Clinical Research Seminar:

Research projects meeting criteria for exemption: Avoiding common pitfalls to improve prospects for successful IRB review!

Mary-Tara Roth, RN, MSN, MPH
BUMC Clinical Research Resources Office (CRRO)

September 18, 2013

CRRO Clinical Research Resources Office

CRRO Clinical Research Resources Office

Supported by the BU CTSI and Office of Clinical Research (OCR)
Serving all BUMC Clinical Researchers

Regulatory Service and Education Program	Recruitment Services Program

• Consultation services
  • Study implementation
  • IRB application submission
• Tools and Resources *(web-site based)*
• Education programs for all levels of the research team
• Support for sponsor-investigators of FDA regulated research
• Quality Assurance Reviews
	• Consultation services
	  • Study implementation
	  • IRB application submission
	• ReSPECT Registry
	  • Community Outreach
	• StudyFinder
	• Resources
	  • Web-based templates, tools, plans, etc.

See our website: www.bumc.bu.edu/crro

FDA Drug and Device Application Workshop

"Best Practices for Preparation and Maintenance of Sponsor-Investigator INDs and IDEs"

Featuring: Jelena P. Berglund, PhD, RAC

Assoc. Director, Regulatory Affairs, Duke Translational Medicine Institute

Friday October 11, 2013

BU Photonics Colloquium Room

8 St. Mary's Street, Room 906

8:30 am: Check in and breakfast

9 am – 12 pm: IND Application Process

1 pm – 4 pm: IDE Application Process

Sponsored by the BU Center for Future Technologies in Cancer Care and the Clinical Research Resources Offices (CRRO)

To register for free, visit: tinyurl.com/BUFDAWorkshop

Objectives

- Define human subjects research;
- List criteria for exemption from human subjects protection regulations;
- Explain what it means to have an exempt protocol in terms of IRB requirements;
- Describe common pitfalls in submitting exempt research studies.

My protocol!

The BEST Scientific Study EVER!!!!

CRRO Clinical Research Resources Office


IRB

Institutional Review Board (IRB)

- Formally designated committee; at least 5 members
  - Function as an ethics committee; primary responsibility: protect rights and welfare of research subjects
- Review, approve, conduct periodic review (at least annually) of biomedical and behavioral research
  - Document that reviews take place in compliance with regs
- Empowered to approve, require modifications or disapprove research

Role of IRB

Keep in mind….

IRBs are rule ***enforcers*** <u>*not*</u> rule ***creators***

Leonard Glantz, JD

Associate Dean Emeritus, Academic Affairs

Professor, Health Law, Bioethics & Human Rights

Re-used with permission; Dr. Jim Feldman
Clinical Research Seminar presentation 4/17/13

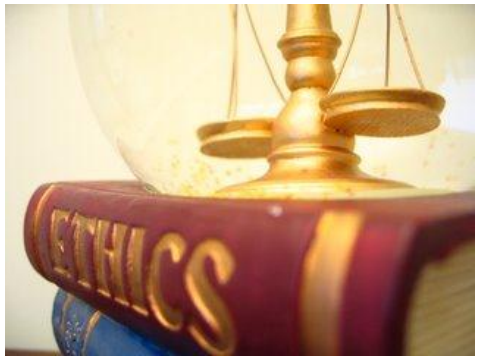
The 111 Criteria:
Criteria for IRB Approval

"In order to approve research covered by these regulations the IRB shall determine that all of the following requirements are satisfied…"

21 CFR 56.111

45 CFR 46.111

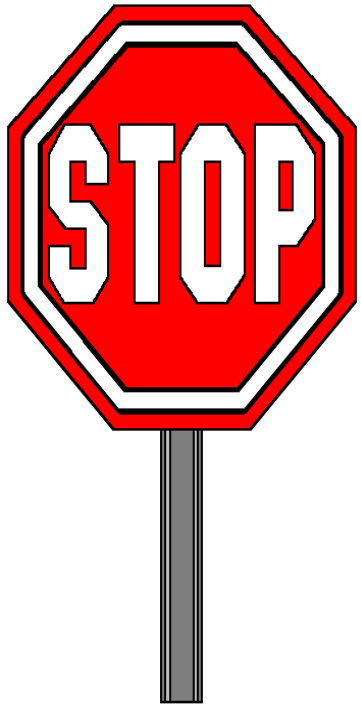
The 111 Criteria



1. Risks to subjects are minimized.
2. Risks to subjects reasonable in relation to benefits.
3. Selection of subjects is equitable.
4. Informed consent process.
5. Informed consent documentation.
6. Adequate provision for monitoring the data.
7. Provisions to protect privacy /maintain confidentiality.
8. Safeguards for vulnerable populations.

Deferral Decision

- Usually because insufficient information provided to the IRB for them to make a determination for one or more of the 111 criteria.
- If reviewed by the board, protocol will have to be revised and resubmitted and come back to the full board.
- Administrative Deferral: Not complete enough to make it to the board.



Regulations Guiding Clinical Research

Subpart A: Protection of Human Subjects

45 CFR 46

OHRP

- Assurance
- Oversight
- Engagement

Informed Consent

IRB Review/ Functions/ Operations

21 CFR 312, 812, 50, 54, 56

FDA

- Sponsor/investigator roles and conduct
- Drug/device dev't & testing process

- Subpart B: Pregnant women, Fetuses, neonates
- Subpart C: Prisoners
- Subpart D: Children
- Subpart E: IRB Registration

45 CFR 160, 162, 164

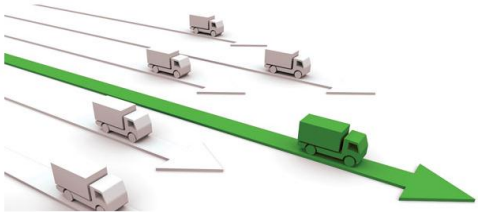
HIPAA (Health Insurance Portability and Accountability Act of 1996)

- Privacy and Security of protected health information

Types of IRB Submission/Review

- Convened Meeting (Full Board)
  - Greater than minimal risk research

- Expedited
  - 8 expedited categories
  - Minimal risk research



- Exempt or NHSR
  - Minimal risk
  - 6 categories of exemption
  - NHSR = not human subjects research
    - No research OR no human subjects

Exempt/NHSR vs. Non-exempt

- Reviewed by one reviewer
  - senior IRB staff-member
- Typically shorter IRB review timeframe
- Shortened application
  - INSPIR “smart” form
- You get a “determination” vs. approval letter
- Usually limited or no consent process
- No continuing review

BUMC IRB Panels

- Blue: Sociobehavioral, public health, international, etc.
  - 2nd and 4th Thursdays, 12-2pm
- Green: Biomedical
  - 1st and 3rd Thursdays, 12-2pm
- Purple: Progress reports
  - 2nd and 4th Wednesdays, 9-11am
- Orange: Repositories and genetic research
  - 1st and 3rd Wednesdays, 12-2pm
- Red: expedited, exempt, NHSR
  - no meetings
- WIRB: multicenter industry-sponsored studies
  - Sponsor has to agree to specific language for the Compensation section of the Consent form

BUMC IRB Review Times

Review Time for Submissions that Reached Final Determination during August, 2013

	Number	Days from submission until final determination*	Days in IRB office*	Days in investigator's office*
New Protocols				
Full-board	17	53 (8-216)	28 (8-95)	17 (0-134)
Expedited	8	34 (4-69)	30 (2-42)	2 (0-36)
Exempt	17	17 (7-48)	17 (7-34)	0 (0-21)
Amendments				
Full-board	17	22 (13-85)	18 (10-50)	1 (0-35)
Expedited/Exempt	72	14 (0-84)	13 (0-69)	0 (0-30)

* These columns show the median number of days (and range).

http://www.bumc.bu.edu/irb/bumcirb/irb-review-time/

Determining when OHRP Regs Apply…

1) Does the activity involve Research? (46.102(c))

If yes, then…..

