Institutions in the United States who receive federal funding to engage in research involving human beings must follow the appropriate regulations, known as “The Common Rule”. Here is a little quiz on this rule:

a) Professor A is beginning a new project, interviewing Latin American domestic workers in Boston on their transnational ties to their homelands. “I don’t have to present my research to my university’s human subjects Institutional Review Board (IRB) since it is ethnographic, not biomedical, and exempt from the regulations.” Is the professor right?

b) Graduate student B is about to leave for Africa to conduct her dissertation research on tourist art sold in airports. “I don’t require IRB approval since my research is part of my education.” Is the student correct?

c) Professor C and his students are frustrated. They are eager to begin their classroom project of ethnographically interviewing exotic dancers at the local nightclub, who are also students, on gender roles and sexuality. The results of the project will be term papers used for the students’ grades. But the IRB chair has advised them against presenting the project for approval. The chair said the IRB would be concerned that the research could embarrass the dancers and would not be likely to approve it. Was the chair acting in accord with the regulations?

d) Professor D is really upset. She is in the third year of her National Science Foundation-supported sociolinguistic research on Japanese children’s use of verb tenses for everyday activities, asking questions like “How would you say ‘the pencil fell from the desk’”. Dr. D has just changed universities and her new institution is insisting that she have a Japanese IRB review her research, and that she get signed informed consent from the parents of the children in accordance with Subpart D of the regulations. Neither her old institution nor the funding agency required these things. The consent form suggested by the IRB is full of vague alarms more suitable for biomedical problems, and she is concerned that the form itself will frighten away potential respondents. What should the researcher do?

If you answered “wrong” for A and B, you are correct. While much ethnographic research, like much of social and behavioral research in general can be exempt from the regulations, an independent institutional authority like the IRB must make that determination. The researcher has a clear conflict of interest in excusing himself or herself from IRB oversight. While classroom exercises are normally exempt from federal oversight, the research involved in a dissertation should be
reviewed by the institution to make sure it follows official regulations.

Example C is about a course requirement and not about human research intended to advance knowledge through publication. While coursework is not covered by the regulations, many institutions extend their implementation to cover a wider range of research activities than the policy calls for. This review should be reasonable and should follow the principle that oversight of research should be commensurate with real risks of harm to human research participants ("subjects"). People who perform in public, like the respondents in C, expect to be observed. The IRB should make sure that the normal confidentiality of respondents is respected without preventing the research from progressing. In this case the IRB chair was improperly interpreting the regulations by being excessively strict. However, readers should note that their IRB is not bound to follow alternative interpretations, since universities are free to adopt policies over and above the Common Rule. What should you do when you disagree with your IRB’s interpretation? This will be discussed below.

How about poor Professor D? This case is more complex, and requires a bit more information to comprehend. Two issues are raised, that of parental consent for research with children, and the requirement for foreign IRB review. The federal government's overall human subjects regulations, the "Common Rule", only refers to "Subpart A" of a total of four parts: Subpart B deals with biomedical research involving fetuses, pregnant women and human in-vitro fertilization; Subpart C involves research with prisoners; and Subpart D pertains to research involving children. The subparts contain additional, stricter informed consent provisions. The Department of Health and Human Services (DHHS) has adopted the subparts, but the National Science Foundation (NSF) has not. Therefore the professor’s prior institution was following the regulations by not demanding additional protections, especially in light of the innocuous nature of the research which involved no harm to the participating children.

Subpart A of 45 CFR 46 has been incorporated into the regulatory structure of 17 federal agencies. Subpart A, known as the Common Rule, as well as the rest of 45 CFR 46 (Subparts B, C and D) may be found at [http://ohrp.osophs.dhhs.gov](http://ohrp.osophs.dhhs.gov) under Policy Guidance. The Common Rule sets forth the role and operation of the IRB, the required elements of the research protocol and the informed consent, and general criteria for IRB review and approval. Many institutions have signed "Assurances" with the DHHS in which they agree to apply all the subparts, in addition to the Common Rule, to all research conducted under their name. Under the prospective "Federal Wide Assurance" that will replace the older "Multiple Project Assurances", institutions will be free to suit the level of oversight to the cognizant (i.e., funding) federal agency's custom. Research like Dr. D's which is funded by an agency that has not adopted Subpart D, need not be subject to these extra provisions. They do not afford extra protection since there is not much risk of harm to protect against in the first place. However if a particular institution elects to follow all subparts, then all research undertaken by institutional representatives like Professor D will have to follow those regulations.

