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WORKING WITH IRBS

If you intend to conduct research involving human subjects, before you can begin, you must obtain the approval of your institution's Institutional Review Board, or IRB.

"The primary role, the primary purpose of the IRB is to protect the rights and welfare of human subjects. That's why they're there."

Daniel K. Nelson
University of North Carolina at Chapel Hill

Most academic or governmental research entities have their own IRBs; there are also independent or commercial IRBs. Regardless, the IRB (sometimes known as an Independent Ethics Committee, or IEC) is the body charged with ensuring that all research conducted at the institution involving human subjects follows regulations and guidelines established by the federal government. The IRB provides the appropriate governmental agencies with written documentation called federalwide assurance (FWA) that commits the institution to follow federal mandates scrupulously in exchange for what is basically a license to conduct human subjects research. On the rare occasion that assurance is breached through research mismanagement or misconduct, the government may impose sanctions or even suspend all research at the offending institution. That has actually occurred more than once in recent years.

Research involving animals is covered by a different set of federal regulations enforced by the U.S. Department of Agriculture, and is controlled at the institutional level by the Institutional Animal Care and Use Committee (IACUC). Here we focus on research involving human subjects, but investigators should also be aware that research involving animals is tightly regulated, and should be prepared to work within the guidelines and requirements in place at their institutions.

IRBs are governed by regulations established by the U.S. Department of Health and Human Services (HHS) and the Food and Drug Administration (FDA). The regulations are virtually identical, but the FDA has more rules in place for any studies involving drugs or medical devices falling within its jurisdiction.

Why Do IRBs Exist?

1. To protect the rights and welfare of human subjects
2. To ensure compliance with federal and other regulations
3. To prevent conflicts of interest
4. To ensure that all research conducted at a facility is reviewed according to a uniform standard

At times there may be confusion about whether a particular project needs to seek IRB review and approval. For example, occasionally there are clinical practices that may or may not qualify. To provide greater clarity, the federal agencies concerned have gone into some detail to define what is "research," and who are "human subjects." If your project falls within these very broad definitions, you must seek IRB review and approval.

Research: A systematic investigation designed to develop or contribute to generalizable knowledge

Human Subject: A living individual about whom an investigator conducting research obtains:

- data through intervention or interaction with the individual, or
- identifiable private information

Code of Federal Regulations, Title 45, Part 46, Section 102 (45 CFR 46.102)

Why Do You Need IRB Review & Approval?

- No one can be objective about their own work
- People underestimate the risks involved in activities they are very familiar with
- People overestimate the benefit of activities that are important to them

HISTORICAL BACKGROUND

In the aftermath of World War II, several Nazi physicians were put on trial for their participation in horrendously abusive medical experiments on concentration camp prisoners. The first codification of ethical principles surrounding the use of human subjects in scientific research, the Nuremberg Code, emerged from the trial verdicts. Among several important statements, the Code firmly established the concept of informed consent.

The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonable to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity.

Reprinted from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10, Vol. 2, pp. 181-182. *Washington, D.C.: U.S. Government Printing Office, 1949.*

The Nuremberg Code was subsequently adapted by the World Medical Association, which produced the first version of the Declaration of Helsinki in 1964. The Declaration has been amended several times since then and continues to be the international standard for the conduct of clinical research.

In the United States, the modern era of human subjects research ethics began in 1974, when Congress established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The panel was formed in response to highly disturbing revelations regarding researcher misconduct, particularly the decades-long Tuskegee Institute trial of untreated syphilis in black males. In that notorious study, which lasted from 1932-1970, patients were left untreated despite the availability of effective therapies such as penicillin, among other profoundly unethical abuses.

The commission ultimately produced a document that remains the ethical bedrock of the practice and regulation of clinical research: the Belmont Report (1979).

The Belmont Report (1979)

Three Core Ethical Principles:

- **Respect for Persons**
  Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. This is the ethical foundation for the concept of informed consent. The three elements of informed consent are specified in the Report:

  Information. *Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research.*

  Comprehension. *The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice. Because the subject's ability to understand is a function of intelligence, rationality, maturity and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information.*

  Voluntariness. *An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence.*

continued

The Belmont Report (1979) *continued*

- **Beneficence**
  Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being…(1) do not harm and (2) maximize possible benefits and minimize possible harms.

  Assessment of Risks and Benefits. *The assessment of risks and benefits requires a careful arrayal of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist in the determination of whether or not to participate.*

The Belmont Report (1979) *continued*

- **Justice**
  Clinical studies should be conducted in a manner that ensures the equitable distribution of research costs and benefits. For example, justice requires attention to participant recruitment, including inclusion and exclusion criteria.