2) Does the research involve Human Subjects? (46.102(f))

If yes, then….

3) Does the human subjects research meet criteria for Exempt from 45 CFR 46? (46.101(b))

Decision Trees: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

Definitions

- Research (OHRP regs: 45 CFR 46.102 (d))
  - *"… a* systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

- Clinical Investigation (FDA regs: 21 CFR 312.3 (b))
  - "… any experiment in which a drug is administered or dispensed to, or used involving, one or more human subjects. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice."

Definitions

- Human Subject (OHRP regs: 45 CFR 46.102 (f))
  - *"… a **living individual** about whom an investigator (whether professional or student) conducting research obtains:*
    - *Data through **interventions or interactions** with the individual, or*
    - ***Identifiable private information**."*

Definitions

- Interaction/Intervention (45 CFR 46.102 (f))
  - Physical procedures by which data are gathered
  - Manipulations of the subject or the subject's environment for research purposes
  - Interaction includes communication or interpersonal contact between investigator and subject.

Definitions

- Private information (45 CFR 46.102 (f))
  - … info about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
  - Private information must be individually identifiable i.e. the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects."

(**See OHRP guidance on coded data/specimens, 2008: http://www.hhs.gov/ohrp/policy/cdebiol.html)

More on Private Identifiable Information (OHRP)

- In general ….. 3 ways by which the identities of subjects' data/specimens can be ascertained
  - **Direct identifiers:** name, medical record number, address, social security number, photographs
  - **Code linking to direct identifiers:** data/specimens assigned a study ID that can be linked to identifiers via a mastercode or key
  - **Deductive Disclosure:** no direct identifiers but identity can be reasonably ascertained from the data itself (small population or specific data elements)

w/permission, excerpted and modified from Mary Banks' Clinical Research Seminar Presentation 3/20/2013

More on Private Information (OHRP)

- **"Anonymous"**: (unofficial term) usually meaning that NO ONE is able to associate the data/specimens with individual subjects- not the holders of the data/specimens; not the recipients
  - The data/specimens don't contain direct identifiers
  - There are no indirect identifiers (linkage by mastercode)
  - There isn't a reasonable risk of deductive disclosure
- **Not Human Subjects** (NHS) – if data/samples are obtained from a repository (not directly from subjects) and the recipients of data/samples cannot reasonably ascertain the identities of the subjects, because
  - Data/samples are truly anonymous OR
  - Data /samples are coded and recipients never get access to mastercode/key and promise to never try to ascertain the identities of the subjects

w/permission, excerpted from Mary Banks' Clinical Research Seminar Presentation 3/20/2013

Exempt determination... 45 CFR 46.101 (b)*

1. **Normal educational practices** in established educational settings
2. Educational tests, **surveys, interviews**, or observation of public behavior -unless identified & sensitive**
3. Research on elected or appointed public officials or candidates for public office
4. Research using existing data, if publicly available or recorded without identifiers (existing = at time of submission to IRB)
5. Evaluation of public benefit service programs
6. Taste and food quality eval./consumer acceptance studies

***None of the categories apply to Prisoner research (Subpart C).**

** **#2 does not apply to research with children except for research involving observation of public behavior when investigator(s) do not participate in the activities being observed.**

CRRO Clinical Research Resources Office

IRB Submission for Exempt or NHSR?

- OHRP guidance on exempt determinations: b/c of potential for conflict of interest, investigators not be given the authority to make an independent determination that human subjects research is exempt.
- A variety of configurations of exemption authority are acceptable.
- BUMC policy: submission to the IRB of an exempt/NHSR application for determination.

http://answers.hhs.gov/ohrp/categories/1564


BACK
TO
THE
HIPAA

Don't forget HIPAA (45 CFR 160 & 164)

- Uses different terminology than OHRP
- HIPAA- looks at data in terms of 18 "safe harbor" identifiers
  - Name, address, SS#, MR#, **Dates (< year)**, ages >89, geographic information <state
- **De-identified** –stripped of **ALL 18** " safe harbor identifiers"
  - The master-code is not one of the identifiers unless it is derived from an identifier (like b-date or last 4 of SS#)
  - Data sets that contain dates (admission, discharge, surgery, birth, death, specimen collection, etc.) can't be called de-identified because dates are identifiers
- **Limited data set (LDS)**- is like a de-identified dataset as most identifiers must be stripped except dates, ages >89 and some geographic information

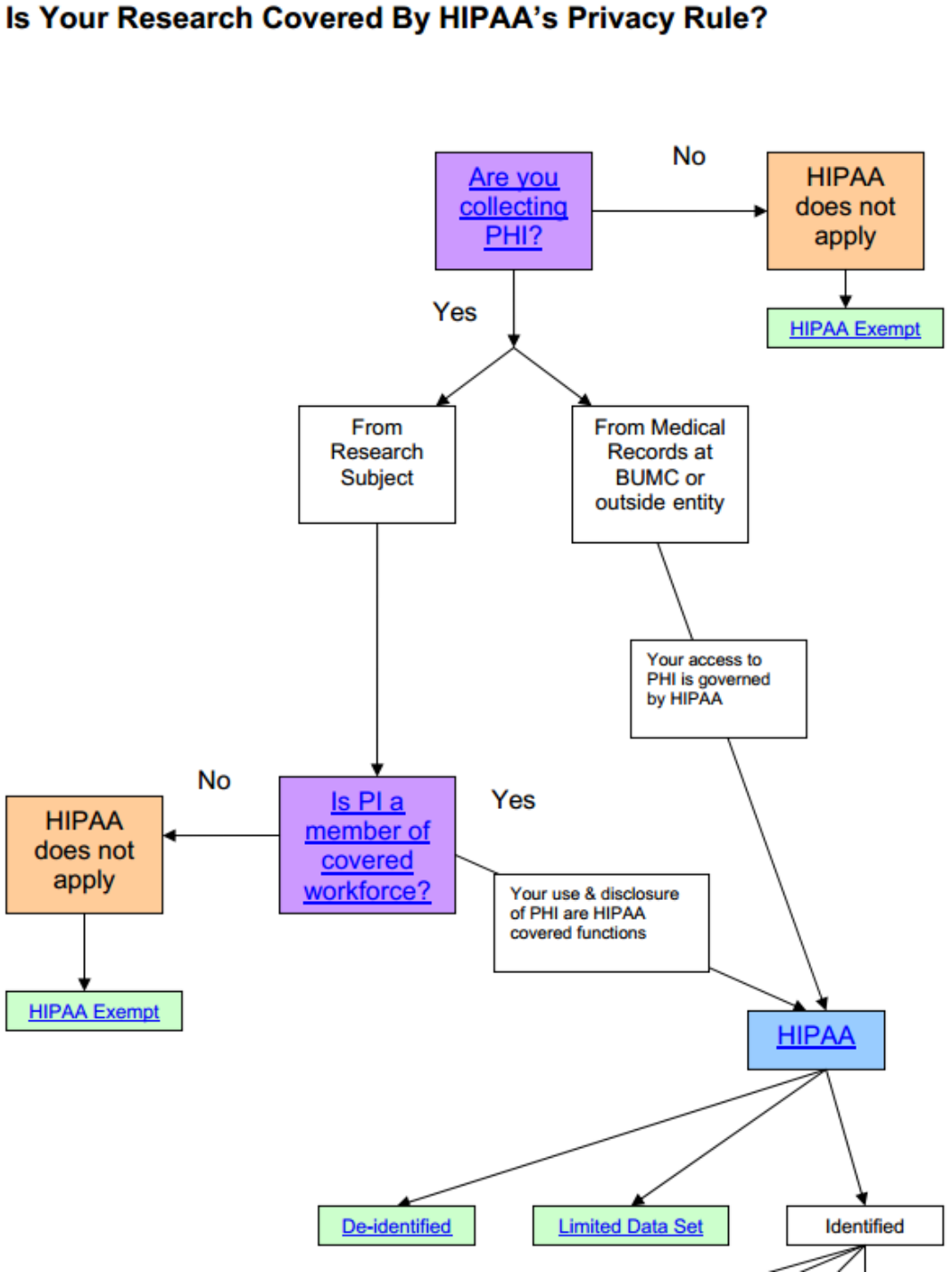
w/permission, from Mary Banks' Clinical Research Seminar Presentation 3/20/2013