How about the need for a foreign IRB to review research conducted in a foreign setting? This makes sense for
biomedical research, since the risks are usually more substantial than for social and behavioral research. Even where a foreign IRB exists, they are usually specialized in biomedical science and often refuse to deal with social science. The regulations mention foreign IRBs but place the primary responsibility for review with the US institution receiving the federal funding. That institution's IRB has the responsibility to get the appropriate expertise -- sometimes about foreign research situations -- to review the research.

The regulations seem complex and daunting on first reading, but in fact they allow a fair amount of flexibility. That assumes they are administered by people with common sense who understand that research is a public good which should not be impeded without a clearly defined, reasonable risk of harm. This article discusses some of the relevant issues for cultural anthropologists. Additional guidance on human subjects issues can be found at the National Science Foundation’s website, http://www.nsf.gov/bfa/dga/policy/guidance.htm#human.

Some Historical Context

The Federal Regulations were developed based on the ethical principles set forth in the Belmont Report. This was issued in response to the Nuremberg Report describing the inhuman outrages perpetuated in World War Two on concentration camp inmates by Nazi doctors in the name of “research”. The Belmont Report sets forth the following ethical principles, which should govern research on human subjects: respect for persons, beneficence, and justice. Respect for persons is upheld primarily by communicating to potential subjects the information a reasonable adult would want in order to decide whether to participate. The information should be in language the person could readily understand and be readable enough so that the individual will actually attend to it. Although university attorneys may recommend several pages of informed consent jargon, participants in simple social or behavioral studies tend to respond to such a lengthy consent document either by rejecting participation out-of-hand, or by signing without reading it. It is just such conflicting mandates – between common sense interpretation of the regulations and the Belmont principles versus the self-protective and self-defeating requests of university lawyers-- which have placed IRBs between the rock and the hard place.

The Current Regulatory Climate

In recent years, the DHHS Office of Human Research Protection (OHRP, and its predecessor the Office of Protection from Research Risks, OPRR), have suspended the federally funded research of entire institutions for lack of compliance with the Federal Regulations with respect to specific biomedical research projects. While the events that triggered such suspensions may well have consisted of a pattern of neglect of the rights and welfare of human subjects, the offenses that were documented often consisted of inadequate paperwork practices of the IRB. These highly publicized and costly sanctions against research institutions produced a climate of anxiety. More recently, several tragic cases of deaths of human subjects of biomedical research were in the news. These cases, and the widely reported shutdowns of entire research programs, heightened the interest of the public as well as the anxiety of IRBs, many of which began to treat all social and behavioral research as if it were very risky. There has been a growing tendency to
follow what seems to be the letter of the basic regulations rather than the spirit of the Belmont principles. This new regulatory climate often involved much bureaucratic iteration before a protocol (for even minimal risk research) was approved; it also engendered disapproval of minimal risk student research; and IRB interference with normal (non-research) classroom instruction, all due to a self-defeating quest for entirely risk-free research in a world where nothing is entirely risk free.

‘What’s wrong with this’, you may ask. ‘Isn’t extra protection for the public worth a bit of bureaucratic hassle?’ If additional protection (meaning a decreased risk of harm) were in fact produced by this behavior, it might be justified. In my experience, listening to anguished complaints of social science researchers whose research is stymied by impossible demands, and discussing these issues with IRB members and administrators worried about their institution being shut down with the attendant bad publicity in their local media, protection is rarely the issue. Please note that I am not attacking IRBs, they are usually hard working groups trying to do a difficult job, balancing the interests of researchers, subjects, and the institution. Rather, I am calling attention to the current climate of “reactive hyper-protectionism” in the words of Dr. Greg Koski, the ex-director of OHRP.

