Responsibility 1 Advising

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September 2008

Whom Does IRB Administrator Advise?

"Advisees"

- Researchers/Staff
- IRB & Chair
- Upper-level Administration

"Advisees" Continued

- Other Administrative Units (e.g. Grants/Contracts, Institutional Biosafety, Clinical Trial Office, etc.)
- Colleagues in IRB Office

Critical IRB Administrator Role

- Managing Conflict Between Needs of "Advisees"

Managing Effectively

- Important for IRB Administrator to be Able to Explain Both What and Why!
- Long-term Goals: Understanding Why & Analytically Apply "What"

"What" Does IRB Administrator Need to Know to Advise?

Core "What"

1. Basic Regulatory Requirements/Policy
2. Additional "Auxiliary" Requirements/Guidance
3. Sponsor Policy/Procedures

Core "What"

4. State Laws
5. IRB/Institutional Policy/Procedures
6. Ethical Principles

Basic Regulations

- Common Rule – 19 Agencies*
- DHHS 45 CFR 46 A, B, C & D*
- FDA 21 CFR 50 & 56*
- Health Insurance Portability & Accountability Act of 1996 (HIPAA)

*Boring: But Read!!

Federal Policy "Common Rule"

- Effective August 19, 1991
- Adopted by 19 Federal Agencies
- Based on Subpart A 45 CFR 46

Common Rule Agencies

7 CFR 1c	Agric	38 CFR 16	VA
10 CFR 745	DOE	45 CFR 46	HHS
14 CFR 1230	NASA	45 CFR 690	NSF
15 CFR 27	Commerce	49 CFR 11	DOT
16 CFR 1028	CPSC	40 CFR 26	EPA
24 CFR 60	HUD	22 CFR 225	AID
28 CFR 46	DOJ	Policy	OSTP
32 CFR 219	DOD	PL 108-458	DHS
34 CFR 97	Education	PL 103-296	SSA
		EO 12333	CIA

Jeff Cooper, IRB 201

Department of Health and Human Services
45 CFR 46

- Subpart A - Core Requirements
- Subpart B - Pregnant Women, Human Fetuses, and Neonates
- Subpart C - Prisoners
- Subpart D - Children

Food and Drug Administration

- 21 CFR Part 50 Informed Consent
- 21 CFR Part 50 Subpart D Children
- 21 CFR Part 56 Institutional Review Board

- IRB Administrator Role is to Know Which Regulations Apply to His/Her IRB & Its Research Program

Which Regulations Apply
Depends Upon:

- Local Policy
- Nature of Research
- Who Funds Research

When Does DHHS, FDA or HIPAA Apply to a Human Research Protection Program?

Applicability: DHHS*

- Submitted to DHHS
- Conducted / Funded by DHHS
- Involves "Research"
- Involves "Human Subjects"

*Local Policy Usually Applies to "All" Research

"Research"

A Systematic Investigation Designed to Develop or Contribute to Generalizable Knowledge.

45 CFR 46.102 (d)

"Human Subject"

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)

Office for Human Research Protection (OHRP)

1101 Wootton Parkway, Suite 200
Rockville, MD 20852
Toll-Free Within U.S.
(866) 447-4777
http://www.hhs.gov/ohrp/

Applicability of Assurance

- Does Your IRB Operate Under an OHRP Approved Federal Wide Assurance?
- What is an Assurance?
- Is Your IRB Registered with OHRP?

Useful Documents

- January 1999 Engagement Memorandum OHRP
  http://www.hhs.gov/ohrp/humansubjects/assurance/engage.htm
- October 2006 Draft OHRP Guidance on Engagement of Institutions in Human Subjects Research
  http://www.hhs.gov/ohrp/requests/engage.pdf

  Engagement Comparison Table
  http://www.hhs.gov/ohrp/requests/engagetable101006.pdf

Useful Documents Continued

- August 2004, OHRP "Guidance on Research Involving Coded Private Information or Biological Specimens"
  http://www.hhs.gov/ohrp/humansubjects/guidance/cdebiol.pdf

Applicability: FDA

- Clinical Investigations
- Regulated Products Drugs, Devices, Biologics, Food/Color Additives

"Clinical Investigation"

Clinical Investigation - Any Experiment in Which a Test Article is Administered or Dispensed To or Used Involving One or More Human Subjects. Clinical Investigation Does Not Include the Use of a Marketed Drug in the Course of Medical Practice.

