

Dispelling Common Myths about the IRB

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BUMC IRB & Human Subjects Protection
- Clinical Research Seminar Series
- June 20, 2007



Misunderstood



“The man who is anybody and who does anything is surely going to be criticized, vilified, and misunderstood. That is part of the penalty for greatness, and every great man understands it; and understands, too, that it is no proof of greatness. The final proof of greatness lies in being able to endure continuously without resentment. “

-Elbert Hubbard, US author (1856-1915)

The IRB Gnome

**Will help by
pointing out myths
about the IRB**



"The IRB reviews clinical trials"



"Basic research is what I am doing when I don't know what I am doing."

-Wernher von Braun, rocket engineer (1912-1977)

IRB Review



- FWA (federal wide assurance)- all human subjects research no matter the funding source
- Review of all research involving human subjects
 - Meets definition of research
 - Meets definition of human subjects
- Includes social behavioral, chart review, student research, international research, surveys, tissue samples, satisfaction surveys, data bases & blood/tissue repositories
- BUMC IRB makes determinations about whether studies are Exempt from further IRB review
 - One of the OHRP Exempt Categories
 - Exempt because it is by definition NHSR
 - Exempt because BUMC is not engaged in the research

“IRB members are a bunch of regulatory functionaries who can’t possibly understand my research”

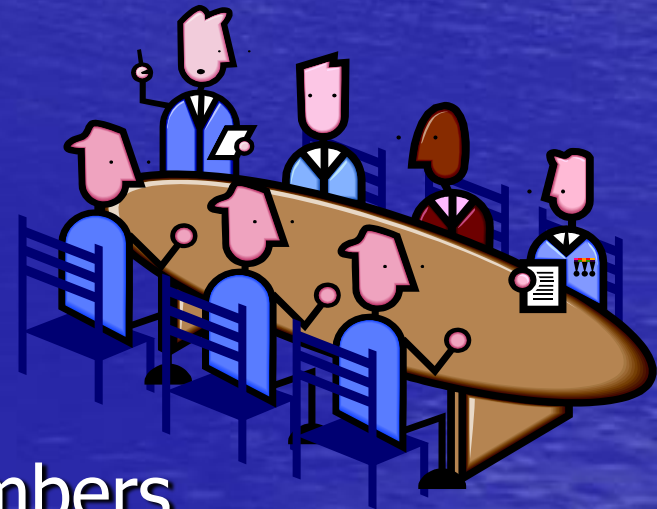


“If we knew what it was we were doing, it would not be called research, would it?”

-Albert Einstein US physicist (1879-1955)

IRB Composition

- MDs, DMDs, RNs, PharmDs, RPhs, MSWs, MPHs, statisticians, administrators, community members, lawyers, ethicists
- Many IRB members are also researchers
- Consultants are used as needed
- IRB understands the challenges of conducting research (recruitment, deadlines, \$\$, etc.)
- Bound by the regulations
- Continuous training as board members



IRB Meetings are Secret

No Investigators Allowed



*All secrets are deep. All secrets become dark.
That's in the nature of secrets.*

- **Cory Doctorow**, *Someone Comes To Town, Someone Leaves Town*, 2005
Canadian science fiction writer

IRB Meetings You are Invited



- Any investigators can attend
- Must make an appointment- call the IRB Office (Tasha) 638-7207
- Lunch is served
- Must declare any conflicts of interest
- Must agree to keep anything that is heard confidential including the vote
- Must leave the room during final discussion and vote of any protocols related to you
- Investigators can also ask to meet with the board to explain aspects of their research or appeal board decisions

“IRB Review is a Moving Target” (the IRB rules are always changing)



“ It is an error to imagine that evolution signifies a constant tendency to increased perfection. That process undoubtedly involves a constant remodeling of the organism in adaptation to new conditions; but it depends on the nature of those conditions whether the directions of the modifications effected shall be upward or downward.”