It will help clarify the discussion to stress some fundamentals:

**First principles of the Human Subjects Research Protection system:**

- **Assumption:** All actors in the research system (funding agencies, institutions, researchers and their staffs) must work hard to avoid the dreaded outcome of harm to a human participant in research. No one should ever be hurt just because they were involved in a research project, if at all possible. That means we all must focus on two things:
  - Minimizing the risk of harm to subjects of research, and
  - Ensuring that research participants understand and accept such risks of harm that are necessarily involved in a research project.
- **Assumption:** Research is a national good. The advance of knowledge in all fields improves the world by enriching peoples’ lives; so research should not be impeded without a good reason.
- **Conclusion:** Therefore, the weight of bureaucratic oversight over research should be related to the level of risk of harm.
- **Assumption:** Doing research with human subjects is a privilege, not a right. An institutional identity legitimizes the research of university-based researchers.
- **Conclusion:** The institution has every right to evaluate the research of its members to make sure that relevant policies are followed.
- **Assumption:** It is in everyone’s interest (researchers, funding agencies, institutional administrators, students) to foster an “*Ethical Climate of Research*” over and above the narrow requirement to minimize harm and maximize informed consent.
- **Conclusion:** Therefore IRBs should engage in serious outreach and education in their institution, and researchers should serve on the IRBs.
In other words, for IRB oversight to protect human subjects, its major focus should be on high-risk research, whether biomedical, behavioral or social. Inappropriate demands placed on researchers and subjects, such as legalistic consent procedures that do not communicate effectively to research participants, do not address the major focus of the enterprise: the protection of participants in research activities. Legalistic procedures are ultimately harmful to subjects, the researcher and the institution, and ultimately to the public interest through impeding science. IRBs and researchers can return to a valid interpretation of the ethical principles under the current regulations, if they make use of the flexibility the Common rule offers for reasonable interpretation of its requirements.

**Biomedical hegemony: One Size Does Not Fit All**

The current regulations, 45 CFR 46, Subpart A (the Common Rule) were written to interpret the “Belmont principles” into regulations of human research primarily funded by DHHS (then HEW). The source of greatest risk to human subjects is biomedical research, which is mainly sponsored by DHHS. Hence the federal regulations of human research were written primarily with biomedical research in mind. There was actually some debate concerning whether to have a separate set of regulations for social and behavioral research. The authorities decided to have just one set of regulations. To accommodate social and behavioral research (which is often but not always of minimal risk) under the same regulations, IRBs were given the prerogative of formally exempting some research from the regulations, of conducting expedited review, and of waiving the requirement of signed consent under certain reasonable circumstances (45 CFR 46.116(c), 117(c)). However, these provisions are contained in bureaucratic language, which is not particularly easy to interpret. For those who wrote the regulations or who regularly interpret them the interpretations are simple and obvious. For everyone else they can be confusing.

The biomedical focus of the regulations has always posed problems for social scientists since biomedical (especially clinical) research requires standards that are often inappropriate for social and behavioral research. Although these problems existed in the 1970s through the 1990s, more flexibility seems to have prevailed during these years. IRBs tended to interpret the regulations in ways that were not unduly restrictive of social and behavioral research. More IRBs exercised their prerogative to exempt research, conduct expedited review, or waive the requirement of a signed consent form as permitted under the regulations, when appropriate. For example, paragraph (2) of 46.117(c) states that the IRB may waive the requirement for a signed consent form

,...if the research presents no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context.”