  Selection of Subjects. *The principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects. Justice is relevant to the selection of subjects of research at two levels: the individual and the social. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only "undesirable" persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.*

Although there were federal regulations regarding human subjects research on the books in the mid-1970s, they were refined and revised in 1981 in the wake of the Belmont Report. In 1991, 17 federal agencies agreed to the Federal Policy for the Protection of Human Subjects, known as The Common Rule, which commits the agencies to follow a single set of regulations. The Common Rule includes additional protections for certain vulnerable research subjects. Subpart B provides additional protections for pregnant women, in vitro fertilization, and fetuses. Subpart C contains additional protections for prisoners. Subpart D does the same for children. Not all agencies or institutions recognize Subparts B-D.

Current regulations from the U.S. Department of Health and Human Services are provided in 45 CFR 46 (the Code of Federal Regulations) www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101.

FDA regulations are detailed in: 21 CFR 50 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=50 (IRBs) and 21 CFR 56 http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=56 (informed consent).

Although the basic structure first encoded in 1981 is still in place, human subjects protection is evolving rapidly as the pace and complexity of biomedical research continues to progress.

"*When the regulations were first drafted 27 years ago, research was a much different beast than it is today. Back then you might have one investigator at one academic center enrolling a small handful of subjects. Now, in a Phase III drug study you might have a few thousand patient/subjects enrolled at one hundred sites across the country, or maybe across the world. Then you have the problem, whose IRB needs to review this study? Do we need IRB review at each of one hundred sites? Is there some way to streamline this? These are some of the issues that are being grappled with today, because clinical research has evolved in a way that really wasn't anticipated when the structure was put into place 27 years ago.*"

—Daniel K Nelson, University of North Carolina at Chapel Hill

LEVELS OF IRB REVIEW

If you have determined that the study you are planning constitutes human subjects research as defined above, you must apply for and obtain IRB review and approval before you can proceed.

Research projects are reviewed according to the IRB's determination of the project's potential risk to the human subjects and the federal guidelines that define the categories of review, which are:

- screening for exemption from full IRB review,
- expedited IRB review, and
- full convened IRB review.

The level of review is determined only by the IRB. You should have a good idea of which level your study may fall under before you apply—often the application will target a specific level.

Potentially Exempt Research Activities

(as defined in 45 CFR 46.101(b))

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.
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.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (b)(2) of this section, if: **(i)** the human subjects are elected or appointed public officials or candidates for public office; or **(ii)** federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Potentially Exempt Research Activities *continued*

4. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
5. Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine: **(i)** Public benefit or service programs; **(ii)** procedures for obtaining benefits or services under those programs; **(iii)** possible changes in or alternatives to those programs or procedures; or **(iv)** possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, **(i)** if wholesome foods without additives are consumed or **(ii)** if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Expedited IRB review typically means that only the IRB chairperson or one or more members will review the study. Obviously, it is designed to be, and usually is faster than, a full board review. To qualify for expedited review, the study must involve no more than minimal risk and must fall into one of the research categories established by HHS for expedited review *(*http://www.hhs.gov/ohrp/policy/expedited98.html*)*. Also, minor changes in previously approved research can be approved by expedited review.

If your study does not meet the strict criteria established for exemption or expedited IRB review, it will need to be considered in a full convened IRB review.

"*The feds expect each institution to take the federal regulations and use them as a foundation for your human subjects program, and that you build on that as appropriate for the kind of research you do…So each institution is going to develop, out of their experiences and their personalities, their own flavor on how they look at human subjects research.*"

—Charlotte Coley, Duke University School of Medicine

"There is a process investigators have to anticipate when they are submitting to an IRB. There will be forms to fill out, whether on paper or online. They will have to answer questions like: What are the risks of this study? What are the benefits of the study? What do you hope to learn? What procedures are to be involved? Where will people be recruited from? Show us the consent form that you intend to use. And so on and so forth. And then all of this is reviewed. The full board or convened meeting review may be anywhere from a minimum of five to as many as twenty members who meet regularly and review anywhere from one to twenty studies at a time, and then give feedback to investigators. Investigators have to be prepared to submit materials to the IRB, and then, depending on the IRB, they'll eventually hear back from the IRB with feedback, or stipulations or conditions."

—Daniel K. Nelson, University of North Carolina at Chapel Hill

IRB REQUIREMENTS

As previously noted, every IRB will be slightly different with respect to its requirements, depending on the institution and its portfolio of research activities. However, all IRBs will have specific expectations designed to ensure complete and conscientious compliance with federal regulations.

For example, virtually all institutions today require all personnel involved in a study to have completed a training module in human subjects protection. The federal requirement is that *key personnel* named on NIH grants undergo such training, but most institutions have chosen to require it of all investigators and staff members.

