Frequently Asked Questions about Human Subjects Research and IRB

What is the purpose of the Institutional Review Board?

The Institutional Review Board (IRB) is an appropriately constituted group that has been formally designated to review and monitor research involving human subjects. The IRB has the ability to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects.

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research.

Who serves on the IRB?

The Institutional Review Board will be composed of three permanent members and four rotating members:

1) Permanent
    a. Director of Institutional Research
    b. Analyst, Institutional Research
    c. Director of Diversity, Equity and Inclusive Excellence
2) Rotating
    a. Faculty Member (2 slots)
    b. One of the following
        i. VP Academic Affairs
        ii. Dean of Health, Science, Math and Industrial Technology
        iii. Dean, Liberal Arts, Business, and Information Technology
    c. Staff Member

Rotating members will server a 2-year term. The Director of Institutional Research will serve as a final appeal should the IRB be unable to make a recommendation.

The Director of Institutional Research will serve as coordinating chair. The committee will be responsible for reviewing and recruiting Team members according to a defined calendar. Open positions will be listed and broadcast to the campus as internal Mover Team opportunities as appropriate and in coordination with any expectations from Human Resources.

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What is the purpose of submitting a Proposal to Conduct Research form?

The purpose for completing a Proposal to Conduct Research form is to protect the rights and welfare of human subjects by ensuring the research does not violate federal regulations. The Lewis & Clark Community College Institutional Review Board (IRB) coordinates this oversight.

How do I know if I need to submit a Proposal to Conduct Research form?

You must submit a Proposal to Conduct Research form if you plan to conduct any research involving human subjects inside or outside the classroom.

If I am using a survey do I still need IRB approval?

Yes.

What if my research is a classroom assignment?

If your classroom assignment involves human subjects you will need to complete a Proposal to Conduct Research form.

Are there different levels of IRB review?

Yes. There are 3 levels of IRB review.

Level 1 - Exempt Review

Researchers who believe their research meets the exemption categories criteria specified by federal regulations may apply for exempt review status by selecting this option when completing the Proposal to Conduct Research form. Two members in the Office of Institutional Research that serve on the IRB will review all proposals for exempt review status.

The following exemption categories are from Title 45, Part 46 of the Code of Federal Regulations for the Protection of Human Subjects.

- Research in common educational settings, involving normal or special educational practices.
- Research involving educational tests, surveys, interviews, or observations unless confidentiality cannot be maintained or disclosure places the participants at risk.
- Research involving elected or appointed public officials or candidates for office, even when confidentiality cannot be maintained or disclosure places the participants at risk.

- Research involving the study of existing data either publicly available or recorded by the researcher(s) in a manner that maintains confidentiality.

- Institutional or organizational research designed to improve service or benefits when approved by the agency's head.

Exceptions to Exempt Review

The following protected populations are not eligible for exempt review status:

- Minors - 18 years of age and below
- Physically or mentally disadvantaged
- Pregnant women
- Prisoners

Level 2 – Expedited Review

Proposals not meeting the standards for exempt review may be considered for expedited review. Proposals designated for expedited review are reviewed by two members in the Office of Institutional Research and one additional IRB member (not including community representative).

Level 3 – Full Review

Proposals involving greater than minimal risk require review by the full IRB. This includes studies with protected populations such prisoners, physically or mentally disadvantaged populations, pregnant women, and minors 18 years of age and younger.

How long does the IRB review process take?

Proposals meeting the criteria of exempt or expedited review typically take 5 to 7 business days. Proposals designated for full review typically take 10 to 14 business days.

How will I know if and when I can begin my research?

You will receive your approved Proposal to Conduct Research form/informed consent form with an assigned IRB number.

What if my proposal is not approved?

If your proposal is not approved you may revise and resubmit it to the IRB.

What is "informed consent"?

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Informed consent is the process where potential subjects are provided with understandable information about a research project when deciding to voluntarily participate. All research projects involving human subjects must include an informed consent form.

Are there informed consent templates available I can use?

Yes. Researchers should use the informed consent form that is applicable to their research.

- Informed Consent for Online Questionnaire
- Informed Consent for Non-Confidential Online Questionnaire
- Informed Consent for Print Questionnaire and In-Person Interview
- Parental Informed Consent for Surveys and Interviews Involving Minors

What materials do I need to submit with my Proposal to Conduct Research?

- Informed consent form
- Survey/Interview questions