The **Common Rule**
for the Protection of Human Subjects– Information for Education Researchers and IRBs

University of Texas at El Paso
First Annual Research and Ethics Day Conference
9/26/08

By
Jeffery W. Rodamar
Protection of Human Subjects Coordinator
US Department of Education
202-260-3353; Jeffery.Rodamar@ed.gov

Beginning a conversation

PART I:
1. Things you wanted to know about reviewing education research
   a. What is "research"?
   b. Exemptions and education research
   c. "Existing" records, etc.
2. Break-out discussions
   * Break

PART II
3. Continuing and emerging issues:
   Children, Intl., other statutes, confidentiality, etc.
4. Questions & discussion

A call is received on the red phone at 3:

- A teacher calls. He wants to report noncompliance with Common Rule for the Protection of Human Subjects requirements.
- He is in his third year of teaching (i.e. no job security under LEA rules). He is in his 50s, teaches math. He had been an engineer, managing multimillion dollar projects for a major international firm. After 9/11 he decided to change his life and become an 8th grade mathematics teacher working with disadvantaged children.
- As part of an experimental study, the principal told him that he MUST use a web-based program in his 8th grade math class. The students are mostly English language learners.

A call at 3 (continued)

- He insists that parent consent is needed to include students in this experimental study. He says the study could pose significant risks for these students. The principal says, "Just do what you're told—and do it during regular class time".
- The experimental program has 25 modules, each roughly 45 minutes long—the equivalent of about five weeks of instructional time.
- The teacher worries that the online instructional modules did not appear to be working well with these English language learners, and that the modules are not well-aligned with the high stakes state test

A call at 3 (continued)

- At the end of the year, 80% of the students in the experimental section fail the state math test. This is a much higher proportion than in classes he's taught in previous years. These students must repeat the math class, and in some cases the entire grade.
- Given the demographics, it is likely that many of the students will in due course drop out of school rather than face the boredom and stigma of repeating the class/grade level. (The school already has one of the highest dropout rates in the state.)
- The principal fires the teacher at the end of the school year, allegedly for failing to implement the grant. This will make it harder to find another job.*

* This is a hypothetical example.

The Common Rule for Protection of Human Subjects in Research

- Adopted by 17 federal agencies – including ED, HHS, NIH, DOJ, DOD, DHS, NSF, and NASA
- Each agency has a separate CFR reference. (For ED it is 34 CFR 97.)

No covered human subjects research can be conducted unless the engaged entities each has a Federal Wide Assurance (FWA) and IRB approval.

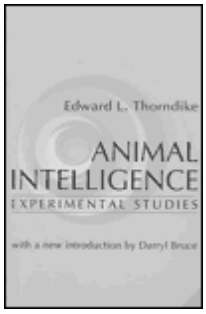
Education research ethics:

Is this new?

Franz Boas --and the flap in Boston area schools--in the late 1890s

Edward Thorndike— A father of education research

- Edward Thorndike (1874-1949) was one of the most prominent researchers in the history of American psychology. During his long academic career, most of which was spent at Teachers College, Columbia University, he authored 50 books and more than 450 articles. In addition Thorndike created numerous intelligence and achievement tests for schools. He was deeply interested in measuring differences in intellectual capacity and performance among school children.
  This includes his empirical “Laws of Learning” and path breaking work on instructional design. (Studying Latin does NOT create a “mental discipline” that leads to improved learning generally.)
- Principles of Psychology (with William James, 1890s)
- Educational Psychology (1903)
- Introduction to the Theory of Mental and Social Measurements (1904)
- The Elements of Psychology (1905)
- Animal Intelligence (1911)
- The Measurement of Intelligence (1927)
- The Fundamentals of Learning (1932)



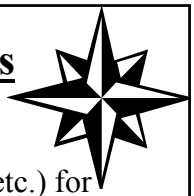
Nothing new:

- For his Harvard dissertation research, an orphanage did not allow Thorndike to conduct experimental studies on how children learn
- —so he used chickens (that his faculty adviser, William James, lodged in his own basement).

