COUNTY COLLEGE OF MORRIS INSTITUTIONAL REVIEW BOARD PROCESS

Process and procedures required by the Board of Trustees of County College of Morris regarding the use of human subjects in research activities Procedures for conducting Human Research at County College of Morris

Institutional Process and Procedures Required Regarding the Use of Human Subjects in Research / Grant Projects

Institutional Review Board Statement of Purpose:

To establish the institutional processes and procedures required by the Board of Trustees of County College of Morris regarding the use of human subjects in research activities. This process recognizes the institution's responsibility to comply with all applicable Federal Regulations; protecting the rights, well-being and personal privacy of individuals; assuring a favorable climate for the conduct of academic oriented inquiry; and, protecting the interests of County College of Morris.

Institutional Review Board Guidelines:

1. Any principal investigator who engages in scholarly research involving human subjects; either onor off-campus, must complete an application and submit it to the County College of Morris
Institutional Review Board (CCM IRB) for approval of the research along with the materials
detailed in Section #5 of Institutional Review Board Procedures. Such approval must be obtained
before any research begins. Individuals who meet the definition of "principal investigator" must
apply for approval from the County College of Morris Institutional Review Board even if their
research has been approved by another institution's or organization's Institutional Review Board.
Approval from another institution does not guarantee approval by the IRB at County College of
Morris.

Under these guidelines, the following individuals may be named as principal investigators:

- County College of Morris faculty, adjunct faculty, and staff.
- County College of Morris faculty or staff who are on leave, and who are conducting research involving human subjects either at County College of Morris, or with County College of Morris students, faculty or staff.
- Researchers not affiliated with County College of Morris who are conducting primary research with human subjects on campus. While at County College of Morris, these individuals may, through the courtesy of an on-campus liaison, conduct CCM IRB approved research on human subjects. The liaison, who is selected by the Vice President of Academic Affairs, should provide the visitor with appropriate institutional forms including this policy and assure that the forms are sent to the CCM IRB before the research is undertaken.
- 2. Research activities involving human subjects are not authorized to begin unless they were reviewed and approved by the County College of Morris Institutional Review Board. The purpose of the review is to determine whether the activity/ research design adequately protects the rights and welfare of the students and employees at County College of Morris.
- 3. Renewal of IRB Petitions / Projects eligible for continuation beyond the duration of the initial project are subject to an IRB review of the renewal application. In addition, any project where the scope of work or activities that involve human subjects changed substantially during the project are also subject to an IRB renewal application review.

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4. Minimum Risk Proposals – Expedited Review

Research activities which involve no more than minimal risk and in which the only involvement of human subjects is as outlined below, may be reviewed and approved by the County College of Morris Institutional Review Board through its expedited review procedure. Under this procedure, the CCM IRB review may be carried out by the chairperson of the board, or in the chairperson's absence, by a member of the board designated by the chairperson. In reviewing research under this procedure, the reviewer may not disapprove the research. A research activity can only be disapproved after review by the full CCM IRB.

The following activities shall be eligible for expedited review:

- Minor changes in previously authorized research during the period for which approval is authorized.
- Research involving survey or interview procedures where all the following conditions occur:
 - Responses are recorded in such a manner that human subjects cannot be identified, directly or through identifiers linked to the subjects.
 - The subject's responses, if they become known outside of the research, would not place the subject at risk of civil or criminal liability or be damaging to the subject's financial standing or employability.
 - The research does not deal with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol, and is not likely to cause the subject undue stress, fatigue, or any other psychological reactions.
 - The research proposal makes adequate provision for obtaining the informed and voluntary participation of subjects.

If, in the reviewer's judgment, the proposal goes beyond the criteria for expedited review, it shall be subject to full CCM IRB review and approval.

The chair shall provide to the CCM IRB summaries of research proposals certified through expedited review procedures and copies of review disposition letters to investigators.

All other cases require a full board review.

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Institutional Review Board Process and Procedures:

- 1. The purpose of the Institutional Review Board is to conduct initial and continuing reviews of projects and applications that involve the use of human subjects in accordance with the institutional process and procedures required by the Board of Trustees of County College of Morris regarding the use of human subjects in research activities.
- 2. The Vice President of Academic Affairs, the Dean of Institutional Research, one (1) academic dean, and three (3) members of the faculty representing each of the college's academic divisions appointed by the President of County College of Morris, to serve three-year terms to ensure that the review board is sufficiently qualified through diversity, maturity, experience, and expertise of its members for advice and counsel to safeguard the rights and well-being of human subjects. The Vice President of Academic Affairs will serve as the Chairperson of the IRB.
- 3. In the event that a conflict of interest arises with a member of the IRB related to a project under review, the member will not participate in the review process for that project.
- 4. The IRB will be guided by and operate in compliance with applicable sections of Title 45, CFR, Part 46, Protection of Human Subjects, effective July 14, 2009.
- 5. The County College of Morris Institutional Review Board will accept petitions for review from principal investigators at any time and will return decisions within twenty (20) business days. Decisions will be in writing. To be eligible for review, Petitions for Review will contain the following information:
 - Name of Principal Investigator with a signature and date, as well as an e-mail address and telephone number.
 - Name of Co-Principal Investigators with e-mail addresses and telephone numbers.
 - Name of division or department that is administering the project.
 - Project duration.
 - Project title.
 - Funding Agency and Proposal ID number (if applicable).
 - Statement addressing real or potential conflict of interest.
 - Indication of whether the project may be exempt from full CCM IRB review.
 - Brief statement of how human subjects are to be involved in the project and how the human subjects will be guaranteed anonymity.
 - Project summary.
 - Supporting documents, such as consent forms, surveys being administered, survey questions, prior approval from an external IRB, etc.
 - Copy of the grant proposal (if applicable).
- 6. A researcher whose research has received approval from another institution's IRB must provide the CCM IRB with a copy of this approval.

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7. In the event the CCM IRB does not grant approval on a project upon initial review, the researcher may resubmit the proposal once more for consideration. The proposal would need to be submitted within ten (10) business days of receipt and will receive a written decision within twenty (20) business days.

On occasion, projects may be deemed by the County College of Morris Institutional Review Board as exempt from review. This determination cannot be made by the principal investigator(s). The following types of projects are exempt from Institutional Review Board review:

Data gathered for the purposes of fundraising; market research for the purposes of admissions recruiting; recruiting efforts for faculty or staff; and statistical data collected for the management of institutional affairs, including surveys of students, prospective students, and alumni. Please note that a project that does not clearly fall into one of these categories should be brought to the CCM IRB Chair for a determination of whether it is exempt.