-Thomas H. Huxley, English biologist (1825-1895)

IRB Strives for Consistency

- IRB rulings based on the regulations- the regulations don't change but the regulatory interpretation does
- In order to conditionally approve a study it must meet all of the 45 CFR 46.111 criteria
- Board Education re: interpretation of the regulations
- Executive Committee
- Some members serve on all boards
- Boards are made up of people - so variations in decisions will occur
- Not all "apparent inconsistencies" are really inconsistencies



If you can't tell
the standard of care from the
research just send it to the
IRB and they will figure it out.

*I'm an idealist. I don't know where
I'm going, but I'm on my way.*

– Carl Sandburg, *Incidentals* (1907)
US biographer & poet (1878 - 1967)



IRB review of protocols

- Don't rely on the IRB to figure out your research because questions=delay
- If the IRB thinks that the researchers do not have a clear idea of what they are trying to do (unclear research question and plan) they are reluctant to approve the research
- Present a well thought out protocol



Deferrals



- Most deferrals
 - Incomplete or insufficient information (i.e. detailed protocol, drug/device brochures, incomplete recruitment plan)
 - Can't distinguish standard of care from the research – if the IRB has to figure this out it will delay the review and create confusion for the reviewers

Before Submitting to the IRB

- Every time a protocol is sent back there is more delay in processing- BEFORE SUBMITTING
 - Check IRB website for human subjects training on file for all persons listed as investigators
 - Get all signatures- can't reroute for signature
 - Answer all items in the mod memo and make the related changes to the protocol
 - Make sure that the attachments can be opened (no symbols in the file name)

Before submitting cont.

- Consent forms
 - Match the risks / benefits section of consent to the protocol
 - Consider the alternatives
 - READ the PRINT version before submission
 - Give the consent to a “objective reader” before submitting
- HIPAA forms
 - Don't just submit the template language
 - Customize them to fit the protocol

**The IRB hates studies with risk
so it is best to say there is no
risk**



*The universe will reward you for taking
risks on its behalf. Shakti Gawain*

RISKS



- People think that the IRB doesn't like risk
- Or can't approve studies with risk
- Or that social/behavioral research has no risk
- Almost all studies have some risk
- Must not consider only risks of physical harm
- Risk of criminal or civil liability, loss of employment, loss of insurability, risk of stigmatization, etc.
- Risk of loss of confidentiality

"I Have IRB Approval, No One Can Stop Me Now"



"Damn the torpedoes, full speed ahead!"

- David Glasgow Farragut (1801-1870)

You cannot conduct human research without IRB Approval, but IRB Approval does NOT mean that you can conduct the research

- IRB review = ethical review
- IDS Pharmacy review
- Scientific review (IBC, HGTC, Biomedical Engineering, Radiation Safety, etc.)
- Department Chair Review
- Departmental review (Nursing, MCH, Psych)
- Fiscal concerns / resources (labs, MRI, etc.)
- Scholastic review for students
- Review by other IRBs or signed agreements
- Permission to conduct research



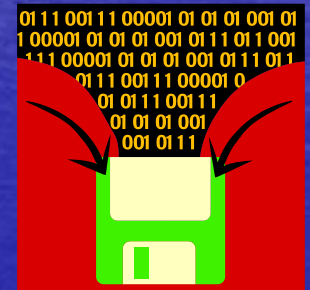
**"Once I collect data
I can keep it and use it
forever"**



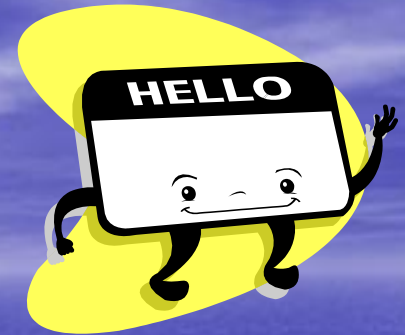
"Possession is nine tenths of the law."
~ old adage (my mother)

