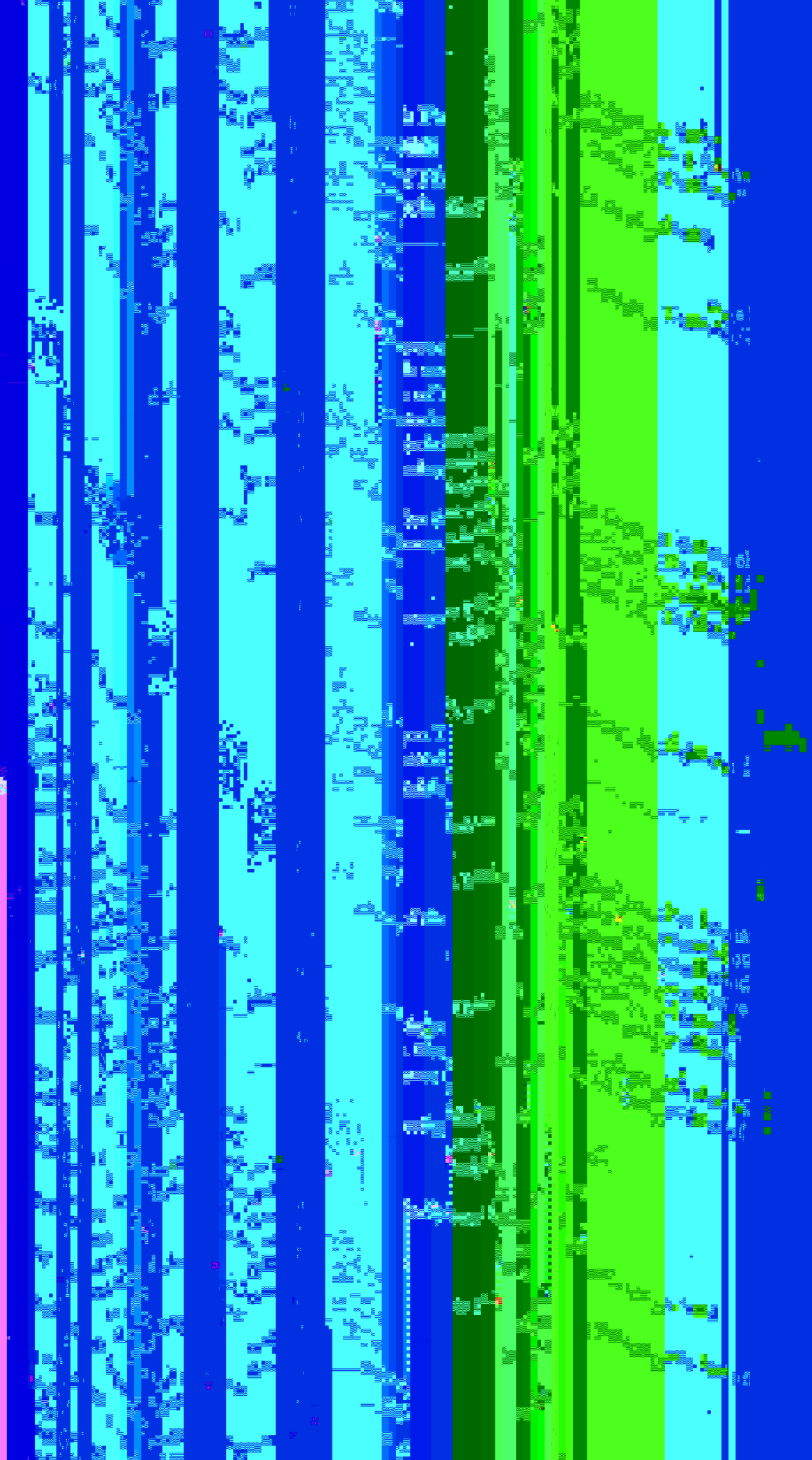


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conducting research obtainable private information. Identifiable information via reports, behavior, or observations obtained by the investigator. Subjects: non-human and non-human primates.