Much if not most social and behavioral research presents no more than minimal risk. The regulations also permit IRBs to exempt specified categories of research and to conduct expedited review. These alternative provisions, buried far into the regulations, and difficult to interpret, posed no problem for IRBs in the first decades of regulation. The IRBs simply used common sense, which produced results consistent with the regulations
The diverse agencies that operate under the Common Rule perform or fund a range of research, including biomedical, social, behavioral, product and drug testing research. However, some of the IRBs that review the social and behavioral research supported by these agencies interpret the requirements of the Common Rule in a manner more appropriate to high-risk biomedical research, ignoring the flexibility available to them in the Common Rule. They impose requirements more appropriate to risky clinical than to minimal risk social-behavioral research. For example many IRBs, in their effort to “go by the book,” routinely require a signed consent form even when this would not attain any of the Belmont goals and would be inappropriate (i.e., in low risk survey research).

Within mainstream Western culture, Singer (1978) and Trice (1987) have found that a significant number of subjects refuse to participate in surveys, or in studies and experiments, respectively, if required to sign a consent form, but would gladly participate otherwise. Among subjects who willingly sign documents, most sign the consent form without seriously reading it. Some cultures consider it insulting to sign an agreement, as though one’s word was not to be trusted. Other cultures, such as indigenous peoples, have had bad experiences, like loss of land, as a result of signing documents, and might gladly participate in a study but refuse to sign a consent form. Although informed consent (in the form of clear, appropriate communication) is a critical requirement, if this requirement is enforced as a legalistic, incomprehensible, long consent form it raises instead of minimizes problems.

In an effort to get a signed consent form, some IRBs have prevented the research from going forward or demanded a form that actually created the anxiety the form is supposed to ameliorate. For example, in the summer of 2002, an anthropology graduate student called to ask advice on how to deal with her IRB. She was about to begin her project studying the reintegration into their cultural group of illiterate African child war combatants. Her IRB, citing Subpart D, was demanding written informed consent (from illiterate persons!). I advised her to point out the requirement for meaningful informed consent, and the regulation permitting the waiving of written documentation (see above).

**Flexible Interpretations of the Common Rule**

Various groups have sought to develop interpretations of the Common Rule that are reasonable for the social sciences. For example, NSF has developed a set of FAQs (frequently asked questions) about the Common Rule, which appear on the website [http://www.nsf.gov/bfa/dga/policy/hsfaqs.htm](http://www.nsf.gov/bfa/dga/policy/hsfaqs.htm). These interpretations are based on a few basic principles such as the following:

1. **IRBs should balance level of oversight with level of risk.**
2. **Informed consent should take the form of an open, easily understood communication process.**
3. **All subjects should receive enough easily understood information to judge whether the risk- such as it exists in the project- is at a level they can accept.**
4. **When the subject can readily refuse to participate by hanging up the phone or tossing out a mailed survey, the informed consent can be extremely brief.**
The cultural norms and life-styles of subjects should be considered in deciding how to approach informed consent. Protocols for research on such populations should show evidence that the researcher is informed about the culture of the intended research population and has arranged the informed consent and other research procedures accordingly.

In some situations, it may be desirable for the researcher to consult with community representatives or leaders first, in order to enhance respect for and well being of individual research subjects.

Some research cannot validly be conducted if all details are disclosed at the outset. Alternatives are to

(a) provide only a description of what the subject will experience, with an agreement that the full details of the study will be disclosed afterward;

(b) engage in concealment or deception with the understanding that peers of the subject do not find such concealment or deception objectionable and that a full explanation will follow participation,

(c) explain that the subject might be enrolled in one of several possible conditions as in placebo research.

In certain circumstances, persons are not in a position to decide whether to consent until after their participation. This includes brief sidewalk interviews which persons are likely to welcome. Deferred (until after the interview) consent is an option.

What to do in cases of disagreement between researchers and IRBs?

Researchers must understand that IRBs have the authority to prevent their project from going forward. Researchers should communicate early and transparently with IRBs, taking their concerns seriously and attempting to work through problems by conversation and negotiation, with all relevant parties (including, sometimes, representatives of the subjects) at the table. And finally, researchers should serve on their IRB if they truly want their perspective to be represented.