HIPAA forms

- If accessing protected health information from a covered entity, include the applicable form(s) attached to your protocol
  - Authorization (written)
  - Waiver
  - De-identified
  - Limited Data Set
  - Decedent
- Link to HIPAA forms on the IRB website
  - Under “Also see…”

HIPAA Research Decision Algorithm

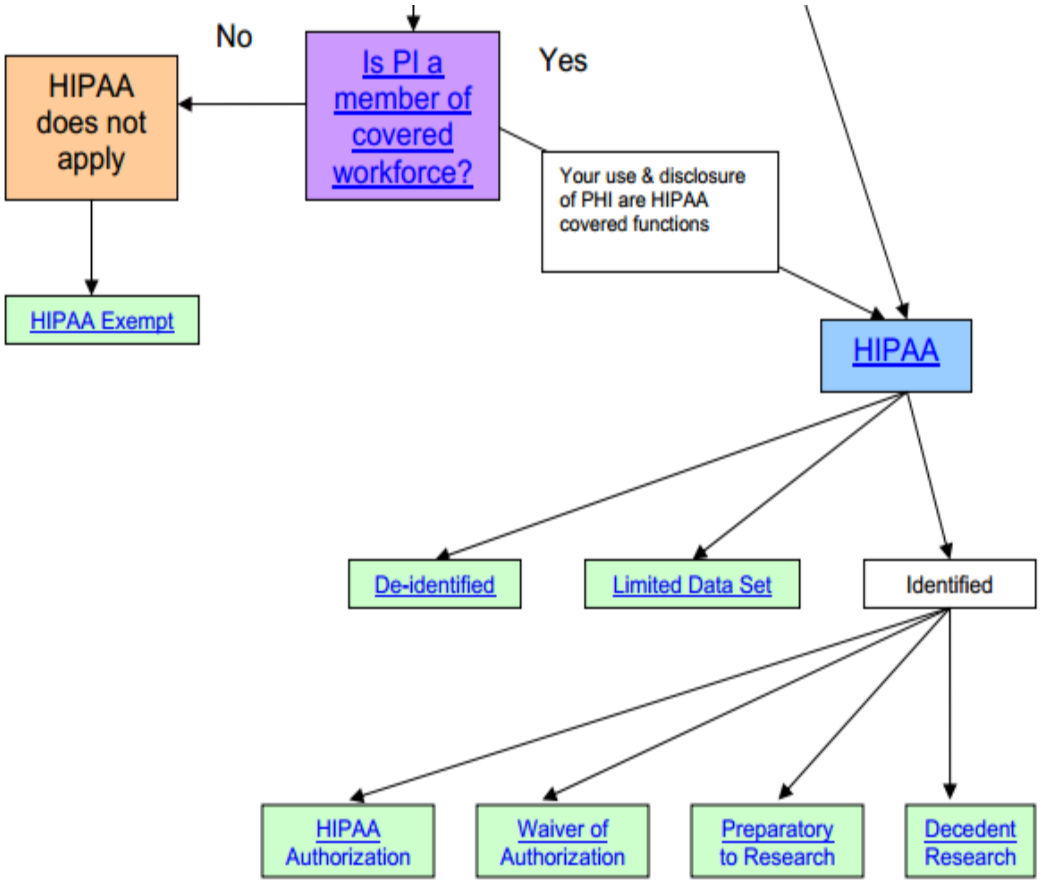
http://www.bumc.bu.edu/hipaa/



CRRO Clinical Research Resources Office

HIPAA Research Decision Algorithm p. 2

http://www.bumc.bu.edu/hipaa/



Mutually exclusive terms re: Data

- Data cannot be
  - Anonymous and coded (that links to identifiers)
  - De-identified and include dates (except year)
  - De-identified and a Limited Data Set (LDS)

w/permission, excerpted from Mary Banks' Clinical Research Seminar Presentation 3/20/2013

Exempt Category 1 (Education)

- Normal Educational Practices and Settings
  - Research in established or commonly accepted educational settings involving normal educational practices
  - Research on regular and special education instructional strategies
  - Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods

Exempt Category 1

- What's likely not exempt
  - Radically new instructional strategies
  - Use of random assignment to different instructional methods
  - Research involving deception or withholding information
- Why?
  - Because these methods deviate from normal educational practices and could increase risk to subjects

Exempt Category 2 (Surveys)

