Criminal Justice Coordinating Council

Institutional Review Boards

Brief

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Research Tools: What is an Institutional Review Board?

The study of human subjects calls for protections of those subjects, whether the research is conducted at a university, a government agency, or a research organization. One mechanism that can protect individuals participating in research from harm is an Institutional Review Board (IRB). An IRB is tasked with ensuring that researchers protect human subjects in the planning and execution of research. For a study to require the review of an IRB it must involve research and human subjects and must not be exempt from review.

History

In 1978, in response to a history of questionable medical and behavioral research such as the Tuskegee study of syphilis, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued the Belmont Report, which included recommendations on how human subjects should be treated.[1] The three core principles of the Belmont Report are: respect for persons, beneficence, and justice; these three elements are core to most, if not all, professional codes of ethics in the United States.

- "Respect for persons" means one should respect voluntary participation and consent, giving as much disclosure as possible to participants around what the study is for, potential harms and benefits, and planned products of the research. This principle is the basis for why studies with human subjects have 'informed consent,' where subjects are given enough information about the study's purposes, procedures, and products to make a thoughtful decision about participating in the research. Unless otherwise approved, there is a record kept of every participant having been given this information as well. An additional element of respect is that researchers should be as truthful as possible, and not deceive their subjects in the informed consent, as well as in the practice of conducting the research.
- "Beneficence" is described in the Belmont report as a stiff obligation to do no harm and to maximize possible benefits while minimizing harms. This includes weighing harms and benefits and making sure the latter is greater. If the benefits of the study do not obviously outweigh the harm that may be caused, the research should not be conducted – or an alternate method of conducting the research should be considered that would not involve unnecessary harm.
- "Justice" dictates that there is a fair distribution of the benefits and burdens associated with research. One group should not bear the brunt of the burden of research, and it should not be done solely to the benefit of another group – the weight should be equally borne. A commonly cited example of violating this rule is exporting clinical trials of drugs to underdeveloped countries.[2]

Defining the Institutional Review Board

Following the Belmont Report, organizations began to establish formal structures to review proposed research to ensure the standards of ethics are upheld. An IRB is a body that is formally organized to objectively review research plans involving human subjects to ensure the research plan adheres to the

[1] https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html
[2] For an example, see: https://depts.washington.edu/bioethx/topics/resrch.html

principles of respect, beneficence, and justice. In the task of reviewing research plans before they are undertaken, this body is charged with ensuring steps are taken before, during, and after completion of research to protect human subjects from harm or potential harm caused by the research.

US Code requires that an IRB be utilized in any plan involving biomedical or behavior research that involves human subjects.[3] Federal regulations established under this code by the U.S. Department of Health and Human Services (HHS) set the standards of review when research involving human subjects is undertaken, and these regulations specifically lay out when a study must be reviewed, to what degree of scrutiny, and which projects are exempt. These regulations are referred to as the "Common Rule." It is a set of rules that apply to research that is funded by the HHS, as well as any agency that has adopted the Common Rule requirements. The Common Rule was revised in 2018 and took effect for HHS in January of 2019. Most federal agencies have since chosen to adopt the Revised Common Rule–20, as of this writing–which requires any research involving human subjects that is conducted by or about that agency, or using funds from that agency, to be reviewed by an IRB. The Revised Common Rule is pending adoption by the Department of Justice (DOJ), and the rules that apply will hold for research supported by DOJ grant money in the very near future; therefore, the description of the functions in this brief reflect the Revised Common Rule.

Because such a large portion of federal grant money is subject to the requirements of the Common Rule and the Revised Common Rule, virtually all universities have IRBs as a great deal of academic research is federally funded.[4] Also, some federal, state, and local agencies house their own IRBs. One of the subparts of the Common Rule and of the Revised Common Rule created a mechanism by which HHS maintains a registry of certified IRBs, and HHS will only fund those projects that are reviewed by a certified IRB. federal agencies use this certification and registration as an indication that the IRB is adhering to the Common Rule requirements.

What is Research?

Agencies and partners measure and report many things, but these analyses are often operational in nature and are not usually considered research. Research is any investigation that is systematic, such as testing or evaluating a policy, which is intended to improve a broader understanding of an area of interest, and "designed to develop or contribute to generalizable knowledge."[5] This differs somewhat from other operational analyses undertaken in government, such as performance measurements, program evaluations, or agency audits, which solely examine the activities of a particular effort. These products are not intended to be generalizable, so they are not considered research, and therefore, would not be subject to IRB review[6]

[3] 42 U.S. Code § 289a

[4] Federal code dictates that any institution that engages in federally funded research involving human subjects must have an IRB (42 U.S. Code § 289a). The Common Rule and the Revised Common Rule are regulations put forth by HHS. The revisions took effect in most signatory agencies in January of 2019.