Is this new?
Moving along the learning curve:

- National Research Act (1974)→ Belmont Report (1979)
- ED adopted Common Rule in June 1991.
- NBAC on implementation, 2001
- Monitoring of implementation, (e.g., NSF & HHS OIGs, …)
- Growing awareness in field: complaints
- Ensuring consistency and compliance

Overview of the ED Clearance Process



1. ED <u>reviews application</u> (Form 424, HS narrative etc.) for nonexempt human-subjects research, and contacts Grantee if yes.

⇩

2.Grantee gets: <u>Assurance(s)</u> (FWA) + **<u>IRB</u>** Approval(s)

⇩

3. <u>Grantee sends</u> FWA info & IRB Approval(s) to ED.

⇩

4. <u>ED clears</u> and informs funding office

Simple as "A"+"B"+"C"

A **Assurance** (Federal Wide Assurance, FWA)

B **Board** (Institutional Review Board, IRB)

C **Consent** (Informed consent in most research)

Context

We need effective protection of human subjects—without creating unnecessary barriers to rigorous research.

From "fad-ed" to evidence-based education--

based on scientific research

Education research is among our nation's most important investments

- **We are at the edge of a revolution in teaching and learning**.
- **We should conduct education research as if it really matters** (including assessments of benefits and risks).
- **Trusted -- and trustworthy.**
  Why do many teachers consider education research irrelevant? Public and private investment (e.g. IES compared to NIH)? What barriers?

How little we know

- Analysis of every article published in AERA's American Educational Research Journal, and Educational Evaluation and Policy Analysis from 1993-2002 found only 6% utilized a randomized trial as primary research method. Even adding studies with matched comparison groups only brought the total to 16%.
- Study of "schoolwide reform" models by AIR found few had systematic evidence of effectiveness.
- "Medical Guesswork" Business Week, May 29, 2006. Studies of medical treatments find relatively few have been systematically assessed (Cochrane Collaboration)

The evidence base:

Some resources for IRBs and others

- "What Works Clearinghouse"
  (US Department of Education http://ies.ed.gov/ncee/wwc/)
- National Registry of Evidence Based Policies and Practices (NREPP) (SAMHSA: http://www.nrepp.samhsa.gov/)
- Cochrane Collaboration (health related) (http://www.cochrane.org/)
- Campbell Collaboration (education, social work, crime prevention, etc.) (http://www.campbellcollaboration.org/)

19

The Changing Context of Educational Research:

"No Child Left Behind" and AYP

Under NCLB, all students in grades 3-8 and in one grade in high school must be tested once a year in reading and mathematics. Students are expected to score at the "proficient" or above on state-administered tests by 2014 and to make "adequate yearly progress" toward that goal by then.

20

Why ED?

- Classic examples: Milgram, Zimbardo, Tudor were at educational institutions or included educational treatments
- "Scared Straight": "Iatrogenic treatment" worsens a condition. Ineffective treatments.
- Recent education examples : Fulbright Hays dissertation survey in middle of a civil war. Palmdale, Ridgewood, science curriculum not aligned with college admissions test

Scientific research in schools

"The final criteria for applying the standards of scientifically based research to CSRD, is that the rights of participants can be protected. In this high-stakes, outcome oriented environment for reforming schools that's a difficult criterion to meet. It's hard to ask a school to maintain a comprehensive school approach that does not seem to be working when they are under incredible pressure to produce results quickly for the duration of the study that you need to conduct. The study needs to be more than a few minutes." (Audience laughter.)

Source: "Scientifically based research' and the Comprehensive School Reform Demonstration Program", Becki Herman, AIR, Feb. 6, 2002, presentation to US Department of Education.

Education Week, Jan. 25, 2006

Come Clean on Small Schools

By David C Bloomfield

"Before scaling up untested models, philanthropists are at least morally obligated to conduct research into the impact their programs will have on students outside the reform bubble".

In sum, high quality education research is needed.

But there are major challenges, including:

- Declining site and individual participation.
- Concerns of intrusiveness (Palmdale School District)
- Concerns of burden and risks (VCU)

Ethical research is both an obligation to research participants—and vital for building the mutual trust essential for future research and its application.