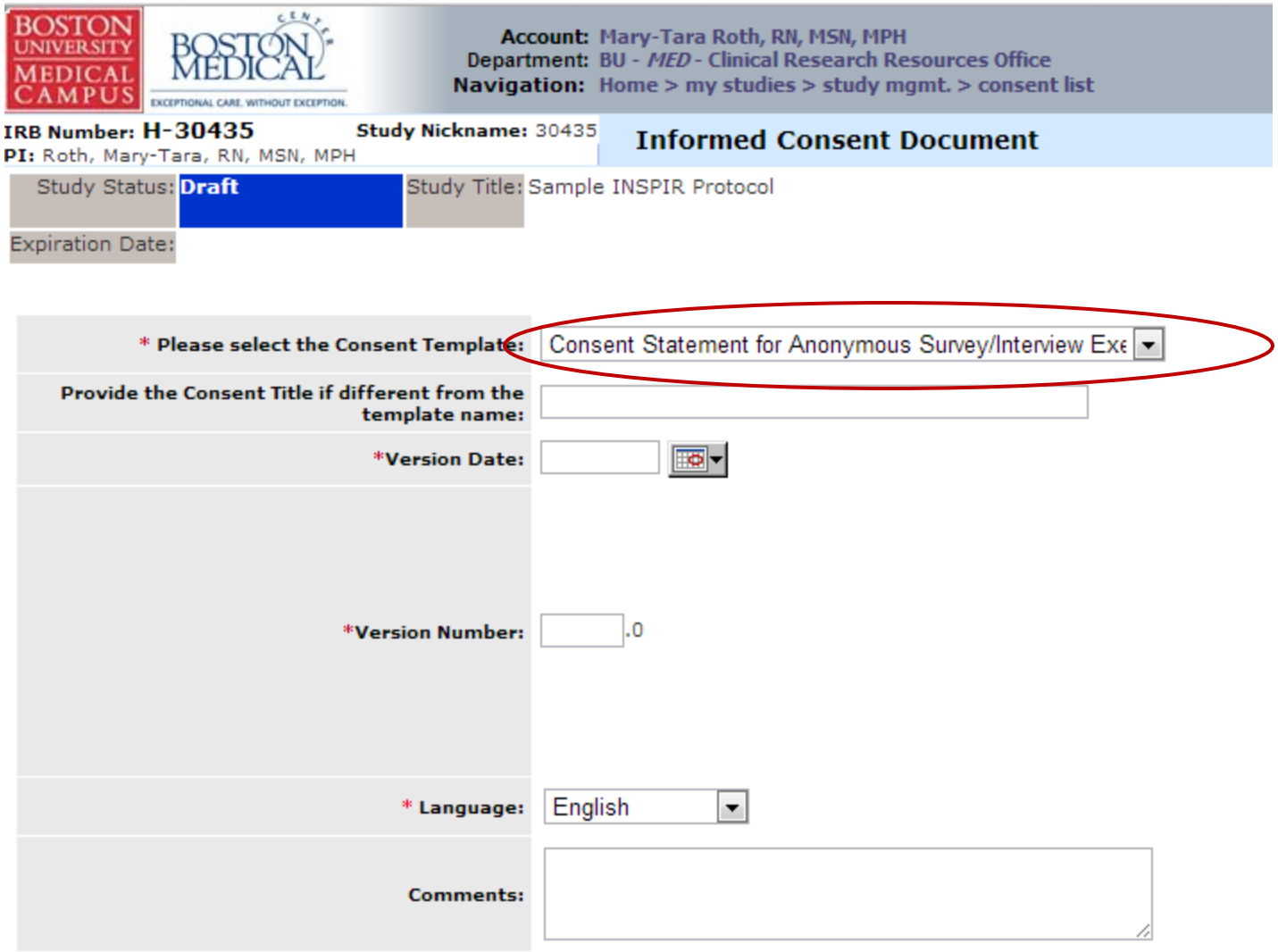
- Anonymous Educational Tests, Surveys, Interviews, or Observations of Public Behavior
  - Information obtained should be recorded in such a way that subjects cannot be identified
  - Subjects should not be placed at harm where any disclosure of responses outside the research could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

Exempt Category 2

- What's not exempt
  - Surveys/interviews of children
  - Surveys, etc. where there are sensitive questions **and** the subject can be identified.
- Why?
  - Because this could mean greater than minimal risk to the subjects

Exempt Categories 1 and 2

- Attach your survey/interview and/or data collection forms
- Consent
  - Consent form does not need to include all required consent elements
  - You DO want to tell people that this is a research study and it's voluntary
  - Use the consent form builder in INSPIR and choose the exempt consent template or modify the non-exempt template as appropriate


Account: Mary-Tara Roth, RN, MSN, MPH
Department: BU - MED - Clinical Research Resources Office
Navigation: Home > my studies > study mgmt. > consent list
IRB Number: H-30435
Study Nickname: 30435
PI: Roth, Mary-Tara, RN, MSN, MPH
Informed Consent Document
Study Status: Draft
Study Title: Sample INSPIR Protocol
Expiration Date:
* Please select the Consent Template:
Consent Statement for Anonymous Survey/Interview Exe
Provide the Consent Title if different from the template name:
*Version Date:
*Version Number:
.0
* Language:
English
Comments:

Cat 2 (Survey) Consent Statement should provide the following information:

- that this is a research study
- the purpose and what the subjects are being asked to do and approximately how long it will take
- that participation is voluntary and if they don't want to participate it will not impact their [jobs][care] in any way
- that they can choose not to answer any questions that they wish
- how their confidentiality will be protected
- payments for participation if any
- who to contact with questions about the study (must be a member of the research team)
- who to contact if they have questions about their rights as a research subject -BUMC IRB at 617-638-7207 or medirb@bu.edu

Exempt Category 4 (Retro review)

- Collection or Study of Existing Data (such as medical or research records)
  - All data/samples must exist at the time of IRB submission
  - All data must be recorded in a manner that subjects cannot be identified
    - No direct or indirect identifiers can be linked to the subject
  - Medical record reviews will ALWAYS involve HIPAA
  - Must describe in detail how records will be obtained and who accesses the medical record.

Exempt Category 4

- What's likely not exempt
  - Existence of HIPAA identifiers beyond a LDS
  - Existence even of an identifier, such as a code, that can be used to identify the subject
    - Should complete a Data Use Agreement, where the provider and recipient agree that the recipient will never receive the key to the code.
- Why?
  - Because this could mean greater than minimal risk as there is a greater chance for breach of confidentiality

Exempt Category 4

- Attach your data collection forms or list of data variables
- Remember HIPAA forms!
- Explain in detail how you will abstract the data from the medical record
  - If possible, utilize the Clinical Data Warehouse!
  - Is the person who is accessing the medical record for research someone who has access for their clinical role?
  - Your description must address specifically that you are not recording identifiable health information

Exempt Cat. 4: Tools to Help You

If you're serious about doing a good job, **these articles are MUST reads** and will save you a lot of time!!

- Working with Data:
  - CR Times Feature article:
    - "Privacy and Confidentiality Requirements in the Use and Disclosure of Information for Research," March, 2013
  - CR Times "From the CRRO" April 2012
    - "Going Retro?... Exempt Category 4 Submissions for Retrospective Chart reviews, and other studies using existing data/samples;" **see link in article to INSPIR app pdf w/comments**
  - Clinical Data Warehouse: Linda Rosen
    - http://www.bumc.bu.edu/ocr/clinical-research-clinical-warehouse-data-access/
    - Submit a data request form

NHSR

- Doesn't meet the definition of human subjects
  - *Data through **interventions or interactions** with the individual, or **Identifiable private information***
- Data/Sample provided to the investigator must be anonymous: NO LINK BACK for recipients
- Recipient completes a "Not Engaged in Human Subjects Research" form if a linking code remains.
  - If repository is collaborating and receiving data back… then not NHSR


Back to the Basics

So … you have a research question!

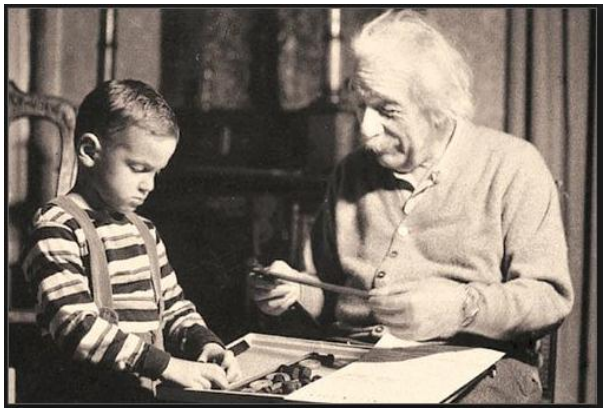
- What you need to get started:
  - Get a faculty advisor experienced in clinical research
  - Decide what your role is…
    - Will you be working on somebody else's protocol as staff member?
    - Or, do you have a new research question?
  - NIH Human Subjects Protections Training on file
  - INSPIR II access
    - BU username and Kerberos password

A Few Considerations….