Databases and Databanks

- May only use data for purposes approved by the IRB
- Cannot keep it and use it for other analysis without IRB approval
- IRB determines whether additional consent will be required
- January 2007 CR Times
- Obtain consent for future use at the time of the original consent



Kinds of Data



- **Anonymous**- identity of subjects cannot be ascertained by
 - Direct identifiers
 - Indirect identifiers
 - Deductive disclosure
- **Identifiable**- data can be linked back to the subjects BY SOMEONE
- **De-identified**- all of the 18 HIPAA identifiers have been removed

Explaining Data Collection and Storage in the Protocol

- Use the same terminology as the IRB
- When possible data must be collected so that direct identifiers are not on the data collection forms – affords additional protection to subjects
- Master codes
 - Used to link study data to subjects' identities
 - Master code stored separately – who will have access
 - Data stored as hard copies in files, on the network, on CD, etc.
- Consider protection from theft or loss



**"Wow, My Study is
Getting
Expedited Review !
That means a fast
approval "**



"I took a speed reading course and read 'War and Peace' in twenty minutes. It involves Russia.

— Woody Allen

US movie actor, comedian, & director (1935 -)

How fast ?



- Expedited does not mean fast-tracked, just needs review by one reviewer rather than full board
- Exempt means exempt from some of the regulatory requirements but not exempt from IRB review
- Turn around time depends on many factors
- Single most significant factor- quality of the submission
- Second most significant factor- rapidity of PI's response to "mod memos"

How Long Does IRB Review Take ?

<u>IRB:</u>	<u>2004</u>	<u>2005</u>	<u>2006</u>
Protocols:	1,360	1,606	1,600
PIs:	509	542	559

- not a lot of national data
- BUMC is as fast if not faster than others



	Days From Submission to Approval or Deferral
All BUMC protocols 1/06-6/06	39.00
Full Board (Mean)	49.55
Full Board (Median)	44.39
Expedited (Mean)	39.83
Expedited (Median)	32.51
Exempt (Mean)	32.23
Exempt (Median)	27.63

**“Thank God, my study is
only a chart review so I
don’t need consent
(because there are no
subjects)”**

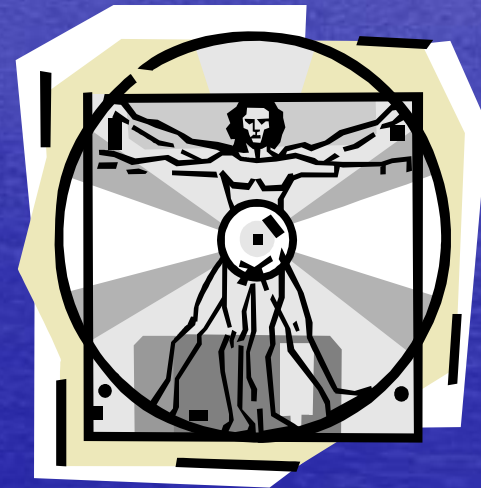


*“Knowledge is of two kinds: we know a subject
ourselves, or we know where we can find
information upon it.”*

-Samuel Johnson, English author (1709-1784)

Consent Requirements

- Consent is required for all non-Exempt research unless waived by the IRB
- Includes chart reviews
- HIPAA research rules
 - Protected health information-authorization needed unless exempt or waived by the PRIVACY BOARD
 - IRB reviews Research HIPAA
- Living individual **about whom** a researcher collects information through
 - Interaction or intervention
 - Obtaining private identifiable information



