



# Institutional Review Board (IRB) Policy Manual

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Appendix B). The Belmont Report summarized the findings from the National Commission for the Protection of Human Participants of Biomedical and Behavioral Research; a group tasked with establishing national standards designed to protect research participants.

As a result of the Commission's work, three basic ethical principles emerged. These include:

1. Respect for Persons – The report calls for investigators to respect individuals and to treat them as *autonomous agents* and for those unable to act with full autonomy (vulnerable participants), it requires that special review be put in place to ensure that they are not subjected to situations which they cannot fully comprehend.
2. Beneficence – Rather than focusing on kindness the report requires investigators to treat individuals with dignity, respect, and in a manner that protects participants from harm while also seeking to *secure their well-being*. Even when benefits may not be readily or ever apparent to participants, studies should seek to *maximize possible benefits and minimize possible harms*.
3. Justice – For the purposes of behavioral research, the commission implores investigators to ensure a *fairness of distribution* regarding the selection of participants, especially where benefits are direct and readily apparent.

The Belmont Report also explores the boundaries between practice, research, and applications. ph(e b)16.1 (o)-1.315 Td



The AU IRB follows the OHRP Single IRB Policy by honoring the decision of the IRB of record on a



4. Disapproval: The IRB determines the project application fails to meet one or more criteria for approval of research. Disapproval cannot be granted through the expedited review mechanism and shall be given only by majority vote at a convened meeting of the IRB. The IRB informs the Investigator in writing of the IRB's concerns. The Investigator can respond to the IRB for clarification. College administration cannot overturn the IRB's decisions without evidence of policy violations (see Policy Violations section below).

#### **Procedures for Existing Projects**

Within 60 days of the expiration date of the research project, the investigator will receive a written notification of the IRB's decision. The investigator will receive a written notification of the IRB's decision.



must meet strict ethical standards in line with accepted best practices, and violations of this policy, regardless of the reason, are taken seriously and will be dealt with by the IRB.

## Appendix A: Belmont Report

[The Belmont Report \(hhs.gov\)](https://www.hhs.gov/belmont-report)

## Appendix B: Code of Federal Regulations 45 Part 46

[eCFR :: 45 CFR Part 46 \(July \(o\)1.4\(\)-166 \(d\)1.166.101\) Subjects](https://www.ecfr.gov/current/title-45/subtitle-B/chapter-166/part-166.101)