Minimal Risk: "[T]he probability that harm or discomfort to the subjects will be greater in and of the nature of routine physical or psychological examinations or tests than that which would be encountered by the subjects in their daily life or during the course of their activities." 45 CFR 46.102

Informed Consent Process: The research involves three key features: (1) providing the subject with sufficient information to make an informed decision; and (2) promoting the subject's welfare. 45 CFR 46.116

Obtaining Informed Consent: A person's agreement, based on adequate knowledge and understanding of relevant facts, is necessary for research. The investigator must ensure that the subject is not coerced or unduly influenced. 45 CFR 50.20 and 50.25

Vulnerable Populations: "[P]ersons who are unable to give legally effective assent or dissent, and who are unable to protect their own interests." Examples include children, pregnant women, and individuals with diminished cognitive capacity. 45 CFR 46.104

5. Policy

Policy details

The Provost is the signatory who appoints IRB members in accordance with the Oregon State University Regulations. The Vice Provost for Research Protections is responsible for the IRB. The IRB is authorized to represent the University in all matters related to human subjects research. The IRB is composed of members from various departments and is chaired by a faculty member. The IRB meets regularly to review and approve research proposals. The IRB's decisions are final and binding. The IRB is located in the Research Administration Office.

The IRB reflects revisions and updates to the IRB procedures as needed to reflect changes in regulations, and University and associated policies.

IRB Membership: The IRB shall consist of at least five members, including one representative of the faculty, one representative of the student body, and one representative of the community. The IRB shall be chaired by a faculty member.

- The IRB shall have at least five members with varying backgrounds to provide a comprehensive review of research activities commonly conducted by the institution.
- The IRB shall include at least one member whose primary concern is the protection of human subjects.
- Each IRB shall include at least one member who is not otherwise affiliated with the institution (45 CFR 46.107(a)).
- Each IRB shall include at least one member who is not part of the institution's family (45 CFR 46.107(c)).
- Each IRB shall include a member who has a conflict of interest (45 CFR 46.107(d)).
- Each IRB shall include a member who is not a faculty member, student, or staff member (45 CFR 46.107(e)).

Supervision: All IRB members will be appointed for a two-year term, with the possibility of reappointment. The IRB shall meet at least once a year.

Review: The IRB shall review every research proposal that involves the use of human subjects. The IRB shall also review research proposals that involve the use of human subjects in a non-research context.

Failure of result: The IRB shall have the authority to suspend or terminate research projects that do not meet the IRB's standards.

Process: The IRB shall review research proposals submitted by faculty, staff, and students. The IRB shall also review research proposals submitted by external organizations.

- The IRB shall not review research proposals that do not involve a significant risk to the health, safety, or welfare of the research subjects.
- The IRB shall not review research proposals that do not involve a potential benefit to the research subjects.
- The IRB shall not review research proposals that do not involve a potential benefit to the community.

Institution: The IRB shall be a permanent committee of the institution. The IRB shall be responsible for the review and approval of all research involving human subjects.

educational settings involving research conducted using normal curricular activities are involved and

- Expedited Status: Grant the participants; and (b) populations; and (d) individuals not anonymous (i.e., participants can be identified)
- Full Board Review: Studies that pose minimal risks to the vulnerable population.

Determination Status: Upon completion of each research protocol application, the IRB will make a determination for the following:

- Incomplete or Not Ready for the IRB (resubmit): Review materials submitted and make a determination if components are missing or incomplete.
- Require Modifications (clarification for the IRB resubmit): Approve if materials submitted require additional clarification or modifications.
- Approve: materials submitted address all required IRB requirements.
- Approve with Conditions: has determined the research, but conditions such as a third-party permission or a partnering university must be met before the research can begin.
- Disapprove: materials submitted do not address all required IRB requirements.

IRB Amendment: If after receiving approval or timeline, the researcher must submit a completed IRB amendment request.

Animal Research: Research involving animal subjects if other methods would be equally effective. Procedures will conform to the AVMA and AVMA guidelines. All researchers must ensure training of animal subjects. PI of the protocol by the IRB requires treatment and maintenance requirements for training research staff to conform to AVMA guidelines.