IRBs should set themselves the goal of fostering an ethical climate of research, meaning serious outreach. IRBs should focus on the meaning, rather than the most restrictive letter of the law, and use the flexibility that it contains. Researchers as well as IRBs should consult with the most knowledgeable agency, that funds the research, for guidance.

With good faith efforts from all participants in the human subjects research system, we can pursue the goals of advancing research while minimizing exposure to risk of harm.

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Glossary

The Common Rule: The federal regulation governing the protection of human subjects in research. Sixteen federal agencies have agreed to implement this rule in a cooperative, coordinated fashion. It is available as Subpart A at [http://ohrp.osophs.dhhs.gov/](http://ohrp.osophs.dhhs.gov/) under "Policy guidance".

Federal Wide Assurance: A contract signed with DHHS by institutions affirming that they will abide by the human subjects regulations. It allows institutions to apply the Subparts selectively, depending on the agency funding the research and the level or risk to subjects.

OHRP: Office of Human Research Protection, the most powerful government watchdog office over human subjects in

**Risk:** The Common discusses the risk of harm to subjects in terms of both the probability and magnitude of harm. The magnitude of the harm is the critical element. As the NSF FAQ on minimal risk points out, “It is virtually certain that we will suffer minor transient harms in normal every-day life (transportation delays; inclement weather; embarrassment; fatigue; etc.). Such high-probability, low-magnitude harms are within the definition of “minimal risk” research.” ([http://www.nsf.gov/bfa/dga/policy/hsfaqs.htm#minimal](http://www.nsf.gov/bfa/dga/policy/hsfaqs.htm#minimal)).

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**Notes**

1 The opinions in this article are the personal, professional opinions of the author and do not necessarily represent the policy of the National Science Foundation. Portions of this article are drawn from Plattner, 2002 and Sieber, Plattner and Rubin, 2002.

2 This regulation is published as Code of Federal Regulations 45 CFR 46 for the Department of Health and Human Services, the largest supporter of such research.

3 Upon becoming part of the code of one of the other 16 agencies, the DHHS code is replaced by the code of the other agency. Thus HHS’ 45 CFR 46 becomes 45 CFR 690 for NSF, 34 CFR 97 for Education, etc. The text remains the same.


5 *Beneficence* requires that the projected benefits of the research, such as they may be, outweigh the risks. *Justice* requires fairness of procedures and fair distribution of risks and benefits among those affected by the research.

6 A (relatively ill) young man named Jesse Gelsinger died while involved in research at the University of Pennsylvania; a (healthy) young woman named Ellen Roche died while involved in research at Johns Hopkins University hospital.

7 Begley, 2002; Gunsalus, 2002;

8 See footnote 3 of the Belmont Report.
For example, the general requirements for informed consent section of the regulations begins as follows:

“Except as provided elsewhere in this policy, no investigator may involve a human being as a subject in research covered by this policy, unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate, and that minimize the possibility of coercion or undue influence. The information that is given to the subject or the representative shall be in language understandable to the subject or the representative. No informed consent, whether oral or written, may include any exculpatory language, through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence.”

The Common Rule states that the following kinds of research projects are exempt: research in educational settings involving educational practices, and research involving educational tests (cognitive, diagnostic, aptitude, achievement) surveys, interviews, or observations of public behavior. However, the exemption does not apply if specific individual human subjects can be identified (i.e., their names, phone numbers, or other unique identifiers are recorded in the data), and if disclosure of their identity could place them at risk of criminal/civil liability, or damage to their financial standing, employability or reputation. When subjects are public officials or candidates for office, the research is exempt even when identifiers are included or disclosure might be harmful.

This could take many forms. In ethnographic cases, venues such as focus groups, group discussions or other kinds of gatherings can serve as the most effective way to gain potential subjects' interest and answer questions. The actual recruitment and consent of individuals could occur at a later time after the collectivity has given approval. In still other cases, as among homeless or other wary groups, meeting with informal leaders or gatekeepers of the group can serve as a first step in getting word to potential subjects about the nature and purpose of the research and what it would entail. This might then be followed up with other meetings, and finally with recruitment and individual informed consent or decline.