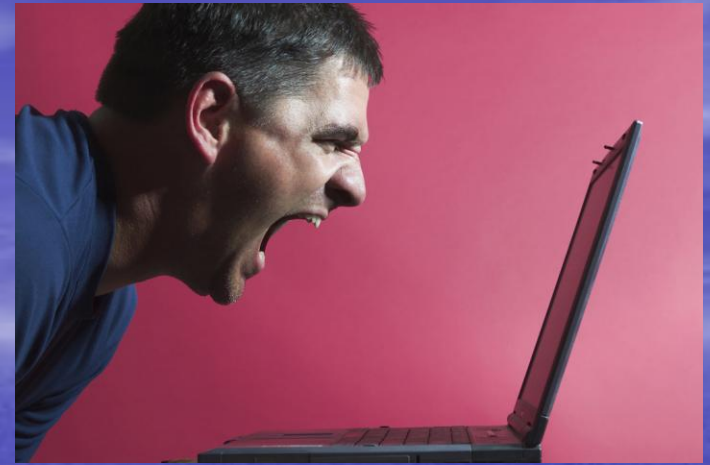
"INSPIR doesn't make sense"



When I'm inspired, I get excited because I can't wait to see what I'll come up with next.

-Dolly Parton

Be INSPIREd



- Change in turnaround time since INSPIR
- Ability to see what the investigators see
- One spot for all of the records
- No more lost files or documents
- Version II- when will it ever be here??

FileEditViewFavoritesToolsHelp

Back

Search

Favorites

Web Search

Search

Address

http://www.bumc.bu.edu/Dept/Content.aspx?DepartmentID=293&PageID=3704

Best of the Web

Channel Guide

Customize Links

Free AOL & Unlimited Internet

Free Hotmail

Internet Start

Microsoft

Windows

Google

Go

Bookmarks

5 blocked

Check

AutoLink

AutoFill

Send to

Settings

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Institutional Review Board

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Getting Started with Research

Human Subjects Protection Training - Certification / Recertification

BUMC IRB Information

Completing an IRB Application

New Application

Exempt Research

Protocol Closure

Adverse Events

HIPAA Privacy Info

Signature Role in INSPIR

Board Reviewers Information

Completing an IRB Application

NEW FORMS

The IRB submission process is now electronic. All submissions to the IRB must be done using INSPIR . For more technical information concerning INSPIR, click on "INSPIR" in the left-side menu.

If you have any questions the IRB Staff will be available to assist you. Our phone number is (617) 638-7207. Please use this number when calling the Office and list this number on all informed consent forms.

There are three panels of the IRB: Panel Blue, Panel Green, and Panel Purple. Panels Blue and Green meets twice per month, on alternate Thursdays. Panel Purple meets once or twice per month as needed, to review primarily Progress Reports. There are a limited number of protocols accepted for each agenda. Studies are placed on an agenda in a rolling fashion, in the next available agenda opening.

As part of our quality assurance effort, all applications must be complete upon submission in order to be eligible for IRB review. An incomplete application will not be placed on an agenda until all required information is submitted. The INSPIR system will help by identifying some, but not all, of the omissions in an application.

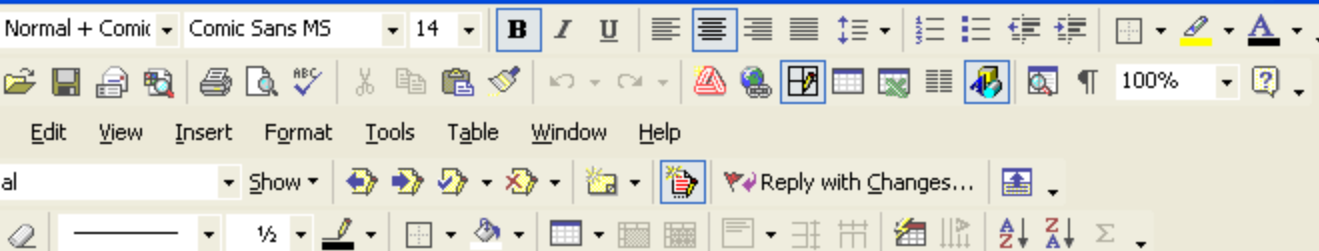
How to complete a new application in INSPIR (.doc)

How to complete a new INSPIR Application for Exempt Research (.pdf)