- You can be Principal Investigator
  - List your faculty advisor in INSPIR section 3.4.
- New project vs. adding yourself to an existing protocol
- Feasibility (recruitment and study procedures)
- KISS Principle: *Keep it Simple Sunshine!* ☺
- Departmental approvals and other resources

Faculty Advisor

- Must be full-time faculty at BU/BMC.
- Help you refine your idea and design the research
- May serve as co-investigator on your protocol, or is PI of a protocol that you are added to.
- Review/submit the IRB application.
- Must sign-off on your protocol if you are PI (list in INSPIR section 3.4)
- Help you carry out the data analysis and write your paper.

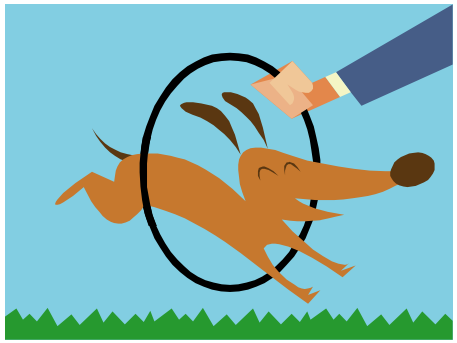


NIH Human Subjects Protections Training

- BU/BMC requires that researchers be “certified” in human subjects protection.

  http://www.bumc.bu.edu/ocr/certification/

- And don’t forget recertification via the Clinical Research Times if you plan to be here conducting research for > 2 years! http://www.bu.edu/crtimes



INSPIR (II)

- Integrated Network for Subject Protection In Research
  - BUMC's electronic, internet-based IRB system
  - https://inspir.bu.edu/iMedris/
- Need user name and kerberos password
  - bumchelp@bu.edu
  - x8-5914
- See CRTimes Feb. 2011
- Update your **personal profile** under "My Assistant," then "My Account."
  - You just have to do this once and you can only do it yourself.
  - Degree, Specialty, Primary number, Location, Affiliation, and Other Affiliation.

Tools to Help You: INSPIR Tutorials

www.bumc.bu.edu/irb

Boston University Medical Campus
Institutional Review Board

This Site | SEARCH

BUMC IRB INFO | INSPIR II | WIRB | UPSER, AES, DSMPS | IRB GUIDANCE | INTERPRETER SERVICES | LINKS

INSPIR II

INSPIR II stands for the **Integrated Network for Subject Protection In Research**. It is BUMC's electronic IRB system. The application runs on the internet so investigators can access it from any internet-connected computer around the world.

INSPIR II went LIVE! Click here (or on the image) to login.

A Farewell Song to INSPIR I

INSPIR II Overview and Announcements

On March 15, 2011, the BUMC IRB switched to a new IRB softwar[illegible] called INSPIR II (replacing INSPIR). All protocols from INSPIR I were migr[illegible]ver to the new system. Below are various resources for investigators to obtain information about INSPIR

- INSPIR II Instructions for Investigators
- Submit a INSPIR II Help Desk Request*
- Submit a Request to IS&T for a BU username and kerberos password
- Registration Form for Scheduling Department INSPIR II Training
- February 2011 CR Times Article
- INSPIR II Introductory Training Video
- INSPIR II Introductory Training PowerPoint

*INSPIR II Helpdesk Request – In order to efficiently route your questions to the most appropriate person in the IRB office, please submit an INSPIR II Helpdesk Request by going to this link.

INSPIR II FAQS

- User name/log-in/Personal Profile issues
- Migration Issues
- IRB Application Issues

Institutional Review Board

- BUMC IRB Info
- INSPIR II
  - INSPIR II Instructions for Investigators
  - Submit a INSPIR II Help Desk Request
  - Submit a Request to IS&T for a BU username and kerberos password
  - INSPIR II Super Users
- WIRB
- UPSER, AEs, DSMPs
- IRB Guidance
- Interpreter Services
- Links
- Research with Other Institutions
- Board Reviewers
- CRC IRB

News »

The February edition of the Clinical Research Times is on the newsstands!

Also See

Tools to Help You: INSPIR Tutorials

www.bumc.bu.edu/irb

Cheat Sheets

- INSPIR II Sections 1-10 (the mandatory sections)

How To

General

- How to log-in to INSPIR II
- How to update your Personal Profile (required for everyone listed on a study)
- How to update the department in your Personal Profile
- How to get the Study Assistant tab if you don't have it
- How to sign off on protocol as PI
- How to sign off on protocol by Department Chairs
- How to check the status of a submission
- How to add new internal investigators/resea
- How to send a study correspondence in INS
- How to view or print out the Approval Lette

New Study – Initial Reviews

- How to create a new protocol draft in INSPIR II
- How to find and open a draft in INSPIR II
- How to add a new Consent Form
- How to add a new Study Document
- How to setup Department Chair and Special Routing Sign Off
- How to sign off on protocol as PI
- How to sign off on protocol by Department Chairs
- How to respond to a Review Response for an Initial Review
- How to revise an existing Consent Form
- How to revise an existing Study Document

Tools to Help You

If you're serious about doing a good job, **these articles are MUST reads** and will save you a lot of time!!

- Working with Data:
  - CR Times Feature article:
    - "Privacy and Confidentiality Requirements in the Use and Disclosure of Information for Research," March, 2013
  - CR Times "From the CRRO" April 2012
    - "Going Retro?... Exempt Category 4 Submissions for Retrospective Chart reviews, and other studies using existing data/samples;" **see link in article to INSPIR app pdf w/comments**
  - Clinical Data Warehouse: Linda Rosen
    - http://www.bumc.bu.edu/ocr/clinical-research-clinical-warehouse-data-access/
    - Submit a data request form