Common Risks in Education Research

Location of risk	Internal to study	External to study
	•"Paper cuts" • "Fatigue" (e.g. from taking another test.) • Privacy (right not to be bothered)	• Disclosure of sensitive information (e.g. sexual activity, attitudes toward organization or curriculum …)
	• Accident (fall from gym equipment) • Invoke traumatic memories • Embarrassment	•Opportunity to learn (tested curriculum)

What's the Risk?

Conducting research in a high-stakes context:

- The changing context of educational research (The NCLB era of time- on-task, high-stakes testing, etc.)
- Evidence-based education: ESRA, NCLB, What Works Clearinghouse
- From momentary boredom to lifelong harms

34 CFR 97
Key concepts

Covered research

For the regulation to apply, the study must be funded by a federal Common Rule agency.

Some entities fill out the FWA pledging to apply the regulation to all human subjects research at the institution, whatever its source of funding.

No covered research can be conducted until the study has human subjects approval.

What is “research”?

Systematic investigation, including research development, testing and evaluation designed to develop or contribute to generalizable knowledge

[34 CFR 97.102.d]

Research	**Not research**
* **Systematic** methods	* Not systematic methods
•Designed to contribute to **new knowledge**	* Not "new knowledge" (e.g. just monitoring implementation of a previously determined treatment")
* **Generalizable,** potentially useful in many times and places.	*Not generalizable ("of local interest only")
* "**Human subjects**"	•Not "human subjects" (aggregate data, the dead, …)

*"**Human subject** means a living individual*

about whom an investigator (whether professional or student) conducting research obtains

*(1) Data through intervention or interaction with the individual, **or***

(2) Identifiable private information. "

-- (34 CFR 97.102 (f)

Cf studies of organizational processes, software testing, etc.

IRB? –Why not just aggregate so it's not "human subjects" research?

Consider

"Simpson's Paradox"*

Data analyzed using different groupings, e.g. individual and classroom levels can often produce what appear to be contradictory findings (e.g. a program "is" and "isn't" working at the same time).

Example 1

Physical education grant: practice or research?

Not research:

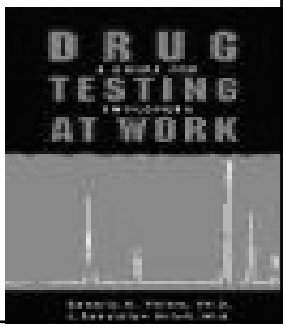
- Funds to buy new equipment
- Measures for proven treatment (e.g. GPRA measures typically "not research").

But includes "research" if learning whether a treatment works in "schools like these".

Example 2

No coerced participation is allowed in covered human subjects research

→What about "school-wide reforms", student drug testing grants, etc.?



Gray/Grey areas

As the old song says:

♫♪ "It's not what you do,
it's the way that you do it." ♫♪

"Quality Improvement" Performance monitoring, …

Increasingly scientific methods are merging with everyday practice (cf. Don Campbell, "The Experimenting Society"):

- If an activity fits the definition of research, then it is research under the regulation.
- Studies often are not "systematic" enough to provide credible scientific evidence, or they are site specific, or they are only monitoring site implementation of a proven practice. Those activities are "not research" under the regulation.

Is it "research"? Intent, publication, etc:

There are several widely used proxy measures to determine whether an activity is "research". Note the definition's focus on design for systematic investigation.

The grantee or researcher:

- May have incentives to consider their study "not research".
- May not know (or care) about the research uses of the study—e.g. an evaluator with a cluster of evaluations in separate grants. (Much of the evidence base in education comes from such "site evaluations").

Teacher research:
"*research?" NEP?*

Student studies:
"*learning to research*" and/or
"*engaged in research*"

The investigator cannot make the determination of whether a study is exempt.

How determinations of exemption are made is determined by the institution. Sometimes it is the IRB, sometimes it is the department chair, sometimes …

Is it exempt?

1. **Normal educational practice** (cf study of effects of spanking on school achievement)
2. Surveys, interviews, ed tests, or observations public behavior -- unless identifiable and harmful to employability, criminal sanctions, reputation, etc. (NB **Subpart D** for children)
3. Educational tests, surveys, observation of public behavior—IF federal statute without exception prohibits disclosure
4. **Existing data if publicly available or deidentified** (cf school information systems)
5. Public service or benefit programs (approved by agency head, and narrowly defined)

What is Normal Educational Practice?