[5] 45 CFR Part 46 §46.102(l)

[6] In the past, under the Common Rule, many considered any product that would be published in a peer reviewed journal to be 'research.' However, HHS has maintained that in the Revised Common Rule, publication does not necessarily mean research. It is common to publish things that are not generalizable, such as case studies, and these are not 'research' for the purposes of the Revised Common Rule.

When Does Research Involve Human Subjects?

If a project is research by Common Rule definition, then the next thing to consider is whether it includes human subjects. There are two scenarios in which research might involve human subjects and would require IRB review: when research includes information about people, or when it involves interaction with people. In both instances, researchers must consider the role of an IRB, and must be vigilant about protecting those people. In justice-related research, it is important to carefully consider the likelihood of potential harm because this work involves vulnerable populations that are at risk for, or already involved in, the juvenile and criminal justice systems.[7] When a project is research and involves human subjects, the IRB ensures that the researchers protect the rights and welfare of those human subjects.

Structure of the IRB

Members of the IRB are independent, and they usually come from tangentially related fields to the work being undertaken, so their expertise is in ethics, rather than in direct relation to the topic being studied. This is because the focus of the IRB is on the logistics of the research and its impact on subjects. Also, visiting members can be brought in if necessary, allowing for subject matter expertise to be shared where relevant.

The Revised Common Rule requires a core membership of five members who are diverse in expertise, race, gender, and culture. Each IRB must include a scientist, as well as a person who is not affiliated with the reviewing institution and cannot include any person who has a conflict of interest. Additionally, if an IRB regularly reviews projects involving vulnerable populations, such as justice involved individuals, the IRB should include someone who can represent the interests of that group. One example is research involving incarcerated persons, where a prisoner representative should be included as they can speak to the experience of prisoners and can consider how research may have unforeseen impacts on them.

When and How Does an IRB Review a Research Plan?

Entities may handle the decision to enlist an IRB differently. HHS and other Common Rule federal agencies require anyone intending to apply for federal funding to support research to register for a Federal Wide Assurance (FWA). The FWA registration is an indication that the entity will comply with the Common Rule and act in good faith when considering the need for an IRB review when studying human subjects. In some cases, in addition to FWA registration, an entity may include a commitment to undergo IRB review in its research plan and application.

Other entities determine the need for IRB review in other ways. For example, university IRBs review all analytic products conducted by persons affiliated with the institution regardless of the type of study.[8] When non-profit or for-profit entities pursue research without some form of government funding, they may opt to use IRB review even if it is determined that the study is exempt. Even where federal funding is not a factor, having an IRB review to verify that a study is exempt is a common practice because it adds a level of confidence in the researcher and in the work, signaling a high degree of thoughtfulness and a high standard of ethics.

If an entity of any sort determines that a study requires review, the IRB process is determined by the type of research being conducted. Reviews by IRBs are one of four types: exempt reviews, limited

[7] Federal regulations have specific rules for protecting vulnerable populations, including persons under 18 and prisoners.
[8] Most universities have their own IRB, but government and other entities may need to seek out an IRB that could charge for its services.

reviews,[9] expedited reviews, and full board reviews. There are many categories of exempt research. Some research that would be otherwise exempt but involves collection of identifiable or sensitive information can be considered by a limited IRB review rather than a much more involved expedited or full board review. Exempt studies include:

1. Educational research that is part of and does not interrupt instruction;
2. Educational testing, or observable public behavior, when:
    - Nothing identifiable about the subject is collected, or
    - Nothing sensitive about the subject is collected, or
    - If identifiers and/or sensitive information[10] is collected, and a limited review by an IRB determines that there are adequate protections of this information. This limited review to determine exemption applies only for those agencies that are subject to the Revised Common Rule.
3. Research involving benign behavioral interventions[11] when:
    - Nothing identifiable about the subject is collected, or
    - Nothing sensitive about the subject is collected, or
    - If identifiers and/or sensitive information is collected, and a limited review by an IRB determines that there are adequate protections of this information. This limited review to determine exemption applies only for those agencies that are subject to the Revised Common Rule.
4. Secondary research where consent is not necessary when:
    - Nothing identifiable about the subject is collected, or
    - Nothing sensitive about the subject is collected, or
    - If identifiers and/or sensitive information is collected, and a limited review by an IRB determines that there are adequate protections of this information.[12] This limited review to determine exemption applies only for those agencies that are subject to the Revised Common Rule.
5. Federal agency studies that are designed to improve service delivery, specifically for social service programs; or
6. Studies that involve taste of food or food products when they are healthy and/or known to be safe.

