HUMAN SUBJECTS PROTECTION AND DATA PRIVACY IN PBRN RESEARCH

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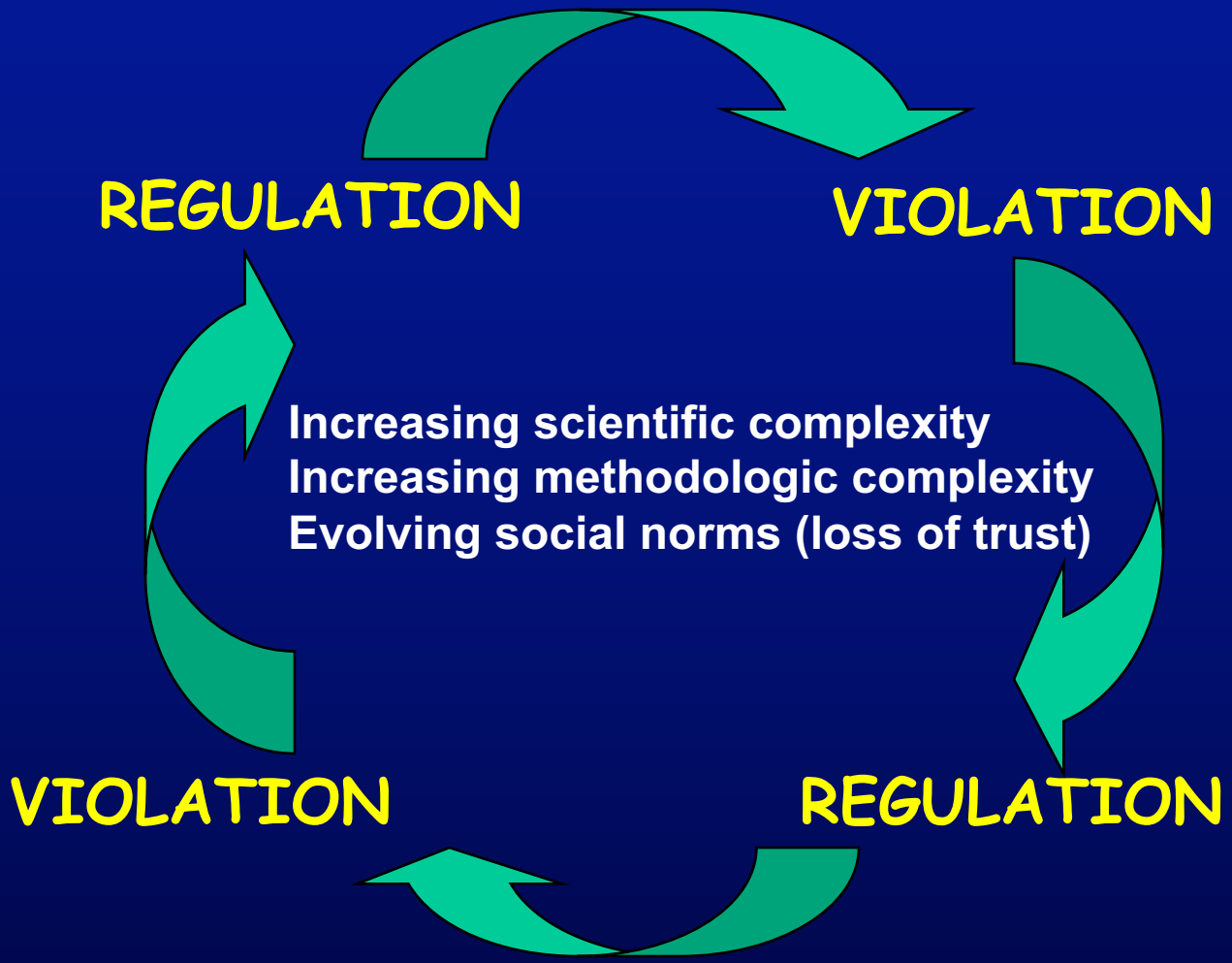
OBJECTIVES

1. Review the charge of the IRB
2. Provide brief overview of the regulations and standards used by the IRB
3. Provide guidelines and “helpful hints” to facilitate successful IRB submissions
4. Identify and discuss the special issues related to human subject protections, privacy, and confidentiality in PBRN

SUMMARY: HUMAN RESEARCH PROTECTIONS IN THE U.S.