Exemption b(1)

" *(1) Research conducted in* ***established or commonly accepted educational settings****, involving* ***normal educational practices****,* ***such as*** *(i) research on regular and special education* ***instructional strategies, or*** *(ii) research on the* ***effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods****.* "

--34 CFR 97.101 (b)1

Normal educational practice

The study involves practice that has been used routinely ("normally")

* at an educational site
* or at most similar schools (e.g. in the city or state)

The study is not introducing new treatments, research data collections etc. that get in the way of normal practice at such sites.

Normal educational practice:

1. **Micro:** At the site (e.g. two or more years)
2. **Macro:** For the population (e.g. all schools in the state)

Consider:

- Testing US students in a test of mathematics achievement—with the test written in Chinese.
- Increased physical discipline to increase student achievement (e.g. spanking).

Exemption (b)2

(2) Research involving the use of ***educational tests*** *(cognitive, diagnostic, aptitude, achievement),* ***survey procedures****, interview procedures or* ***observation*** *of public behavior,* ***unless****:*

(i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through ***identifiers*** *linked to the subjects;* ***and***

(ii) Any ***disclosure*** ***of the human subjects' responses outside 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.***

--34 CFR 97.101(b)2

Note Subpart D
Protections for children

If a study involves minors, then Exemption 2 for survey, interview or interactive observation does not apply (unless observing public behavior and don't interact with subjects):

Surveys, focus groups etc. of children need IRB review even if the survey is anonymous.

Exemption (b)3 and the IES Confidentiality statute

- National Center for Educational Statistics and other IES contracted studies are exempt under 34 CFR 97 (b) (3)

(ii) ***Federal statute(s) require(s) without exception that the confidentiality*** *of the personally identifiable information will be maintained throughout the research and thereafter.*

--34 CFR 97 101(b)3

47

"Don't fool with the Common Rule'

- Study stopped--data lost.
- Lose funding for grant – and may lose eligibility for future funding.
- Campus-wide shutdowns of research (e.g. Duke, U Penn, VCU, ...)
- FWA and IRB registration
- Researcher unable to publish study, etc.
- **Do the right thing.**

48

Your turn:
Discussion panels

- Topic 1: “The Practical School Action Project”
- Topic 2 : Risky City School System Needs Project
- Topic 3: Cyber Study of Latina adolescents
- Topic 4: The Understanding Police Understanding Project

BREAK TIME

Part II

1. Some other laws that may apply: FERPA and PPRA
2. Informed consent and assent
3. Confidentiality: "You have no privacy, get over it"
4. International and transnational studies
5. Reporting adverse events
6. Working with your IRB for effective protections and rigorous research

OTHER LAWS THAT OFTEN APPLY TO EDUCATIONAL RESEARCH :

- FERPA
- PPRA
- HIPAA

Family Educational Rights & Privacy Act (FERPA)

Protects privacy of student education records

- Applies if school receives funds under any ED program
- Applies whether or not use is for "research"
- Generally requires written permission of parent or eligible student before a school can release information from a student's education record.

Protection of Pupil Rights Amendment (PPRA)

- Protects rights of parents and students in administration of surveys that touch on one or more of eight protected topics
- Applies if school receives funds under any ED program (i.e. not just to surveys directly funded by ED)

PPRA protected topics

1. Political affiliations or beliefs
2. Mental or psychological problems
3. Sex behavior or attitudes
4. Illegal, anti-social, or demeaning behavior
5. Critical appraisals of close family relations
6. Privileged relations, eg lawyers, physicians
7. Religious practices, affiliations, or beliefs of the student or student's parent; or
8. Income

Rights under PPRA for protected information surveys

1. Right to receive notice: Parents receive general annual notification
2. Right to consent for ED-funded surveys (no waiver, elements differ from Common Rule)
3. For non-ED funded surveys, right to receive notice and opt student out of the survey.
4. Right to inspect surveys

PPRA: Responsibilities for ED-Funded Surveys

- Schools must obtain written parental consent before minor student required to participate in "protected information" survey funded in whole or in part by ED
- Active consent only

Common Rule and FERPA

•If ED funded a PPRA survey, or if it's a FERPA record, cannot waiver written consent

• Required elements of informed consent differ between FERPA and Common Rule. If a study is covered by both, the consent form must meet both sets of requirements.