"*Most of us said, whether you're named on a grant or not—if you are, for example, a research nurse that's getting consent—we want that person to be sensitized to these issues just like the principal investigator whose name would be on top of the grant. Maybe even more so, because the PI may never see the subjects, but the study nurse would.*"

—Daniel K. Nelson, University of North Carolina at Chapel Hill

The content of the training is left to the discretion of the individual IRB. Depending on how the IRB you will be dealing with chooses to satisfy the requirements, you may have to complete an online module, a month-long course, or perhaps read designated books. Regardless of the approach, it is practically a given that every IRB will require some type of training or education before a study will be approved.

Similarly, the number of forms and types of information required by IRBs will vary from institution to institution. All will ultimately require a full description of the proposed study, with a complete delineation of the study's protocol and the methodology to be employed. These modules will often be included in a standard application or submission form. The IRB will also want to review any related print materials or other documents associated with the study, such as questionnaires, advertisements, press releases, brochures, etc.

All IRBs will also expend considerable care and effort reviewing informed consent plans and documents, as that is one of the core elements of their mission to protect the rights and welfare of research subjects. Many IRBs have informed consent document templates on hand, which can be customized for particular studies.

"*We have staff in our office who are writers who review new consent forms the first time they come in for a new study, and they are available here to help people who don't know how to write a consent form. We've also put templates and standard language on our website, both in English and Spanish.*"

—Charlotte Coley, Duke University School of Medicine

Informed consent can be a complex undertaking. The nature of what is truly informed consent (a topic of considerable ongoing debate among bioethicists) often depends on the population the researcher wishes to use as subjects and the history and experience of the individual institution.

"*If you're at an institution doing behavioral research with migrant workers, then obviously you're going to have a lot of experience and perhaps guidelines for how you write a consent—in what language, at what level. If you do research with migrants who maybe only have an elementary school education, you're going to write it much simpler than if you're doing research with airline pilots, who have to have a college degree in order to have their job. If you're in this part of the country, you're going to have Spanish, as we do. If you're in another part of the country where Chinese or Korean or French is a prevalent language spoken by a lot of people who are potential subjects, then you're going to have to have [consent] standards requiring those languages.*"

—Charlotte Coley, Duke University School of Medicine

Although there may be considerable variation, the acquisition and documentation of informed consent must meet very specific criteria spelled out in the federal regulations.

Basic Elements of Informed Consent
(45 CFR 46.116(a))

In seeking informed consent the following information shall be provided to each subject:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others which may reasonably be expected from the research;
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

Basic Elements of Informed Consent *continued*

6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and
8. A statement that participation is voluntary and that refusal to participate or to discontinue participation will involve no penalty or loss of benefits to which the subject is otherwise entitled.

Additional Elements of Informed Consent
(45 CFR 46.116(b))

When appropriate, one or more of the following elements of information shall also be provided to each subject:

1. A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;
2. Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's consent;
3. Any additional costs to the subject that may result from participation in the research;
4. The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;
5. A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and
6. The approximate number of subjects involved in the study.

Under certain circumstances, informed consent requirements can be changed, or waived altogether. Consult with your IRB for more information if you think your study might qualify.

Once your study is approved and underway, you will still need to maintain ongoing communication with the IRB. The IRB is responsible for conducting continuing review of research appropriate to the degree of risk involved, but not less than once per year. Some protocols initially approved in a full board review may be eligible for expedited review thereafter if the level of risk to subjects is unchanged, or if only minor changes have been made to the protocol. In conducting continuing review of research not eligible for expedited review, all IRB members should receive and review a protocol summary and a status report on the progress of the research, including:

- the number of subjects accrued,
- a description of any adverse events or unanticipated problems involving risks to subjects or others, and of any withdrawals of subjects from the research or complaints about the research,
- a summary of any recent literature, findings obtained thus far, amendments or modifications to the research since the last review, reports on multi-center trials or any other relevant information, especially information about risks associated with the research, and
- a copy of the current informed consent document.

HOW TO SUCCESSFULLY WORK WITH YOUR IRB

As with any new undertaking, working with an IRB for the first time can be a daunting proposition. The first and best advice is to arm yourself with as much information as you can gather as soon as you know your study will need to go before your institution's IRB for review and approval. The more you know, the more you will know what to expect, and what will be expected of you.

***"In your department**, there's going to be somebody, or several people, who are IRB members. Go to them and get advice and guidance. Call the IRB office, because it's a great resource of information and help, and they have people on staff who answer specific questions, all the way to doing training on an individual or group level. And all of the universities that are doing research have pretty good websites with more information than you could shake a stick at. So, go to the local IRB member, to the IRB staff, and to their website, and you will have three very good places to start your journey.*

—Charlotte Coley, Duke University School of Medicine

As the time approaches to submit your information to the IRB, be prepared, be proactive, and be thorough. Take full advantage of the assistance you have lined up with a mentor, the IRB staff, the IRB chairperson—whoever can help walk you through the process.