"Human Subject"*

"...an Individual Who Is or Becomes a Participant in Research, Either as a Recipient of the Test Article or as a Control. A Subject May be Either a Healthy Human or a Patient."

*21 CFR 50.3(g)

FDA Device Definition of Human Subject

"A Human Who Participates in an Investigation, Either as an Individual on Whom or on Whose Specimen an Investigational Device is Used or as a Control. A Subject May be in Normal Health or May Have a Medical Condition or Disease."

21 CFR 812.3(p)

FDA

Good Clinical Practice Program
gcp.questions@fda.hhs.gov

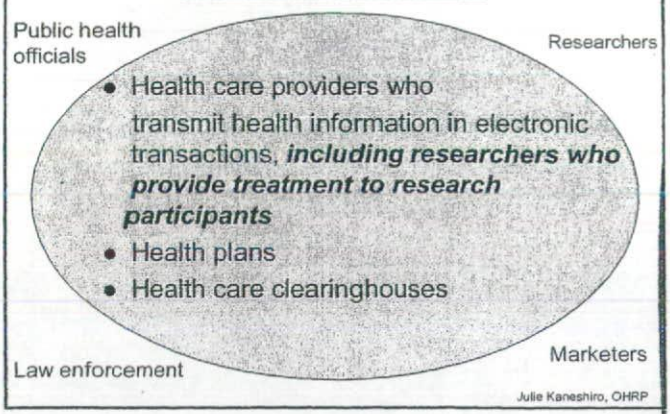
When Does HIPAA Apply to Research?

Applicability

HIPAA
DHHS/Office for Civil Rights

Health Insurance Portability and Accountability Act of 1996

Who is Covered?



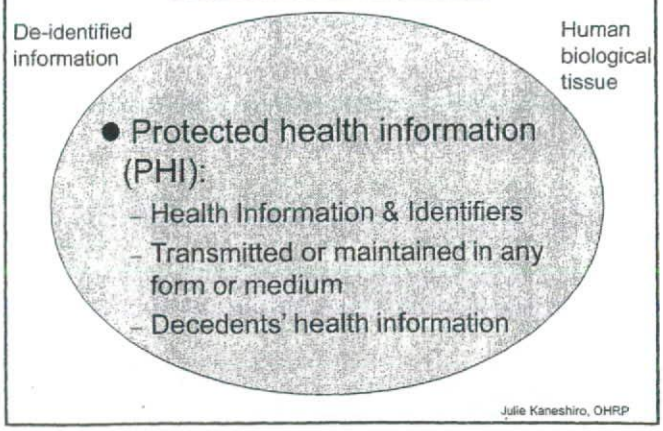
Julie Kaneshiro, OHRP

Types of Covered Entities

- Free Standing, Single Entity
- Hybrid Entity
- Affiliated Covered Entity (ACE)
- Organized Health Care Arrangement (OHCA)

Pearl O'Rourke
Partners Health Care

What is Covered?



Julie Kaneshiro, OHRP

What is an Identifier in the Privacy Rule?

The Privacy Rule defines 18 identifiers

- Names
- Geographic info (including city, state, and zip)
- Elements of dates
- Telephone #s
- Fax #s
- E-mail address
- Social Security #
- Medical record, prescription #s
- Health plan beneficiary #s
- Account #s
- Certificate/license #s
- VIN and Serial #s, license plate #s
- Device identifiers, serial #s
- Web URLs
- IP address #s
- Biometric identifiers (finger prints)
- Full face, comparable photo images
- Unique identifying #s

Lora Kutkat, NIH Office of Science Policy

Basic Regulations

- Common Rule – 19 Agencies*
- DHHS 45 CFR 46 A, B, C & D*
- FDA 21 CFR 50 & 56*
- Health Insurance Portability & Accountability Act of 1996 (HIPAA)

*Boring: But Read!!

Basic Regulations
What is Administrator's Role?