Tools to Help You

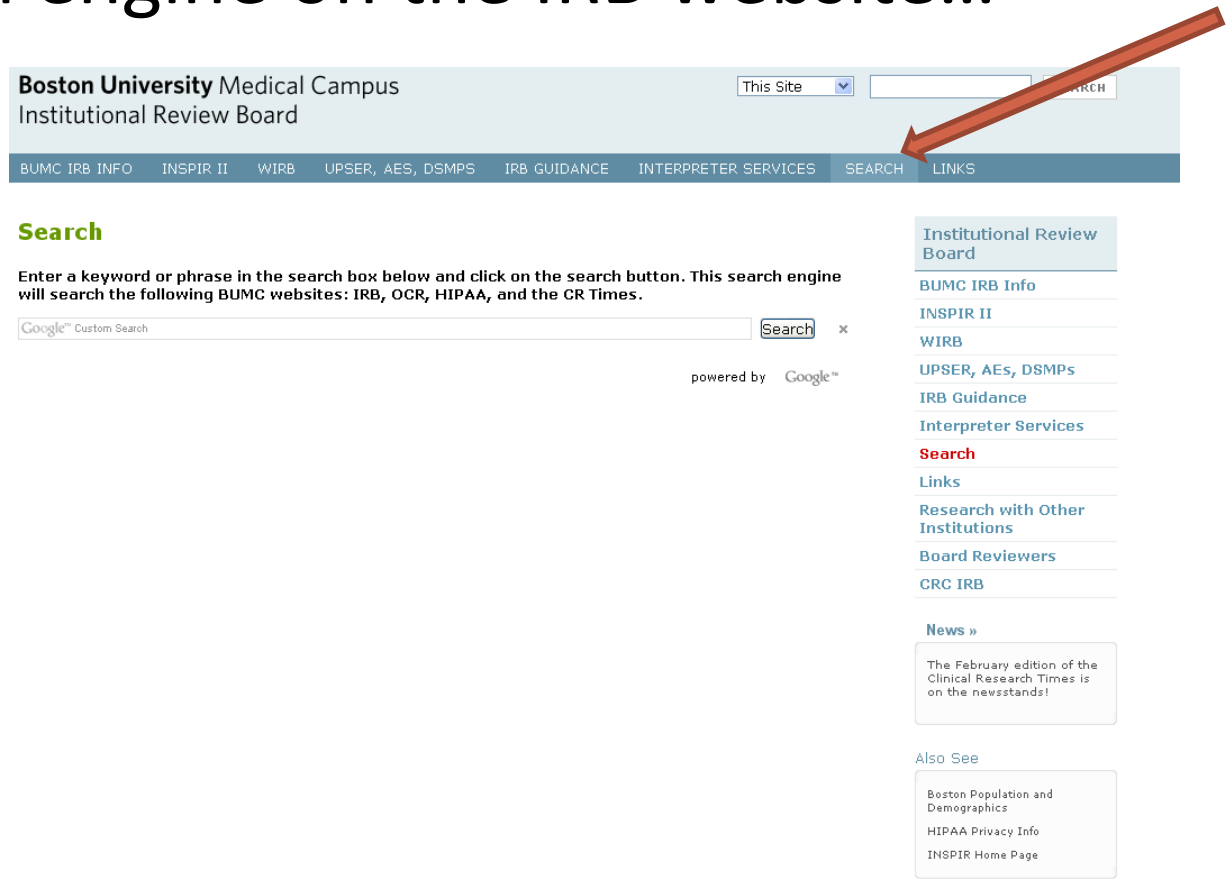
- CRTimes: www.bu.edu/crtimes
  - In particular, read the November 2011 feature article https://dcc2.bumc.bu.edu/ocr/ClinicalResearchNewsletter/article.aspx?article=369 (Improving IRB turn-around times)
- CTSI: http://ctsi.bu.edu/
  - Biomedical informatics, GCRU, statistical support, etc.
  - **REDCap** (Research Electronic Data Capture): secure web application for building and managing online surveys and databases.
  - **StudyTRAX:** electronic data capture system for clinical research
  - **Profiles**: web-based research networking tool
  - Much more!!!!
- Biospecimen Archive Research Core:
  - http://www.bu.edu/cores/cores/biospecimen-archive-research-core-barc/

Tools to Help You

- Clinical Research Resources Office (CRRO): www.bumc.bu.edu/crro
  - Regulatory and Recruitment support, consultation, services and tools.
  - ReSPECT Registry
    - Recruit participants from a Registry of individuals who sign up to hear about research studies taking place at BUMC.
  - StudyFinder
    - List your study to find participants or use it to look for someone with expertise and study interest you are looking for.