Consent and assent

Informed consent is a keystone in the system to protect human subjects.

Consent is required in covered studies unless an IRB modifies or waives the requirement.

If children are subjects in a study: (1) parent consent is required unless waived by an IRB; (2) For ED and other agencies that have adopted Subpart D, a survey, focus group etc. that includes children is not exempt from review under exemption 2 even if anonymous.

Informed consent and risk management

- Informed consent is an element of respect for each individual who participates in a study.
- It is also a tool in risk management, because many risks depend on individual characteristics or context. (For example, a school nature walk is minimal risk for most children—but could be very risky or even fatal for a child with severe allergic reactions to bee stings.)

"Does anybody read these things?"

Some problems with informed consent:

- Signed informed consent in survey research can discourage participation (Eleanor Singer)
- Readability is often low (including after IRB review)
- Limits of informed consent : many members of the public don't understand the scientific process, what an "experiment" is, don't understand risk probabilities, and so on.

Informed consent

- Don't promise what you can't deliver (e.g. evaluation contracts)

Adverse side-effects? Four risks of informed consent procedures in survey research:

- Statistical power (achieved sample size)
- Statistical bias (nonrespondents not missing at random)
- Erosion of baseline and change measures
- Indirect effects on budget and timelines—and ability to complete a valid study

Certificates of confidentiality

- **Certificates of confidentiality (issued by NIH http://www.hhs.gov/ohrp/humansubjects/guidance/certconf.htm)**

- **Look ahead:** Consent applies beyond the conduct of the study. If it may be important to archive the data to allow replication, review, etc., those longer term uses should be included in the consent.

Children as research subjects

United States Department of Health & Human Services

Office for Human Research Protections (OHRP)

Special Protections for Children as Research Subjects

When a proposed research study involves children and is supported or conducted by HHS, the research institution's Institutional Review Board (IRB) must take into consideration the special regulatory requirements that provide additional protection for the children who would be involved in the research. If the proposed research involves FDA-regulated products, then FDA's parallel regulations apply.
FAQs on Research with Children

By regulatory definition, children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally the law considers any person under 18 years old to be a child.

When reviewing research with children as subjects, in addition to ensuring adherence to the general regulatory requirements of 45 CFR part 46, Subpart A, the IRB also must consider the potential benefits, risks, and discomforts of the research to children and assess the justification for their inclusion in the research. In assessing the risks and potential benefits, the IRB should consider the circumstances of the children to be enrolled in the study-for example their health status, age, and ability to understand what is involved in the research-as well as potential benefits to subjects, other children with the same disease or condition, or society as a whole.
For any protocol involving children, the IRB must determine which of the four categories of research apply to that study, if any. OHRP recommends that the IRB document the rationale for this choice.
The HHS regulations at 45 CFR part

http://www.hhs.gov/ohrp/children/

Special Protections for Children in Research

The regulations at 34 CFR part 46, subpart D permit IRBs to approve three categories of research involving children as subjects:

34 CFR 46.404 - Research not involving greater than minimal risk to the children.
To approve this category of research, the IRB must make the following determinations:

- the research presents no greater than minimal risk to the children; ***and***
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

34 CFR 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research.
To approve research in this category, the IRB must make the following determinations:

- the risk is justified by the anticipated benefits to the subjects;
- the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; ***and***
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

34 CFR 46.406 - Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition.
In order to approve research in this category, the IRB must make the following determinations:

- the risk of the research represents a minor increase over minimal risk;
- the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
- the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; ***and***
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

Special Protections for Children in Research

A fourth category of research requires a special level of HHS review beyond that provided by the IRB.