How to Close a Study in INSPIR (.doc)

http://www.bumc.bu.edu/Dept/Content.aspx?DepartmentID=293&PageID=3704

Internet



Type a question for help

How to Complete an INSPIR Application

Section	Type of Information	New Protocols
A1	Title	For sponsored protocols be sure to include version number
A2	PI	<p>Must be a member of the faculty or staff of BU/ BMC</p> <p>Cannot be intern, resident, fellow</p> <p>Does not have to be the PI listed on the grant (can be a co-investigator from the grant)</p> <p>PI must be listed in the INSPIR database (list of all investigators who have registered for to use INSPIR) and have a forwarding email in INSPIR. See INSPIR web page. If no email address is listed when the PI's name is selected, then the PI must update his/her BU directory listing by clicking on the link in blue ink in the paragraph below or by contacting the BUMC IT Help Desk at 617-638-5914.</p> <p>A PI must have an email address in INSPIR to be allowed PI status in the system. A PI may opt NOT to receive emails regarding individual protocols by using the SET PRIVILEGES function but he/she must still have a forwarding email address listed in the BU directory.</p>
A2	Required Approval	<p>PLEASE NOTE: THIS IS A CHANGE FROM PREVIOUS INSTRUCTIONS:</p> <p>Your Department/Section/Center profile no longer determines who will approve your protocol before IRB review. You can use these fields to select your own department, school and section under your name.</p> <p>To select a department signature, go to the "Certification/Submit for Approval" section, and under "Routing", select the required department chair signature from the drop down list.</p>
A3	Admin Contact	<p>PLEASE NOTE: THIS IS A CHANGE FROM PREVIOUS INSTRUCTIONS:</p> <p>Use this section to name the Study Coordinator or Key Contact person (other than the PI) for the study. You are not required to list an administrative contact if there is none. You can NOT list</p>



Progress Reports are a Waste of Time

*If there is no struggle, there is no
progress.*

- **Frederick Douglass**
US abolitionist (1817 - 1895)



Progress Report



- Opportunity to check in with the IRB
- Opportunity for investigators to review the protocol and consent and make sure they accurately reflect the current status of the protocol
 - Right investigators
 - Right interventions, time frames, tools/forms
 - Consent procedures and consent forms
 - Recruitment practices including all ads, internet materials
- **Be sure to include DSMB report, sponsor's update, safety updates
- Long term follow-up vs. research interventions continue
- Read the complete protocol and make sure it is consistent with the current research
- Read the PRINT version of the consent form



**“If the IRB doesn’t
approve your study just
give up because it is
never going to be
approved”**

*“If at first you don't succeed, try, try, and try
again. Then give up. There's no use being a
damned fool about it. “*

— William Claude Dunkenfield (W. C. Fields)



How to Get IRB Help

- IRB almost never disapproves studies, frequently defers
- IRB staff tries to review protocols prior to sending to the board and administratively defer incomplete submissions
- Nancy Bartlett, IRB Educator **414-4347** or nbartlet@bu.edu will help investigators
- Investigators can come to the IRB meeting (but proposal must stand alone)
- Investigators can appeal the IRB decision (in writing)
- Investigators can meet with IRB staff to draft their responses to the modification memo



**“ I’ve done my NIH
(Human Subjects)
training so I never have
to do it again”.**

*“A little learning is a dangerous thing but a lot
of ignorance is just as bad.*

—Bob Edwards

Human Subjects Training Requirements

- Initial certification
 - Live training BUMC class or
 - NIH on-line training
- Recertification every two years
 - Feature articles in the CR Times
 - Answer correctly 75% of the test questions
 - No substitute for CR Times reading
- **Recertification due by 6/30/07**
- For more information www.bu.edu/crtimes



**“She is never
going to stop talking”**



“Nothing is more despicable than a professional talker who uses his words as a quack uses his remedies.”

— *Francois de Salignac*
French archbishop & author (1651 - 1715)

The End

“Don't let it end like this. Tell them I said something.”

— Pancho Villa, last words

Mexican bandit & revolutionary (1877 - 1923)