Computer Lab S2-307D

7/3/2017: Closed for July 4th

6/19/2017: Important UMMS IRB Updates and Short Survey

6/9/2017: Intermittent Network Outages 6/9-6/10

All News & Announcements..

Association for the Accreditation of Human Research Protection Programs, Inc. — Full Accreditation

Federalwide Assurance:
FWA#00004009
Expiration Date:
8/8/2021

IORG#0000160

IRB Registration #:
IRB 1: IRB00000269
IRB 2: IRB00000270

Statement of Compliance

Submit a Question

Login

Checklists and Worksheets

These documents provide support regarding determinations that the IRB must make before a project may be approved. These documents may be used as additional guidance in preparing your submission to the IRB. Not all checklists/worksheets apply to all research. You may use, as a guide, those which are applicable to your research. Additional help is always available at the IRB office by calling (508) 856-4261 or e-mailing IRB@umassmed.edu

Please Note: *The following Checklists and Worksheets are form fillable, and are compatible with the most up-to-date version of Adobe Reader. Should you experience trouble opening a PDF in your internet browser, please download the document (we recommend saving it to your desktop), and try opening it with Adobe Reader from the saved location on your computer. Should you experience further difficulty, please contact the IRB office for assistance.*

Checklists

- HRP-300 CHECKLIST: Waiver of Consent HHS
- HRP-301 CHECKLIST: Waiver of Consent Emergency Research
- HRP-302 CHECKLIST: Waiver of Consent Leftover Specimens
- HRP-303 CHECKLIST: Waiver of Documentation of Consent
- HRP-305 CHECKLIST: Pregnant Women
- HRP-306 CHECKLIST: Neonates of Uncertain Viability
- HRP-307 CHECKLIST: Nonviable Neonates
- HRP-308 CHECKLIST: Prisoners
- HRP-309 CHECKLIST: Unexpected Incarceration
- HRP-310 CHECKLIST: Children
- HRP-311 CHECKLIST: Wards
- HRP-313 CHECKLIST: Non-Significant Risk Device
- HRP-320 CHECKLIST: HIPAA Waiver of Authorization

Worksheets

- HRP-400 WORKSHEET: Criteria for Approval
- HRP-402 WORKSHEET: Advertisements
- HRP-403 WORKSHEET: Payments
- HRP-404 WORKSHEET: Short Form
- HRP-411 WORKSHEET: New Information
- HRP-414 WORKSHEET: Adults Lacking Capacity
- HRP-420 WORKSHEET: Pre-Review
- HRP-421 WORKSHEET: Human Research
- HRP-422 WORKSHEET: Engagement
- HRP-423 WORKSHEET: Exemptions
- HRP-424 WORKSHEET: Expedited Review
- HRP-425 WORKSHEET: Drugs

Templates	
Investigator Study Plan Template with Instructions	Use this template to develop the Investigator Study Plan. Instructions are included within the document. *Updated 8/8/17*
Request for Not Human Subject Research Determination	Use this document if you are seeking a written determination that your activity is Not Human Subjects Research or you are unsure as to whether your quality improvement/assurance project, program evaluation, or other activity requires IRB review
Consent Form Template	Use this document to create the consent form for your research. *Updated 2/3/16*
Assent Template	Use this document to create an assent form for children involved in research. *Updated 3/18/14*
Fact Sheet Template	Use this document when the study is no more than minimal risk (e.g., simple blood draw, survey, focus group) and when you are requesting a waiver of written documentation of consent. *Updated 5/16/14*
HIPAA Authorization	Use this document to obtain authorization to use /disclose PHI from participants of the research Need some clarity on HIPAA Authorization/Waivers? Click **here** to see the presentation slides on **"HIPAA and Research"**
HIPAA Waiver	Use this form when requesting a waiver of HIPAA authorization
Authorization to Contact	Complete this form if you would like someone to contact you about the Research
Short Forms: (English version)	Select the preferred form below when obtaining and documenting informed consent from subjects who do not speak English. **Note: Non-English speaking subjects can only be enrolled into a Research Study if this is indicated in the approved Investigator Study Plan.

Available in 12 languages

eIRB Job Aids

Job Aids are one-to three -page step-by-step instructions to aid eIRB users as they walk through specific actions.

Description of what you need	Links to Aid
• How to log into eIRB • Forgot my password • Forgot my user name	How to Log into eIRB/Forgot My User Name or Password
• How to edit your user profile	How to Edit User Profile View the Video (1:16)
• How to update research personnel	How to Edit Research Staff View the Video (2:31)
• How to change the PI of the study protocol	How to Change Principal Investigator
• How to create a new research study submission • How to complete the electronic application (Smartform) • How to submit the research study to the IRB (PI ONLY)	How to Create and Submit a New Research Study Submission View the Video (5:02)
• How to create and submit a Modification	How to Submit a Modification View the Video (3:28)
• How to create and submit a Continuing Review, Continuing Review/Modification, or Study Closure	How to Submit a Continuing Review, Continuing Review/Mod, or Closure
• How to create a Reportable New Information submission • How to edit a Reportable New Information submission	How to Submit a Reportable New Information

FMCH IRB Guidelines

1. The Department Chair is ultimately responsible for all IRB-approved studies within FMCH. Thus…
2. Prior to submitting your IRB application (ISP) in eIRB, a review within FMCH is required.
3. Faculty who are listed as the Advisor for a student, resident, or fellow must also have the ISP reviewed prior to submission.
4. Please allow 2 weeks for this pre-review, though often these reviews are completed in much less time.
5. This not only provides for the departmental review process, but it's likely that we can help with the submission process in clarifying some of the ISP language, if needed.
6. Submit your IRB application materials to Judy Savageau.
7. Once the departmental pre-review occurs, you may submit the application through the eIRB processes. The department will be notified that it has been submitted.

IRB Q & A

- **Questions?**

Selected Bibliography and Contact Information

- DHHS.gov web site: http://ohrp.osophs.dhhs.gov/irb/irb_introduction.htm. NOTE: This website has an abundance of historical information about conducting research using human subjects, plus dozens of useful and interesting references and links to other pertinent information.
- Aita M, Richer MC. Essentials of Research Ethics for Healthcare Professionals. Nursing and Health Sciences 7:119-125, 2005.
- Grady C. Payment of Clinical Research Subjects. The Journal of Clinical Investigation 115(7):1681-1687, 2005.
- Grant RW, Sugarman J. Ethics in Human Subjects Research: Do Incentives Matter? Journal of Medicine and Philosophy 29(6):717-738, 2004.
- Wolf LE, Walden JF, Lo B. Human Subjects Issues and IRB Review in Practice-Based Research. Annals of Family Medicine 3(Supp 1):S30-37, 2005.

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