34 CFR 46.407 - Research that the IRB believes does not meet the conditions of 34 CFR 46.404, 46.405, or 46.406, but finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.
If the IRB believes that the research does not meet the requirements of 34 CFR 46.404, 46.405, or 46.406, but finds that it presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, it may refer the protocol to HHS for review. The research may proceed only if the Secretary, HHS, or his or her designee, after consulting with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following an opportunity for public review and comment, determines either: (1) that the research in fact satisfies the conditions of 34 CFR 46.404, 46.405, or 46.406, or (2) the following:

- the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
- the research will be conducted in accordance with sound ethical principles; ***and***
- adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

For more information on 34 CFR 46.407 review process see OHRP Guidance, Children Involved as Subjects in Research: Guidance on the HHS 45 CFR 46.407 ("407") Review Process [PDF - 37.5KB]

Remember Subpart D

For ED and other agencies that have adopted Subpart D Protections for Children in Research, Exemption 2 for surveys, interactive observations etc. does not apply —even if the survey or interaction is anonymous.

Confidentiality and privacy

Education research often includes data that is directly or indirectly identifiable.

"You have no privacy, get over it."
--Scott McNealy, Sun Microsystems

If you have three variables…

- Birthdate, sex, and ZIP code (5 digit)--alone uniquely identify 87% of the US population.

  --Sweeney et al. "Confidentiality and Privacy of Electronic Medical Records" JAMA

- Education research often involves small samples, with longitudinal data, of students in classrooms in schools that may be linkable to external data sources to reidentify subjects.

- And …

Some populations may be at particular risk of indirect identification

- For example, criminal records--or even arrests without convictions-- may create records that can be linked to study data to identify study participants.

- In inner cities, more than half of all black men do not finish high school. By their mid 30s, 6 in 10 black men who had dropped out of school had spent time in prison.

- External linkable data sets: As of May 2007, 177,870 forensic profiles and 4.6 mn offender profiles had been accumulated in the FBI/States' CODIS database, making it the largest DNA database in the world. As of June 2007 CODIS had produced over 49,400 matches to requests, assisting in more than 50,343 investigations.

Is the data deidentified?

If data is "coded" and identities are not "readily ascertainable", the study may be exempt

- e.g. "can be identified, directly or through **identifiers** linked to the subjects(e.g., 34 CFR 97.101.b(2)

However, education research often involves many direct and indirect identifiers, e.g. :

- Relatively small samples, hierarchically clustered within a few classrooms, within a few schools, often includes longitudinal data.
- Reidentification is increasingly fast, easy and cheap with

("data-mining" software) + (external linkable data sets) [73]

Ability to protect confidentiality:

- Sometimes state or other law requires disclosure of data.
- Evaluators etc. often pledge confidentiality to respondents—but cannot provide it if the entity contracting for the study demands the identified data it unless confidentiality protections are included in their contract. For example, if an evaluator is fired, he/she can be required to turn over the identified data to the entity that hired him/her (eg school district) even if the evaluator promised confidentiality to teachers.

Cross boarder and intl studies

34 CFR 97.101 (g)(h): International and transnational research

(g) This policy does not affect any foreign laws or regulations which may otherwise be applicable and which provide additional protections to human subjects of research.

(h) When research covered by this policy takes place in foreign countries, procedures normally followed in the foreign countries to protect human subjects may differ from those set forth in this policy. [An example is a foreign institution which complies with guidelines consistent with the World Medical Assembly Declaration (Declaration of Helsinki amended 1989) issued either by sovereign states or by an organization whose function for the protection of human research subjects is internationally recognized.] In these circumstances, if a department or agency head determines that the procedures prescribed by the institution afford protections that are at least equivalent to those provided in this policy, the department or agency head may approve the substitution of the foreign procedures in lieu of the procedural requirements provided in this policy. Except when otherwise required by statute, Executive Order, or the department or agency head, notices of these actions as they occur will be published in the FEDERAL REGISTER or will be otherwise published as provided in department or agency procedures.

http://www.hhs.gov/ohrp/international/index.html#regstd

- IRB Registration
- Assurances
- Regulations
- Policy and Guidance
- Frequently Asked Questions (FAQ)
- Compliance Oversight
- Education
- Conferences
- Quality Improvement
- SACHRP
- OHRP News
- Public Outreach
- International

Office for Human Research Protections (OHRP)

International Issues

OHRP provides quality improvement consultation and research ethics training to domestic and foreign institutions involved in international biomedical and behavioral research. These services help ensure that recognized ethical protections are afforded to persons participating in research conducted in countries outside the United States.

