COLLEGE of SOUTHERN MARYLAND

IRB Procedures

The College of Southern Maryland's Institutional Review Board (IRB) reviews human subjects research proposals to ensure that the rights and welfare of human subjects used in research studies by College personnel are protected. The basic principles that govern the IRB are from "The Belmont Report"
[see https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html].

https://www.csmd.edu/about/pier/institutional-review-board/

What research needs IRB approval?

All research involving human subjects must submit paperwork for review by the IRB. Depending on the research, exempt, expedited, or full review paperwork must be submitted.

Who are the IRB members?

A minimum of 5 voting members with varying backgrounds but requiring 1 member be from a science area, 1 nonscientific area member, and 1 not affiliated with the institution.

Information Protection

The researcher must state how long the participant's information will be kept and that it will ultimately be destroyed. Data must be password protected and encrypted. Paperwork must stay in locked cabinets. Identifying information (such as informed consent signatures) must be kept separate from data.

No Coercion

A participant should not be compelled to participate; therefore, the researcher must have no power over the participant, such as being the participant's teacher.

Informed Consent

The most common reason proposals get denied are due to missing elements of informed consent. The subject must know the risks and benefits to participation, that participation can end at any point without reprisal, how the participants information will be used, how the participant information will be protected, and how long the participant is needed. Basic elements of consent can be found at https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=83cd09e1c0f5c6937cd9d7513160fc3f&pitd=20180719&n=pt45.1.46&r=PART&ty=HTML.

Which form to fill out?

Exempt form: Research done as part of the educational experience for students where research is NOT disseminated beyond the classroom.
Expedited form: Research with no or minimal risk to the participant including noninvasive biological specimen collection and its data, data from recordings, surveys and focus groups, or continuation of previous research.
Full review form: More than minimal risk to the participant
[see https://www.hhs.gov/ohrp/regulations-and-policy/decision-charts/index.html].

What is in the paperwork?

- Summary of the study
- Purpose of the study
- Study design including procedure
- Procedure for protecting the participant including privacy
- Compensation for participation or injury
- Informed Consent
- Copies of materials provided to the subject

Paperwork Submission

Completed paperwork and any questions are to be submitted to the IRB Chair. Once the IRB has reached a conclusion about the proposal, the chair will provide a response in a letter to the Principle Investigator. If approved, it is the researchers responsibility to obtain permission from involved parties. Approval does not encumber any CSM employee to help with the research such as participating or soliciting participants. Approval only means that the research is safe to conduct.

IRB Response

- The IRB meets monthly and proposals are either Approved, Approved with Contingency, Tabled, or Not Approved.
- If Not Approved, the researcher gets 1 opportunity to resubmit the proposal with changes for the IRB to review at the monthly meeting.
- If Approved with Contingency, the researcher submits the contingency requirements to the IRB Chair. The Chair will approve that the requirements have been met. The IRB does not need to re-look at the proposal.

Approved

Once approved, the research can commence according to the procedures outlined in the proposal. If changes are needed or the research extends beyond a year, the Continuing Review Questionnaire must be submitted to the IRB Chair. This questionnaire must be completed at least once per year for the duration of the research.

Not approved for the 2nd time

The PI may write a notification of appeal to the IRB Chair. The chair will name an ad hoc committee of 3+ CSM affiliated non-IRB members to review the protocol. The committee will notify the researcher of the decision and the decision is final.

Grievances

The IRB shall be informed of all grievances against the researcher; however, the IRB will defer to the college policy on grievances and the IRB would only serve in an advisory capacity if requested.

The IRB seeks objectivity in order to adequately protect the rights of human subjects at CSM. The IRB is autonomous and is not influenced by other college divisions. IRB members will be assessed for potential conflicts of interest with each proposal and removed from review if conflicts exist.

To obtain the needed forms to begin the research approval process and to get more information on the IRB and proposal submission:

https://www.csmd.edu/about/pier/institutional-review-board/

Submit your completed forms and send any questions to the IRB Chair at mdosterhouse@csmd.edu

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