- Be Expert on Basic Regulations
- Use Knowledge to Advise on "What"
- Use Knowledge to Explain "Why"

Key Resources Available

- FDA Information Sheet Guidances: Guidance for Institutional Review Boards, Clinical Investigators, and Sponsors
  http://www.fda.gov/oc/ohrt/irbs/default.htm
- OHRP Listserv
  http://www.hhs.gov/ohrp/news/distributionlist.html
- OHRP Compliance Oversight Activities: Significant Findings and Concerns of Noncompliance
  http://www.hhs.gov/ohrp/compliance/findings.pdf

Key Resources Available Continued

- Office of Human Research Protections (OHRP)
  http://www.hhs.gov/ohrp/
  - Guidance on Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events (January 2007)
    http://www.hhs.gov/ohrp/policy/AdvEvntGuid.pdf
  - Guidance on Continuing Review (January 2007)
    http://www.hhs.gov/ohrp/humansubjects/guidance/contrev0107.pdf
  - Guidance on Written IRB Procedures (January 2007)
    http://www.hhs.gov/ohrp/humansubjects/guidance/irbgd107.pdf

Key Resources HIPAA

- NIH's Protecting Personal Health Information: Understanding the HIPAA Privacy Rule
  http://privacyruleandresearch.nih.gov/
- NIH's Institutional Review Board and the HIPAA Privacy Rule
  http://privacyruleandresearch.nih.gov/irbandprivacyrule.asp

US Department of Veteran Affairs

- Do You Work at a Veteran Affairs IRB or at an Affiliated IRB that Reviews VA Research?
- If So, Numerous Additional Basic Regulations/Policies Apply
- Must be an Expert

Veterans Affairs

- 38 CFR Part 16 and Sections of Part 17
- Veteran Health Administration Handbook 1200.5
- Accreditation Required

Veterans Affairs

- Program for Research Integrity Development, and Education (PRIDE) (202) 461-1811 http://www.research.va.gov/programs/pride/default.cfm
- Office of Research Oversight (ORO) (202) 461-8084 http://www1.va.gov/oro/

Other Core "What"*

2. Additional "Auxiliary" Requirements
3. Sponsor Policy/Procedures
4. State Laws
5. Institutional/IRB Policy/Procedures
6. Ethical Principles

*Will Only Discuss 2, 3, & 6

Administrator Role for Auxiliary Requirements

- To Identify When Auxiliary Requirements Apply
- To Know Where to Find Requirements
- To Have a General Working Knowledge
- Use Knowledge to Advise

Examples of Auxiliary Laws

- Dept of Education
  - 34 CFR 97 Subpart D
  - 34 CFR 98
  - 34 CFR 99
  - 34 CFR 350.4(c)
  - 34 CFR 356.3(c)
- Dept of Justice
  - 28 CFR 512 Subpart B
- Dept of Energy
  - Order 443.1
  - Order 481.1A
  - 10 CFR Part 850
- Dept of Defense
  - 10 USC 980
  - DoDD 3216.2
  - DoDD 6000.8
  - DoDD 6002.2
  - AFI 40-402
  - AFI 40-403
  - AR 70-25
  - AR 40-38
  - SECNAVINST 3900.39B
  - NMRDINST 3900.2
  - BUMEDINST 6000.12
  - NSHSBETHINST 6000.41A
  - USUHS Instruction 3201

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Examples of Auxiliary* Requirements

- FDA Investigational Drug Exemptions 21 CFR 312, 314
- FDA Investigational Device Exemptions 21 CFR 812, 814

*See IRB Resource Guide for Examples

Examples: Auxiliary

- 21 CFR Part 20 & 814.124 Medical Devices: Humanitarian Use Devices (HUD) – 6/96
- "Informed Consent Requirements for In Vitro Medical Device Clinical Investigations Conducted Under FDA's Interim Final Rule at 21 CFR 50.23(e)", June 2006, OHRP http://www.hhs.gov/ohrp/humansubjects/guidance/invitrodev.pdf

DHHS Guidance

- "Financial Relationships and Interests in Research Involving Human Subjects: Guidance For Human Subject Protection"
- Federal Register/Vol. 69 No. 92/ Wednesday, May 12, 2004/ p. 26393-26397

Example: Auxiliary Requirements

- Confidentiality Certificates DHHS http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.pdf
- Family Educational Rights and Privacy Act (FERPA) http://www.ed.gov/offices/OII/fpco/ferpa

Not All Auxiliary Requirements or Guidance are Federally Issued

Examples: Additional Auxiliary Guidance

- Association for the Accreditation of Human Research Protection Programs
- Joint Commission on Accreditation of Healthcare Organizations
- Model Tribal Research Code

Sponsor Policy/Procedures

- Sponsors: Agency that Funds Research
- Can be Federal or Industry or State or Private Foundation or ??