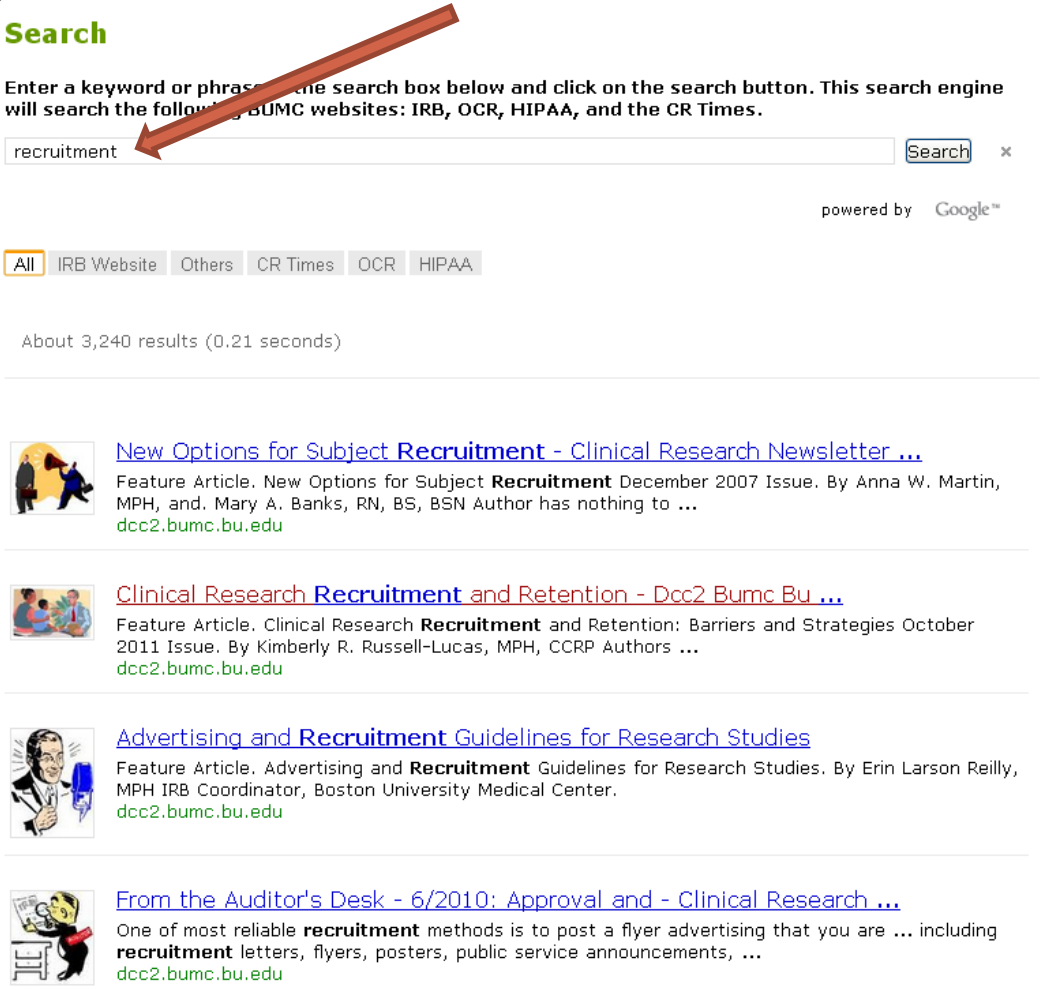
Tools to Help You

- Get an answer to your question with a simple search engine on the IRB website…

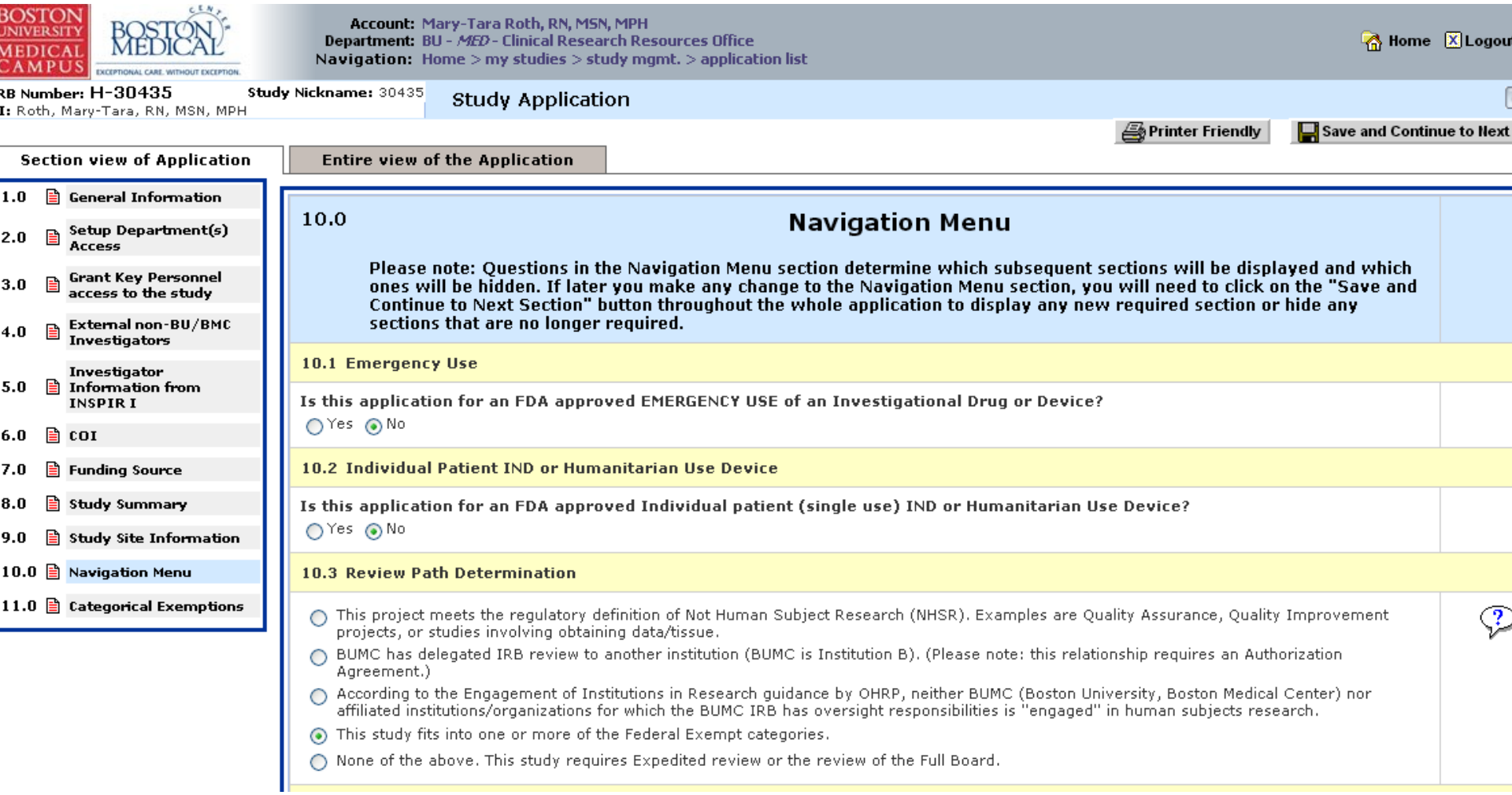


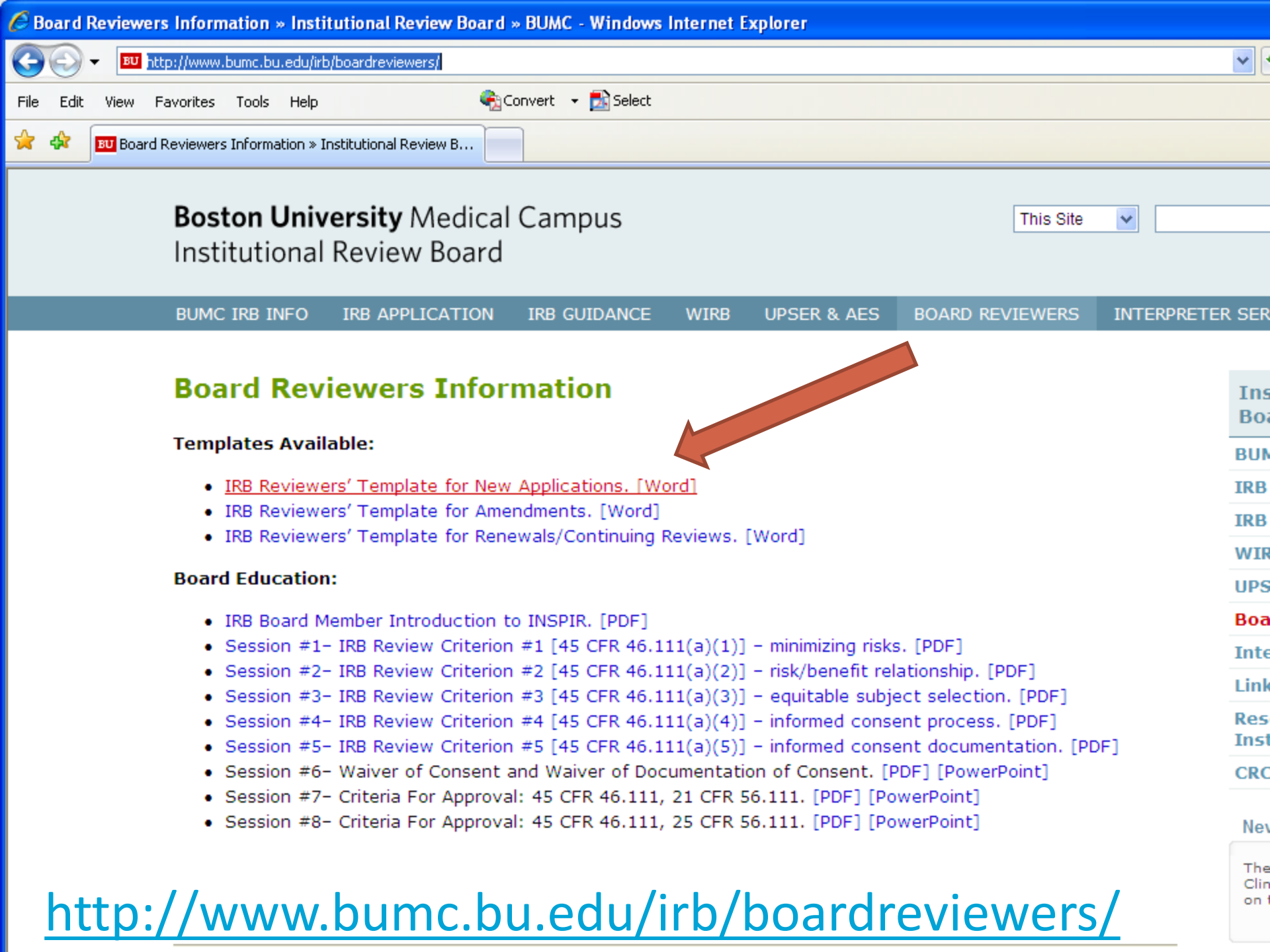
Tools to Help You

- Get an answer to your question with a simple search engine on the IRB website …



