

# Understanding IRB and IACUC

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One of the questions that may come up when you are ready to submit a paper for publication in an academic journal is around IRB approval. Hugo mentorship projects are not designed to provide IRB or IACUC approval. This is important to understand as you embark on your research, especially if you are aiming to create a publishable paper. Many students are not familiar with this topic so we hope this resource will provide a very brief overview of what is and why it matters.

Any research involving humans or other vertebrate animals is a privilege, and must receive approval of an Institutional Review Board (IRB) or Institutional Animal Care and Use Committee (IACUC) to receive funding and/or qualify for eventual publication. Hugo mentorships are not affiliated with any specific university, and as such, cannot receive such approval. Students of any discipline aiming for peer-reviewed publication of their research involving humans or animals should read this article to determine if their methods need redesign to qualify for eventual publication.

Why does this matter to you? If you are hoping to do a project that includes a survey that you want to administer, and then plan to use the data to write an article for submission to an academic journal, you will likely find that your paper will not qualify because the journal requires IRB approval. We want you to be able to understand this at the beginning when you are setting your goals for your project and defining your final deliverable.

## Different Types of Data

### Data that Does Not Require Approval

If your study is using metadata (data collected from across many other experiments), or is using publicly available data sets that others have already cleared with an ethics review board (such as US Census data, or other government databases), you will not require additional approval from an institutional review board, and may skip the reading the rest of this article if you choose. If you are not sure if your data falls into one of the categories listed above, you should ask your mentor before proceeding with your research, and read the rest of this article.



## Data That Requires Approval

If you are collecting any data including survey data from humans, or on animals with a spinal column (vertebrates of any kind), your experimental methods will need to be reviewed and approved by an ethics review board if you are interested in referencing or including it in an article you plan to submit for publication in an academic journal. This is a mandatory, extremely complex, iterative, and exacting process that takes a year or more to complete. Hugo mentorship projects do not qualify for approval by an ethics review board because mentees are: (1) usually minors, (2) not affiliated with a university research group, (3) not IRB and IACUC ethics-certified.

If you are conducting research requiring ethics review (you are conducting surveys, interviews, or animal research on a vertebrate species), but do not wish to publish your data in an academic journal, you may conduct your research under the supervision of your mentor. You can share these types of survey findings in other ways, including referencing them in articles, presentations and publishing them in other spaces that do not explicitly require IRB approval. However, you will still want to review the ethical design of your study with your mentor so you are familiar with the ethical considerations needed for your future research career.

Beyond the moral implications, there are other benefits to following all guidelines, regulations, rules, and procedures outlined by governing boards and committees. When research subjects receive standardized care and handling, data is more reliable, less variable, and experiments may be replicated with a higher degree of accuracy. Receiving the approval of (or voluntarily following the protocols of) an ethics review board makes you a more reliable expert and voice of authority in your field. You therefore increase your likelihood of being accepted (or even invited!) to present talks, posters, or submit articles to competitive journals.

## An Introduction to Research Ethics

You will take ethics certification coursework as an undergraduate or graduate student that covers animal and human subjects in detail. For a non-exhaustive review of research ethics, we've provided an introduction below. This document does not and is not intended to fulfill or replace the requirements associated with a certified ethics training course.

### What is an IRB, and why does it exist?

In accordance with FDA regulations, an Institutional Review Board (IRB) is a group designated to review and monitor research involving human subjects. An IRB has the authority to approve, require modifications in, or disapprove research. Researchers operating at a research institution that receives federal funding, receiving federal funding directly in the form of grants, and/or wishing to publish in a peer-reviewed research journal must first receive approval from an IRB.



Despite the long history of unethical research performed on enslaved, imprisoned, and disadvantaged peoples, the need for ethical guidelines in human research was only formally recognized by the international community when the atrocities of WWII Nazi research were reported at the Nuremberg Trials. Unfortunately, the resulting Nuremberg Code was found lacking as it was difficult to interpret and/or overly specific. After many iterations, the scientific community has landed on their current code of ethics, which include the ethical pillars of:

- *respect* for persons (respect for personal autonomy/informed consent, and recognition that individuals may not be capable of self-determination and require protection),
- *beneficence* (protecting subjects from harm and securing well-being), and
- *justice* (groups of vulnerable or disadvantaged people are not excluded from or systemically selected for clinical trials, or prevented from access to therapeutic benefits derived from publicly funded research).

Racist, coercive, or eugenic practices conducted in the United States have been uncovered from the time of WWII with the Tuskegee Study of Untreated Syphilis in the Negro Male (now referred to as the USPHS Syphilis Study at Tuskegee, or The Tuskegee Experiments), to as recently as the 1990s, emphasizing the ongoing need for ethical review and evaluation in human research.

## What is an IACUC and why does it exist?

An institutional animal care and use committee (IACUC) is responsible for oversight of the animal care and use program and its components as described in the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals and the Guide for the Care and Use of Laboratory Animals. Similar to an IRB, an IACUC supports, facilitates, and promotes ethical and humane use of animals by upholding the standards set forth in all applicable laws, policies, and guidance (totalling over a half-dozen statutes, laws, regulations etc.). An IACUC has the authority to approve, require modifications in, or disapprove research. Animal researchers operating at a research institution that receives federal funding, receives federal funding directly in the form of grants, and/or wishes to publish in a peer-reviewed research journal must first receive approval from an IACUC.

*If your research does not use living animal subjects, you do not need IACUC approval.* If your research involves invertebrates, cephalopods, or fertilized eggs you do not need IACUC approval unless your animal system is recognized as an endangered species.

Animal welfare has grown as a concern since research on animals increased in popularity during the nineteenth century. Attempts at regulating animal care can be seen in the British Cruelty to Animals Act of 1876, and have taken the form most US researchers recognize since an amendment to the Animal Welfare Act of 1985. The three ethical pillars that guide animal research in the United States include:



- *respect for life* (respect for all forms of life is an inherent characteristic of biological and medical scientists who conduct research involving animals)
- *non-maleficence* (you have an obligation not to hurt others)
- *societal benefit* (your research contributes to the advancement of knowledge and the acquisition of understanding).

If you are interested in learning more about IACUC training and regulation, a collection of links to institutional IACUCs, training programs, occupational health programs, vivaria, and departments of comparative medicine can be found [here](#) .

## Other considerations

If your research is observing (yes, even just looking or remote tracking) or otherwise interfering with wild animals or endangered species, you will need additional permits and approvals. You should expect each permit or approval to take a minimum of 12 months or more to complete, and you will need adult/expert co-sponsorship (your Hugo mentor will likely qualify for this role).

Talk to your mentor and Program Coach if you are considering research that will require permits, as this is an additional process that does not usually fit into the scope of a Hugo mentorship. In some cases, with some additional training or certifications you may be able to conduct your research under your mentor's permits, licenses, and approvals.