Administrator Role for Sponsor Policy/Procedures

- To Identify When Sponsor Requirements Apply
- To Know Where to Find Requirements
- To Advise IRB & Researchers

Examples/Sponsor
US Department of Education

- Subpart D
- Membership
- Protection of Pupil Rights Amendment (PPRA) [No Child Left Behind] http://www.ed.gov/offices/OII/fpco/ppra

Example Sponsor
National Science Foundation (NSF)

- NSF http://www.nsf.gov/bfa/dias/policy/hsfaqs.jsp
- America Creating Opportunities to Meaningfully Promote Excellence in Technology, Education, and Science (COMPETES) Act of 2007
  - Postdoctoral Research Fellows Mentoring Activities – Research Ethics Training
  - Responsible Conduct of Research – Undergraduate Students, Graduate Students, & Postdoctoral Researchers
  - Fact Sheet: http://www.whitehouse.gov/news/releases/2007/08/20070809-6.html

Other DHHS/Sponsors
Examples

- National Cancer Institute
- Centers for Disease Control
- General Clinical Research Centers/National Institute of General Medical Sciences
- Department of Defense
- US Department of Energy

Core "What"

Ethical Principles

Ethical Principles

- Respect for Persons
  - Consent, Privacy, Confidentiality
- Beneficence
  - Risks Versus Benefits
- Justice
  - Equity

Belmont Report, 1979

Ethical Principles
IRB Administrator Role

- Understand Ethical Principles & Be Able to Apply Them
- Assist Investigators in Applying Ethical Principles in Designing Protocol
- Advise IRB on Ethical Issues Should Raise During IRB Review

Ethical Principles
IRB Administrator Role Continued

- Use Ethical Principles to Explain Why IRB Requested Changes
- Use Ethical Principles to Explain Why Federal and IRB Regulations/Policies are in Place

Responsibility #2 Managing Protocol Review

Thanks to Susan Kornetsky
Childrens Hospital, Boston MA

What Requires IRB review

- What is an administrator's in responsibility in determining whether an activity is research and involves a human subject?

A systematic investigation designed to develop or contribute to generalizable knowledge.

A living individual about whom an investigator... conducting research obtains (1) Data through intervention or interaction with the individual, or (2) identifiable private information.

PI Quotes

- "Just tell me what to do and I will do it"
- "Why does it always take so much time"
- "You approved it last time, why are you requesting a change this time"
- "The IRB has no business questioning the science"
- "I really don't understand what the IRB is asking and why"
- "The overhead from my grant pays your salary"

Administrators should:

- Recognize methods do not always define research
- Understand the different types of research (qualitative, quantitative research, record reviews, public database)
- Publication may not always define research
- Problematic areas
  - Innovation
  - Quality improvement-program evaluation
  - Educational initiatives
  - Social science disciplines
  - Student research projects
  - Case reports
- Caution "IRB creep"

Managing Protocol Review

- What requires IRB review
- Process of review
  - Exempt
  - Expedited
  - Full
- Types of review
  - Initial review
  - Continuing review
  - Revisions
  - Adverse Events
  - Informed Consent

Is this research with human subjects?

- I want to interview holocaust survivors for a book I am writing
- I'm only looking at records that are linked to an code, but no actual name.
- I'm only using pathology tissue from a deceased individual?
- I'm just a psychology student doing a project for my course.
- This is a QI initiative but I may want to publish it
- I just want to review billing information
- I'm just performing an innovative procedure
- I am trying to compare two methods of teaching to better educate students
- I am doing field observation for a book I am writing about Africa

Exercise: What would you do?

During the past few months several staff members have contacted you about implementing "simulation exercises" to better train healthcare providers about the importance of communicate during emergent situations. Groups of health care providers who commonly work as a unit will be asked to undergo a simulation exercise. The group will be provided with a scenario and asked to respond. The simulation exercise will be videotaped. The group will then review the videotape with a experienced communication trainer and provided with comments about improving communication. The group will then be asked to address another scenario which will be videotaped. Both sets of the videotapes will be reviewed by individuals who were blinded as to which simulation occurred before the feedback session. The videos will be rated in accordance with a communication rating scale.

1) What questions might you ask to determine if this is research?
2) Who might you contact for assistance?

Review Continuum

Level of risk determines route of review

Exempt	Expedited	Full
(administrator/chair)	(chair/IRB member/admin)	(full IRB)
Low	Minimal	Higher

So what if it is still not clear?