INSPIR example




Board Reviewers Information » Institutional Review Board » BUMC - Windows Internet Explorer
http://www.bumc.bu.edu/irb/boardreviewers/
File Edit View Favorites Tools Help
Convert
Select
Board Reviewers Information » Institutional Review B...
Boston University Medical Campus
Institutional Review Board
This Site
BUMC IRB INFO
IRB APPLICATION
IRB GUIDANCE
WIRB
UPSER & AES
BOARD REVIEWERS
INTERPRETER SER
Board Reviewers Information
Templates Available:
IRB Reviewers' Template for New Applications. [Word]
IRB Reviewers' Template for Amendments. [Word]
IRB Reviewers' Template for Renewals/Continuing Reviews. [Word]
Board Education:
IRB Board Member Introduction to INSPIR. [PDF]
Session #1- IRB Review Criterion #1 [45 CFR 46.111(a)(1)] - minimizing risks. [PDF]
Session #2- IRB Review Criterion #2 [45 CFR 46.111(a)(2)] - risk/benefit relationship. [PDF]
Session #3- IRB Review Criterion #3 [45 CFR 46.111(a)(3)] - equitable subject selection. [PDF]
Session #4- IRB Review Criterion #4 [45 CFR 46.111(a)(4)] - informed consent process. [PDF]
Session #5- IRB Review Criterion #5 [45 CFR 46.111(a)(5)] - informed consent documentation. [PDF]
Session #6- Waiver of Consent and Waiver of Documentation of Consent. [PDF] [PowerPoint]
Session #7- Criteria For Approval: 45 CFR 46.111, 21 CFR 56.111. [PDF] [PowerPoint]
Session #8- Criteria For Approval: 45 CFR 46.111, 25 CFR 56.111. [PDF] [PowerPoint]
http://www.bumc.bu.edu/irb/boardreviewers/

New Application

Name of Investigator: IRB Study #:
Title of Protocol: Date of Meeting:
Primary Reviewers:

SECTION A: TITLE, INVESTIGATORS & GENERAL INFORMATION	YES	NO	N/A
1. Does the staffing and expertise appear sufficient to conduct this research?	☐	☐	☐
2. Have Conflict of Interest forms been submitted?	☐	☐	☐
3. Is there any conflict of interest for the PI or other study personnel?	☐	☐	☐
Comments:			

SECTION D: BACKGROUND/RATIONALE/PURPOSE	YES	NO	N/A
1. Is there suitable justification for a study involving humans?	☐	☐	☐
2. Is the research problem/hypothesis adequately stated?	☐	☐	☐
3. Are the specific aims of the research and how these will contribute to scientific/medical knowledge adequately described?	☐	☐	☐
Comments:			

SECTION E: PROTOCOL RISKS/SUBJECTS	YES	NO	N/A
1. Is this research more than minimal risk? **Risk:** The probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude of possible harm may vary from minimal to significant. Federal regulations define only "minimal risk." **Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.102(i)]. For example, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of	☐	☐	☐

Make sure your IRB submissions are complete and "ready for prime-time" BEFORE submission to the IRB….. (and avoid common pitfalls!)

From many IRB letters……

"Administrative deferral:

This protocol has been administratively deferred because it is incomplete and not ready for IRB review."

Common Pitfalls to IRB Approval

What stands between you and a "smooth road" to IRB approval?

- Not seeking mentorship and guidance from experienced faculty.
- Failure to answer the INSPIR II questions in full.
- The summary fails to describe the research in lay language.
- The Background does not justify why the study should be done.
  - There is no clear answer to the “So what?” question.
  - There is no supporting evidence or justification from the literature.
  - SOC procedures vs. research procedures are unclear.

- Informed Consent Form is too complicated or the justification for why informed consent should be waived is missing/incomplete.
- Inappropriate recruitment plans or recruitment plans that are just not well-described.
- Key documents are missing.
  - e.g. surveys; data collection forms; the grant, project prospectus or thesis proposal.
- Study data collection forms have direct identifiers on them, such as name or MRN.

- Inconsistent terminology
  - Anonymous, de-identified, coded
- Insufficient routing of the application
  - (Biosafety, Pharmacy, GCRU, etc.)

Put your IRB Hat on!

- “Subjects will be given unique identifiers, and medical record numbers will not be used.”

Put your IRB Hat on!

- **IRB item (retro chart review):** Describe in detail how the research population will be identified and your methods for contacting potential subjects. If this study is a chart review or medical record review, explain how you will identify potential records to be reviewed.
- Response:

  As this is a retrospective chart review, there is no recruitment for this study.

Put your IRB Hat on!

- **IRB item (retro chart review):** Describe in detail how the research population will be identified and your methods for contacting potential subjects. If this study is a chart review or medical record review, explain how you will identify potential records to be reviewed.
- Response:

  No identification from the charts reviewed - they will NEVER be linked back to the subjects.

Put your IRB Hat on!

- **IRB item (anonymous survey study):** Describe in detail how the research population will be identified and your methods for contacting potential subjects. If this study is a chart review or medical record review, explain how you will identify potential records to be reviewed.
- Response:

  Households will be selected from within each community using a simple random sampling design. Heads of each household will be recruited for the study by visiting each household and requesting their participation in the study.

Put your IRB Hat on!

- Protocol says:
  - "The subjects will voluntarily fill out the anonymous survey during their clinic visit, and return the survey upon leaving. The survey will assess presence and, if present, the severity of xxxxx in the subject's life…."
- Questionnaire says:

B. Please fill in the following information:

Examiner Name:_____ Patient Name:_____

Today's Date:_____ Sex:_____ Date of Birth:_____

Year Symptoms Began:_____

Medications:_____ Dosage:_____

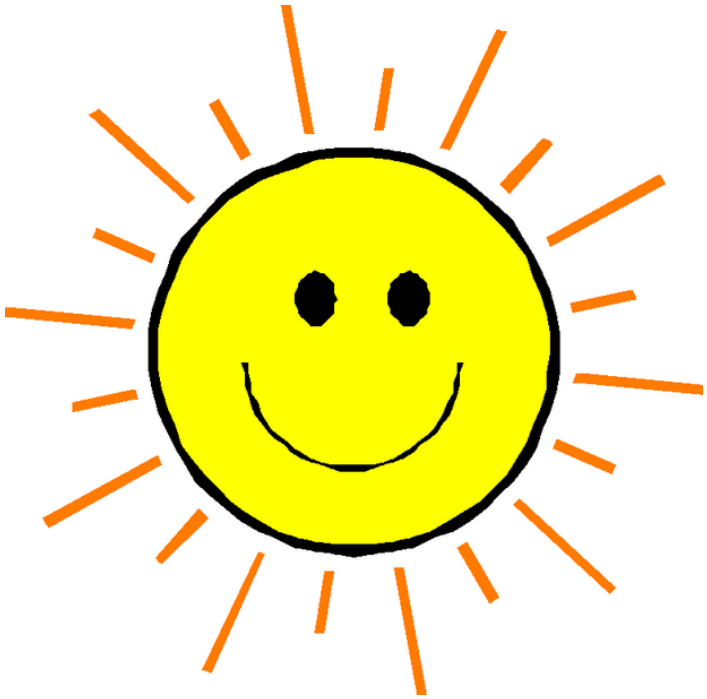
_____ _____

_____ _____

_____ _____

KISS Principle

Keep it Simple Sunshine!



Thank you!

Any questions?