"*The more willing the investigator is to sit down and make sure the protocol has all of the i's dotted and t's crossed, it's going to make the process go much more smoothly…the more work you do up front to find out what the requirements are—meet with the chair, meet with the administrator, make sure that everything is in place so that by the time it hits the committee it's done—that's probably one of the best things you could do.*"

—Jon F. Merz, MBA, JD, Ph.D., University of Pennsylvania School of Medicine

"*Take the process seriously. This is not put here just to make your life miserable. It's not here because we think you're a bad person or we don't trust you. It's required for a reason. If you are thorough and professional in your approach to this, we will do everything we can on our end to expedite things, to move things along to help you get up and running as fast as possible.*"

—Daniel K. Nelson, University of North Carolina at Chapel Hill

Answer questions honestly and fully, and be sure to leave adequate time for the IRB to work through its process, which can sometimes take weeks to even months—don't wait until you're ready to enroll subjects, or until your grant deadline is looming. As part of your initial inquiries, find out how long your IRB typically takes to review and approve, and plan your submission accordingly.

"*Read the questions that the IRB puts to you carefully, and answer them thoroughly. Provide as much information as you can. Don't just say, 'does not apply,' or answer in one sentence what might take a paragraph to give the IRB the full context. Anything you leave out opens the door for the IRB to have to come back and say, 'we're sorry, we just don't understand what it is you're trying to do or what you're trying to say' and then there's this back and forth ping-pong effect that drives everybody nuts. So be thorough, be complete, and provide all of the materials requested.*"

—Daniel K. Nelson, University of North Carolina at Chapel Hill

"Take the process seriously. This is not put here just to make your life miserable. It's not here because we think you're a bad person or we don't trust you. It's required for a reason..."

Daniel K. Nelson
University of North Carolina at Chapel Hill

It is somewhat unusual for an IRB to either completely approve or completely deny a protocol on first pass. More typically, the IRB will provide the researcher with feedback or suggestions for improvements. In that sense, the relationship with the IRB can be seen to be one of negotiation.

"*We have 4,000 research studies going on at any one time here at UNC-Chapel Hill. When they come in the door, I don't like to see IRBs just say, 'no, you can't do this.' I like to see them say, 'well, there's a potential problem with the way you proposed it, but how about if you try it this way?' So there's a negotiation to get to the point where all parties can say, 'OK, here's how we'll move ahead.' There can, and under the best of circumstances there should be a negotiated agreement.*"

—Daniel K. Nelson, University of North Carolina at Chapel Hill

"*IRBs are sometimes criticized for being too protective and requiring things that are kind of ridiculous. Only if an investigator knows what the rules are and can say why what he or she is proposing to do is ethical and within the rules can they make the arguments to the IRB and show that the IRB is wrong…So just because an IRB initially says something, that doesn't mean you have to do it that way. There's wiggle room. On the other hand, the IRB doesn't have to approve everything. If you're proposing something and the IRB has really good justification for why they don't want you doing something within that institution the way you propose, then obviously your choices are to abandon it or do it in some other way.*"

—Jon F. Merz, MBA, JD, Ph.D., University of Pennsylvania School of Medicine

Remember, IRBs are groups of individuals who have been charged with the duty of protecting the rights and welfare of human research subjects. History has shown that investigators, despite their best intentions, have a built-in conflict of interest. Their primary goal is often to see the research itself go ahead. That does not mean they want to hurt subjects, but they have come to be seen as being too close to the goals of the research—whether that's publishing their results, getting another grant, developing a new drug, or winning a Nobel Prize—to be able to step back and think through some of the issues that are seen only from the subject's perspective. That outside perspective, the objective analysis brought to bear by the IRB, is there to help you, not hinder you. If you approach the process in the spirit in which it is intended, you will be successful and the IRB will be your ally as you move forward with your research agenda.

"Investigators wrongly view the IRB as this black box. They either view it as a bureaucratic hurdle and impediment, or they view it as this magic black box where you put in this complicated medical, legal, scientific issue and get out the one right answer. Truth be told, this is a group of human beings looking at this work from the outside and trying to, given the information they have in their hands at this point in time, use their judgment to say, 'yes, this can go ahead,' or 'it can go ahead in this manner.' But it's very much a subjective human judgment call and reasonable people will disagree."

—Daniel K. Nelson, University of North Carolina at Chapel Hill

Further Resources

FDA FAQ's
http://www.fda.gov/RegulatoryInformation/Guidances/ucm126420.htm

IRB Forum
http://www.irbforum.org/

NIH IRB Guidebook
http://grants.nih.gov/grants/guide/notice-files/not93-209.html

U.S. Dept. of Health and Human Services
http://www.hhs.gov/ohrp/assurances/irb/

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