- Keep account of persistent questionable "gray areas"
- Seek regulatory guidance
- Consult others at similar institutions
- Cooperatively develop guidelines/policy with input from those involved
- Disseminate guidance
- Guidance on Research Involving Coded Private Information or Biological Specimens. August 10, 2004

What is an Administrator's role: Exempt Research?

- In consultation with Chairperson/IRB:
  - Determine if IRB accepts all exemption categories
  - Define who has authority to review exemptions
  - Determine how and when exemptions are reviewed
  - Develop recordkeeping systems
    - Forms
    - Databases
- Prepare written policy
- Communicate with investigator community

Mechanisms for Review

- Exempt
- Expedited
- Full Committee review

What falls into these categories?

Administrator's role in facilitating each process

- forms
- systems
- tools for evaluation

Expedited Review

- Review carried out by IRB chair or by one or more experienced reviewers
- Reviewers may approve or modify, but may not disapprove
- Rigor of review the same, number of reviewers different
- Must advise IRB of research approved by expedited review

What is an Administrator's Role: Expedited Review?

- Expedited does not mean quicker
- Screen for initial determination
- Determine process for review?
- Review with Chair or other designated IRB member
  - Coordinate appropriate review
  - Determine specific category
  - Prepare questions for PI, obtain responses
  - Prepare final approval
- Establish files (paper/electronic/databases)
- Notify IRB
- Document policies/procedures used
  - Definition of minimal risk
  - What is a minor modification/revision

Exercise: What would you do

- All the protocol materials for the next meeting have been assembled and distributed to the committee members. The IRB meeting is Friday morning. It is Thursday morning and one of the investigators, who has a protocol on the agenda, was just notified that the cooperative group modified the protocol and revised the consent. He calls to tell you he needs to change his protocol before the IRB reviews it. What do you advise?

Exercise: What would you do?

- An investigator informs you a grant agency needs approval of his research within a week, otherwise a million dollar grant will not be funded. He asks for an expedited review. What would you do?

Models for Protocol Review

- Prescreening
- Primary/Secondary
- IRB members contact investigator prior to meeting
- Investigator attends

- No prescreening
- All members review
- No contact with investigator prior to meeting
- No/optional attendance

- Dependent on volume of protocols
- Culture of institution
- Time allocated to meetings
- Use of subcommittees and prior submission procedures

What is an Administrator's Role: Pre-Meeting Preparation

- Establish deadlines
- Pre-screening of protocols/continuing reviews
- Logistics of meeting
  - Location, catering, conference lines, schedule with PI
- Assign Reviewer(s)
- Assemble/Distribute Materials for review
  - Agenda
  - Minutes
  - Summary expedited reviews
  - Continuing renewals (subcommittee)
  - New protocols
  - Adverse events (subcommittee)
  - Amendments (subcommittee)
  - Other items (articles, educational materials, draft policies)
  - Reviewer worksheets

IRB Administrator's Role: During IRB meeting

- "Quorum counter"
- Regulatory advice
- Institutional memory, consistency
- Institutional policies and procedures
- Record IRB's final vote, rationale, (notes, tape)
- Liaison with other Institutional committees
- Conflict of interest issues addressed
- Provide input on review

What would you advise?

- You are towards the end of the meeting but have 4 more protocols that require review. One of the members gets an urgent, unexpected call and needs to leave the rest of the meeting. You now have lost quorum, what would you advise?

What would you do?

- After a meeting you go back to the office to prepare the letter to the investigator. As you go through the protocol file you note a few things:
  - There are some issues that were not commented on. You are bothered that the IRB missed these issues.
  - The IRB wants to ask a question, however you noted it is clearly answered on page 6.

IRB Administrator's Role: After IRB Meeting

- Notify investigators in writing of action
  - Draft letters
  - Obtain appropriate review and signatures
  - Consider best notification methods (letters, e-mails, web based applications, telephone)
- If appropriate, assist PI's in interpreting/ responding to concerns
- Coordinate re-review/response process
- If IRB disapproves, provide reason, provide investigator an opportunity to respond

Other Types of Review

- Continuing Review
- Amendments and Revisions
- Adverse Events
- Emergent Requests (Medical)

What would you do?

Two different PIs come to you very upset after receiving the IRB report of action.

One PI is very upset and states the committee' comments are unreasonable and shows evidence they did not read the protocol ? What would you do?

Another PI comes to you and states that he is aware who is on the committee and he strongly suspects that one member, who does not see "eye to eye" with the investigator reviewed the protocol and provided unfair criticisms. What do you do?