Ethical Codes

- Declaration of Helsinki
- Belmont Report

Regulatory Standards

- 45 Code of Federal Regulations 46
- 21 CFR 50 and 21 CFR 56
- International Conference on Harmonization - Guideline for Good Clinical Practice
- CIOMS International Ethical Guidelines

- Canadian Tri-Council Policy Statement
- Indian Council of Medical Research [PDF]

Compilation of National Policies

- The International Compilation of Human Subject Research Protections is a listing of the laws, regulations, and guidelines that govern human subjects research in many countries around the world.
- ***Disclaimer: Though this Compilation contains information of a legal nature, it has been developed for informational purposes only and does not constitute legal advice or opinions as to the current operative laws, regulations, or guidelines of any jurisdiction. In addition, because new laws, regulations, and guidelines are issued on a continuing basis, this Compilation is not an exhaustive source of all current applicable laws, regulations, and guidelines relating to international human subject research protections. While reasonable efforts have been made to assure the accuracy and completeness of the information provided, researchers and other individuals should check with local authorities and/or research ethics committees before starting research activities.***

Equivalent Protections

- July 7, 2006 Notice on Interpretation of Assurance Requirements [PDF - 57.2KB]
- Federal Register Notice Soliciting Public Comment on Recommendations of HHS Workgroup [PDF - 67.6KB]
- HHS Workgroup Report [PDF - 134KB]
  - Appendix [PDF - 66.8KB]

Working with your IRB

Research site or "engaged in research"?

- If an entity is "engaged in covered research" it must have an Assurance and IRB approval.
- While simple in principle, this can get complex in practice as you deal with school districts, etc.
- The distinction can turn on "small details" such as who hands out and collects informed consent forms or surveys.

→ It often makes sense to design studies to be rigorous (e.g. with an adequate number of sites), but with field operations that minimize the number of entities that must go through the approval process.

Reporting Adverse Events

Risks in education research vary widely, from student surveys, to studies of traumatic brain injury, to studies of sensitive topics conducted under repressive regimes.

If an adverse event or unanticipated risk is encountered during the course of a study, report it to the IRB.

- The event can be internal to the study. For example, a survey item that causes a traumatic reaction by a subject, a student who is injured in the course of physical education study
- The event may be external to the study—such as teachers punished or fired for information revealed during a study, students arrested for information disclosed during a survey, parental abuse of a child for information disclosed during a survey, students who fail the class or grade level for study-related reasons (e.g. "opportunity to learn"), and so on. (Cf. 8th grader Larry King; Palmdale School District court case, etc.)

Destroy the data?

Should data sets, or at least all identified data sets be destroyed at when a study is complete?

- FERPA requires data destruction for some studies.
- Data access –with appropriate protections--is often a vital part of the scientific process:
  - Identifying error and research misconduct
  - Replicating studies
  - Use for secondary analysis
  - And so on.

A balanced approach that both protects data confidentiality and enables rigorous research is needed. The informed consent sets a benchmark for what can be done.

Working with your IRB

While surveys of researchers routinely find wide support for the basic values of protection of human subjects, concerns about actual IRB operations are common, including:

- "What's the rush?" Timely review.
- "No right to research?" Appropriate review.
- "No such thing as passive consent?" informed consent issues.
- "IRB ping-pong" When IRBs don't agree?

NMAP's Final Recommendation

- "Unnecessary barriers to research should be lowered. Although existing guidelines for the protection of human subjects must be fully respected, Institutional Review Board Procedures should be streamlined for educational research that qualifies as being of low or minimal risk. …"

-- National Mathematics Advisory Panel, Final report, final recommendation, (p. 65)