- ✓ Over-regulated
- ✓ Designed for clinical trials
- ✓ Counter-intuitive
- ✓ May present significant roadblocks to research

HOW WE GOT HERE



HISTORY

PRINCIPLES / GUIDELINES	REGULATION
1947: Nurenburg Code	
1964: Declar. of Helsinki (WMA)	1966: NIH requires IRB appr.
1979: Belmont Rep't (Nat. Comm)	1981: CFR 45, Part 46
	1986: CFR 21, Part 50
1990: ICH Guidelines / "GCP"	
1995-01: Nat'l Bioethics Advis. Com	2000: HIPAA
2001-06: Pres. Council on Bioethics	
2006 - : Sec'y Adv. Comm. On Human Research (SACHRP)	

IRB: Purpose, Responsibilities

- Protect human subjects (harm)
- Support and facilitate the ethical conduct of human subjects research (rights, integrity)
- Assure institutional compliance with regulatory agencies
- Assist investigators in complying with the ethical and regulatory standards

IRB Regulations

Regulations: CFR 45, Part 46
CFR 20 (FDA)
OHRP Guidelines
HIPAA

Specifications:

IRB composition, operation
Requirement for review, approval
Requirements for informed consent
Components of informed consent
Protection of vulnerable subjects

Submission Guidelines

- Allow enough time
- Prepare the protocol
- Write the informed consent form (ICF)
- Complete the checklist
- Obtain necessary approvals / support letters

Submission Guidelines: Allow enough time

Example: (*BEST* case scenario)

- **Submit to IRB on Friday, April 1**
- **Application copied, distributed to IRB on 4/7**
- **Reviewed at Board meeting Tuesday, 4/12**
- **Returned to investigator for corrections 4/19**
- **Re-submitted to IRB 4/26**
- **Approval letter sent 5/ 2**

Submission Guidelines: Write the Informed Consent Form

Remember:

- The informed consent form (ICF) is the IRB's **only** measure of subject autonomy
- Translating a complex scientific project into lay language is very difficult
- Required components of the ICF are mandated by federal regulations
- There is no ICF that can't be improved

Submission Guidelines: Write the Informed Consent Form

Informed consent tutorial:

www.uhhs.com

- ➡ research
- ➡ IRB
- ➡ Forms and Templates
- ➡ Consent language tutorial

Submission Guidelines: Informed Consent Form (ICF)

Components:

- Purpose
- Study procedures
- Risks
- Benefits
- Costs
- Compensation
- Confidentiality
- Alternatives

INFORMED CONSENT: Risks

Do not minimize

Include: psychological
placebo (no treatment)
wash-out (worsening)

* Be clear about differences from “standard care”

INFORMED CONSENT: Benefits

Surveys, Phase I trials, descriptive research offer NO BENEFITS

Do not include $$ compensation

May include benefit to society, others

INFORMED CONSENT: Financial

Costs: include a statement that there is no cost associated with participation

Payment: compensation for participation

- reasonable
- accrue to subjects (not parents)
- proportional to participation

INFORMED CONSENT: Confidentiality

HIPAA: standard language

include within consent form

Anonymity vs. de-identified

ALTERNATIVES

- There is always an alternative (i.e. to not participate)
- Be as specific as possible (e.g. briefly describe the standard therapy, state there are other approved medicines for the condition, other treatments, the choice of no treatment, etc)

VULNERABLE POPULATIONS (children, prisoners, students)

WHY? Limits to ability to protect self

- ✓ Additional regulation
- ✓ Justification
- ✓ Extra measures to assure freedom from coercion
- ✓ Limits to acceptable risks
- ✓ Limits to acceptable compensation