IRB Administrator's Role: Continuing Review

- System for identifying studies due for review (computer generated, email, paper, telephone)
- Process for notifying researchers of need for a report. Allow time for resubmission (1st 2nd notices)
- Determine which may be expedited
  - –research with no further direct subject participation
  - –minimal risk research (not under IND or IDE) where no additional risks have been identified

IRB Administrator's Role: Continuing Review (cont)

- Process to track for non-response/terminations
- Process for terminating approval for research that approval lapses
- Reviewer(s) must receive copies of full protocol/ complete file
- Consider subcommittee's or primary reviewer
- No such thing as extensions

IRB Administrator's Role: Amendments/Revisions (cont)

- Check consent to determine if revisions required
- Summarize expedited changes for full IRB
  - Put on agenda for next full meeting/subcommittee, if necessary or send for expedited approval
- May need to notify others affected by revisions(pharmacy, clinical trial units, schools)
- Consider if change impacts scientific review

What would you do?

- A PI calls and realizes her protocol is about to expire and is late submitting her continuing review. A meeting is not scheduled for another two weeks. She asks whether if the fact that she has submitted it to the office will allow her to continue to enroll and recruit subjects. What questions would be important to ask? What do you advise?
- A continuing review is submitted and you note that there is information missing. The deadline to get the material to the IRB members is at the end of the day, what do you do?

IRB Administrator's Responsibility: Adverse/Unexpected Events and Unanticipated Problems Involving Risk

- Understand difference between AE, SAE, unexpected events and unanticipated problem
- Regulations are not consistent (drugs, devices), ***OHRP/FDA new draft guidance***
- Assist in developing and communicating institutional policies
- Perform preliminary review upon submission
- Follow institutional policies
- Consider databases for tracking
- Request reports from and submission to data and safety monitoring

IRB Administrator's Role: Amendments/Revisions

- Ask PI to provide
  - Rationale for modifications
  - New documents with changes noted (track changes not just highlight where changes are)
  - Electronic systems can show where changes made
- Perform initial review to suggest type of review
- Follow institutional procedures for review
  - IRB chair
  - Assigned members

Exercise: What would you do

- You receive a phone call from an investigator who is reporting a very serious unexpected adverse event thought to be related to the research. It is Friday at 4:30 and the chairman is away.
- An investigator calls you to report that she cannot locate 10 questionnaires. What do you ask? What do you advise? When you advise the chair he asks whether you think this is an unanticipated event that involves risk and reporting to OHRP , what do you advise her?

Emergent Requests

- Patient requires emergent investigational drug for a life threatening situation.
  - No approved IRB protocol
  - No time for IRB review
- HHS: Regulations do not prevent MD from administering treatment in an emergent situation
- FDA: Has procedures, report to FDA and IRB within 5 days, allows informed consent waiver
- Intended to be used only once
- Institutions establish their own policies

IRB Administrator's Role: Informed Consent

- Advice to PI
  - Forms
  - Process
- Develop templates/policies
  - Formats
  - Language
  - Recruitment
- Finalize consent documents (insert approval, expiration dates)
- Provide input/ pre review
- Point out to the IRB when they are inconsistent

IRB Administrator's Role: Emergency Requests

- Establish and follow institutional policies
- Many institutions perform pre–review/notification when possible (verbal or written)
  - An example
    - PI submits clinical history, summary of therapy, risks, benefits, explain why emergency, consent, investigational brochure (if pertinent)
    - IRB Chair contacted to review or assign a reviewer
    - Emergency exemption granted, consent finalized
    - Pharmacy, nursing etc contacted
    - Follow-up requested
- IRB gets summary of emergency exemptions

IRB Administrator's Role: Informed Consent

- Understand the difference and regulatory criteria for
  - complete waiver of consent (no consent at all)
  - alteration of process or elements (verbal consent, allowing one of the required elements to not be included)
- Make sure when waivers, alterations are granted all elements considered and documented

Informed Consent

- Process
- Documentation
- Alterations and Waivers

Exercise: what would you do

- You have noted that the IRB is very inconsistent about the language and issues that need to be addressed in informed consent for genetic research or focus groups. Investigators have complained to you that that IRB just requested changes of language that you approved last year.

Responsibility #3 Education*

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*Acknowledgement
Helen McGough, MA, CIP

Whom to Educate?