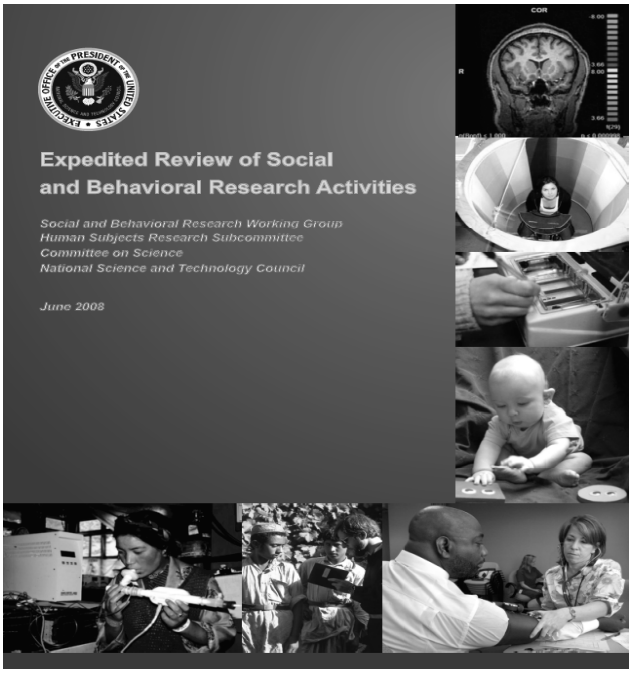
American Association of University Professors (AAUP)

- Research on Human Subjects: Academic Freedom and the Institutional Review Board

http://www.aaup.org/AAUP/comm/rep/A/humansubs.htm (2006)

Some IRB Review Risks

Location of risk	Conduct of study	Study findings
	• Poorly informed review that doesn't accurately assess risks and benefits (e.g. emerging research methods); • Biased review (professional bias, conflict of interest, etc.)	• **Statistical power** lost due to reduced size of achieved sample • **Statistical bias** caused by consent process
	• Site and subject recruitment harmed by poorly designed consent procedures, etc. •Delays (costs, lose baseline data) • IRB "ping pong"	• Invalid study •"Burn rate": attrition of studies not successfully completed due to review-related delays, costs



http://www.ostp.gov/cs/nstc

Toward the efficient frontier in managing risk to human subjects

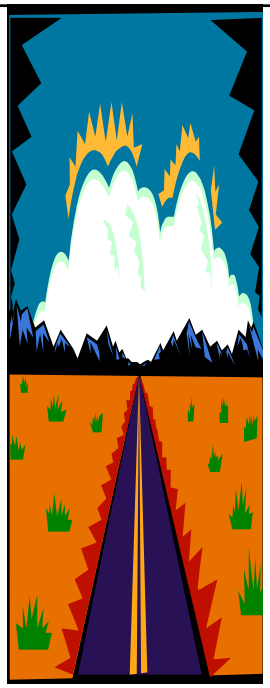
- You can use empirical evidence to move beyond anecdotes Evidence helps to:
  - identify research risks.
  - Identify effective consent procedures, and other human subjects protections.
- That is, evidence-based practice in study design and IRB review can help move beyond 'zero-sum games' to more effectively protect human subjects and enable rigorous research.

TIPS

- **Be IRB savvy** —understand what is expected by the IRB, be "bi-lingual" (Here "IRB" does not mean "Intl. Rugby Board").
- **Plan ahead** --timelines, budgets, whether sites will be "engaged", etc.)
- **Do the right thing**– it's easier in the long run.

In sum

- Do research as if it matters
- Be trusted—and trust worthy
- "Don't fool with the Common Rule"



Suggestions for improvement?

1. What guidance, information etc. would help you do your work better?

2. What would help applicants better understand and successfully navigate the process?

3. How to move from anecdotes to evidence-based protection of human subjects?

Some additional resources

- ED Protection of Human Subjects, Family Education Rights and Privacy Act (FERPA) and Protection of Pupil Rights Amendment www.ed.gov/about/offices/list/ocfo/humansub.html
- OHRP http://www.hhs.gov/ohrp/
- Expedited Review of Social and Behavioral Research Activities http://www.ostp.gov/cs/nstc

- Confidentiality and Data Access Committee (OMB, Federal Committee on Statistical Methodology) http://www.fcsm.gov
- American Statistical Association (http://www.amstat.org/comm/cmtepc/index.cfm?fuseaction=main)

- CITI Collaborative Instiutional Training Initiative (https://www.citiprogram.org/dev/aboutus.asp?language=english)
- University of Texas at El Paso (http://research.utep.edu/Default.aspx?tabid=47162)

Thanks!

We look forward to working with you for effective protection of human subjects, rigorous education research, and better teaching and learning.