When a study is not exempt, and it is determined that a limited review is not enough, the IRB conducts either an expedited or a full review. Both reviews are based upon the three ethical principles of research

[9] The limited review is a new level of review established in the Revised Common Rule.

[10] Guidance from HHS states: "The definition of sensitive information includes, but is not limited to, information relating to sexual attitudes, preferences, or practices; information relating to the use of alcohol, drugs, or other addictive products; information pertaining to illegal conduct; information that, if released, might be damaging to an individual's financial standing, employability, or reputation within the community or might lead to social stigmatization or discrimination; information pertaining to an individual's psychological well-being or mental health; and genetic information or tissue samples." Retrieved from: https://www.hhs.gov/ohrp/sachrp-committee/recommendations/2014-july-3-letter-attachment-b/index.html#_ftn1

[11] Benign interventions are defined in the regulations as "brief in duration, harmless, painless, not physically invasive, not likely to have significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing."

[12] Exception also exists here with any study using federal agency data on behalf of that agency so long as any identifiers collected are maintained within the agency's system and in compliance with the Federal Privacy Act.

outlined above: respect, beneficence, and justice. The level of exposure to risk determines whether it will be an expedited or a full review, but in either process, all facets of harm and benefit are considered.

An expedited review is generally done when research already has IRB approval but there are minor changes to the originally approved research plan. The expedited review is conducted by the chair of the IRB instead of the full board, and generally is a much quicker process.[13] A full review is the most extensive and can take multiple submissions and meetings to be approved. The role of human subjects in all stages of research is considered, including: data collection, information storage and access, reporting of findings, and eventual destruction of stored information.[14] The board reviews confidentiality, informed consent, and the exposure of subjects to any form of harm at every phase of the project. The result of the review can be an approval, conditional approval, requirements for serious revision, or full rejection. No research submitted to an IRB should begin until full approval is granted. In the case of a full review, the IRB generally keeps the review open until the research project is complete, monitoring the project to make sure the researchers follow through with all promised protections.

Some basic questions that an expedited or full review would ask include:

- Have the risks to subjects been minimized using procedures that are consistent with sound research design?
- Are the risks reasonable in relation to anticipated benefits?
- Is the selection of subjects equitable?
- Are adequate procedures in place to ensure privacy and confidentiality?
- Is there a plan to monitor the data and safety of the subjects, if necessary?
- Will informed consent be sought and appropriately documented? Do proposed alterations or waivers of informed consent meet the criteria for approval?
- Are safeguards in place to protect vulnerable populations?[15]

IRBs in the District of Columbia

DC Health is the only District government entity with an IRB. This agency IRB does not generally review research plans unless it involves one of their employees or DC Health data, so when a District government justice agency requires a review they must seek a nongovernmental IRB. There are federal criminal justice agencies within the District that have IRBs, including the Federal Bureau of Prisons (BOP).[16] And, there are criminal justice agencies that are in the process of establishing IRBs, including the DC Superior Court (DCSC), Court Services and Offender Supervision Agency (CSOSA), and the Pretrial Services Agency (PSA).

[13] There is no standard of how long a full review takes (often months at the university level, and weeks at a private IRB), so the expedited review is quicker, but only in a relative sense.

[14] A good example of what is considered by the full review can be found here: https://humanresearch.gwu.edu/sites/g/files/zaxdzs2446/f/downloads/IRB_Basic_Tips_GW_OHR.pdf through the George Washington University Office of Human Research.

[15] Online training is available for those participating in human subject research and for those overseeing review of human subject research. This list of questions is quoted from a training document in the nationally certified training site Citi Program: https://about.citiprogram.org/en/homepage/

[16] The Revised Common Rule will be adopted by federal justice agencies when the DOJ becomes a signatory which is slated to occur in the near future.

Some useful links:

- US Department of Health & Human Services, IRB Procedures: https://www.hhs.gov/ohrp/regulations-and-policy/index.html
- Text of the Belmont Report: https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html#xbenefit
- Human Subject Regulations Decision Charts by HHS: https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html#c1
- Flowchart on how to determine exemption see Oregon State University: http://research.oregonstate.edu/sites/research.oregonstate.edu/files/irb/exempt_05122016.pdf