- IRB Members, Chairs, Staff, SO
- Researchers and Research Staff
- Others: Institutional Administrators, Medical Records, General Public, Legislatures

How to Educate?

- Multi-faceted
- Use existing delivery systems
- Continuously

Educating IRB Members: Why?

- **45 CFR 46.107(a):** "The IRB shall be sufficiently qualified through the experience and expertise of its members…to promote respect for its advice and counsel in safeguarding the rights and welfare of human subjects."
- **OHRP guidance**: "Institutions may wish to consider including additional pertinent information in their written IRB procedures, such as…procedures for training and educating IRB members and staff and investigators…."
- **Audits**: Letter to prominent university from OHRP cited lack of written procedures in this area
- **Accreditation**: "…a formal process … educating investigators and research staff about their ethical responsibility to protect research participants…."

OHRP Requests for Public Comment

- July 2, 2008 Request for Information and Comments on the Implementation of Human Subjects Protection Training and Education Programs

  Due September 29, 2008

  http://www.hhs.gov/ohrp/documents/fedreg20080701.htm

Educating IRB Members: What?

- Ethical Principles: The Belmont Report
- Federal Regulations: Common Rule; DHHS & Subparts; FDA; HIPAA
- State Regulations
- Local Policies
- International Policies: Helsinki Declaration; Council for International Organizations of Medical Sciences(CIOMS) ; International Conference on Harmonisation (ICH)

Education IRB Members: What?

- IRB Member Responsibilities
- Knowledge of Special Research Areas
- Knowledge of Vulnerable Subject Populations

Educating IRB Members: How?

- Procedures and Policy Manual
- Mentor-Trainee Relationships
- Formal Education Workshops
- Seminar Series on Special Topics
- Informal "Just-in-Time" Sessions
- Newsletters, Listservs
- Distribution of Relevant Journal Articles
- PRIM&R Membership

Educating IRB Members: How?

- Conferences (National and Regional) (e.g. IRB 101)
- Videotapes
- Web-based Tutorials
- Checklists
- CE Credit
- Protocol Specific Training
- Subscriptions
- Quality Improvement Program

Educating Researchers: Why?

- Protect the Safety, Rights, and Welfare of Research Subjects
- Ensure Compliance with Applicable Regulations and Policies

Educating Researchers: Why?

- Required for NIH Investigators and Key Personnel
- Required for Veteran Affairs Investigators and Key Personnel
- Core Accreditation Standard

Educating Researchers: What?

- Ethical Principles: The Belmont Report
- Federal regulations: Common Rule; DHHS & Subparts; FDA; HIPAA
- State Regulations
- Local Policies

Educating Researchers: What?

- Investigator Responsibilities
- International Policies: Helsinki Declaration; Council for International Organizations of Medical Sciences (CIOMS); International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH)
- Knowledge of Vulnerable Subject Populations
- Good Clinical Practices (GCP)

Educating IRB Staff: Why?

- Historical Institutional Memory
- Empowerment/Effectiveness
- Compliance
- Train-the-Trainers

Educating Researchers: How?

- IRB Policies & Procedures
- IRB Feedback – Positive and Negative
- IRB Attendance and/or Membership
- Involvement in Designing Policies and Procedures
- Researcher Newsletters; Listservs
- Existing Education: GCP/GLP/HIPAA Training; Responsible Conduct of Research (RCR) Education; New Staff/Faculty/Graduate Student Orientation; Credentialing

Educating IRB Staff: What

- Federal regulations:
  - Common Rule and Subparts B, C, and D
  - Food and Drug Administration (FDA)
  - Veteran Affairs (VA)
  - Health Insurance & Accountability Act of 1996 (HIPAA)
  - Family Educational Rights and Privacy Act (FERPA)
  - Assurances
  - Inter-institutional Agreements

Educating Researchers: How?

- Manuals/Booklets
- Web-based or Face-to-Face Tutorials
- Issue- or Discipline-based Workshops
- Monitoring/Auditing/Quality Improvement
- CE Credit
- Conferences: Regional, National, Local (e.g. IRB 101 or IRB 250)

Educating IRB Staff: What (Cont.)

- International policies and guidelines
  - Nuremberg Code
  - Declaration of Helsinki
  - Council for International Organizations of Medical Sciences (CIOMS)
  - International Conference on Harmonisation of Technical Requirements of Pharmaceuticals for Human Use (ICH)
  - Tribal regulations