IMPAIRED DECISIONAL CAPACITY

(children, dementia, mentally ill)

WHY? Added risk of coercion + threats to autonomy

- ✓ Specific means of testing capacity
- ✓ Procedure for surrogate consent
- ✓ Stronger limits to acceptable risks
- ✓ Assent forms

LARGE SUBJECT PAYMENTS

Why? Threat of coercion

- ✓ Amount corresponds to time, burden
- ✓ Payment for repeated visits is apportioned over visits
- ✓ No “completion bonus”

HINTS

- Ask BEFORE submission if unsure
- Long protocols = tired reviewers
- Long consents = decreased comprehension
- The consent form has to stand alone
- Format matters

COMMON “Pending corrections”

- Mismatch between protocol, check list, and consent form (e.g. payment, # of subjects, duration of study, # of visits)
- Typo’s
- Technical language / reading level
- References

SUMMARY

- IRB functions are mandated
- IRB office is your best resource
- Use the web site
- Ask when unsure

PBRN / HSR ISSUES

- Typically present low physical risks but high risk to privacy and/or confidentiality *
- Need to access data from many medical records (HIPAA)
- Difficulty in obtaining standard informed consent
- Status of collaborating practitioners

**privacy = protection of person from unwanted intrusion*

confidentiality = protection of data / information

Need to access data from many medical records (HIPAA)

HIPAA allows:

- access to data by members of the practice
- review of records by researcher to identify eligible subjects or prepare a protocol (on-site)
- use of de-identified data (none of the 18 prohibited identifiers) provided by the practice

Need to access data from many medical records (HIPAA)

HIPAA DOES NOT allow:

- Removal of data from patient records without either consent or a waiver
- Use of patient data by the clinician for research without either consent or a waiver

Need to access data from many medical records (HIPAA)

Options:

- Get consent
- Request a waiver (partial for recruitment, full for data use)
  - Study cannot be "practicably" done without waiver
  - Study cannot be done without data
  - Study poses minimal risk to privacy because…
  - Information will be protected by…

(see web site for template language)

Difficulty in obtaining standard informed consent

IRB rules *generally* require:

Consent for participation in any research (including surveys)

Consent for use of medical record data

But……

Requirement for consent can be waived (e.g. for surveys)

QI projects do not require consent

Waiver of Consent

- ✓ Study involves no more than minimal risk
- ✓ Waiver will not adversely affect rights of subject (e.g. patient would not ordinarily be asked for consent)
- ✓ Research could not be “practicably” carried out without waiver
- ✓ Subjects will be provided information after participation when appropriate
- ✓ Research not subject to FDA regs

- ✓ Use “information sheet”

QI vs Research: Murky territory

Research: “systematic collection of data for the purpose of producing generalizable knowledge”

QI: systematic collection of data for the purpose of improving performance of one specific entity

TERMINOLOGY

Expedited: research that poses minimal risk, may be administratively reviewed by IRB chair/vice-chair

Exempt: research that uses publicly available data, anonymized data, anonymous surveys, educational evaluations, etc

Non-research: not intended to produce generalizable data (e.g. QI)

Not human subjects: not involving living persons, or not involving any contact with living person and no identifying data

STATUS OF COLLABORATING PRACTITIONERS

Options: co-investigator vs study site

Co-investigator:

- fuller engagement in project
- has full access to records
- can contact patients directly to recruit
- must be CITI certified

OPTIONS FOR LARGE NETWORKS

- Use of blanket consent forms, similar to "registries", using pre-mailed information sheets and CITI-certified clinician consent procedure or follow-up phone consent
- Completion of "Data Use Agreement" between researchers and practice, covering provision of limited data sets (no identifying info except city, zip, date)
- Use of "honest broker" in charge of QI data, to provide de-identified data to researchers (i.e. separate QI and research components)
- Use Research Coordinator
- Research regulatory consultant

TRENDS

- ✓ Accreditation (AAHRPP)
- ✓ Public perception / media
- ✓ Sentinel events
- ✓ EHR
- ✓ Electronic submission