

HAYWOOD COMMUNITY COLLEGE	ADMINISTRATIVE RESEARCH REVIEW PROCEDURE	Procedure 2.4.1.1
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Unless specifically exempted by this policy, all research conducted at or sponsored by Haywood Community College that involves human subjects must obtain Research Review Committee (“RRC”) approval prior to any involvement of human subjects. This includes research conducted by faculty, staff, students and agents of the College.

A human subject is a living individual about whom a researcher or investigator conducting research obtains:

- (1) Data through intervention or interaction with the individual, or
- (2) Identifiable private information or identifiable bio specimens.

All human participants in a research project must voluntarily consent to participate.

The Research Review Committee is a multidisciplinary group which reviews, approves, and oversees all College research involving human subjects. To protect the safety, welfare and rights of human participants in research, the RCC review ensures the protection of the safety, rights and welfare of human subjects and that applicable legal requirements are met.

The RCC has authority to:

- (1) approve, require modifications for approval or disapprove research involving human subjects
- (2) Suspend or terminate approval of research not being conducted in accordance with the RRC’s requirements or that has been associated with unexpected serious harm to human subjects;
- (3) Take actions determined necessary to ensure legal compliance and adherence to College policy, and to mitigate issues associated with unanticipated problems or risks to human participants and others;
- (4) Observe, or have a third party observe, the consent process or conduct of the research; and
- (5) Conduct continuing review of research annually or at intervals appropriate to the degree of risk.

The President’s Council will serve as the College’s Research Review Committee. Upon receipt of these items, the director of Institutional Excellence, Research, and Grants will forward them to the RCC for consideration electronically or at the next scheduled President’s Council meeting, as determined by the director. President’s Council meeting minutes will serve as the record of the decision for all scheduled meetings. The determination of the RCC will then be conveyed to the researcher. In determining whether to approve a proposed project, the RCC shall use the criteria adopted by the Department of Education as outlined in 34 C.F.R. § 97.108 - §97.123.

For the purposes of this procedure, research involving human subjects includes:

- (1) A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- (2) A clinical investigation, meaning any experiment that involves a test article and one or more human subjects; and
- (3) Any other activities meeting the legal requirements of research involving human subjects or human participants.

Any research involving human subjects should involve minimal risk to participants. Minimal risk means “that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.” The College does not permit any research involving human participants that requires greater than minimal risk to the participants.

Procedure to Conduct Research at the College

A person interested in conducting research involving human subjects should complete the **"Permission to Conduct Research on Human Subjects at Haywood Community College"** (located on the website under Institutional Excellence, Research, and Grants) in order to submit the following information:

- (1) A brief description of the study, including its purpose; how HCC employees, students, or data will be used in the research; and how confidentiality will be maintained.
- (2) If conducting research through another institution (e.g., as a graduate student), affirmation from that institution showing IRB approval to conduct the research. If such approval is contingent upon HCC approval, include a statement from that institution explaining that tentative approval has been granted pending HCC approval.
- (3) The cover letter that will be sent/read to participants.
- (4) Projected opening and closing dates of the research.
- (5) The steps that will be taken to ensure that HCC is informed of the research findings so that the College can benefit from the research.

Any research involving human subjects conducted on behalf of or for a federal or state agency will comply with all applicable laws and regulations of the sponsoring government agency.

Exceptions:

The following types of research and surveys shall not apply to this Procedure:

- (1) Institutional research conducted by HCC in order to improve College operations, practices and student outcomes.

- a. Institutional research generated by departments other than the Institutional Excellence, Research, and Grants department is subject to approval by the President's Council. Those interested in conducting such research should speak with the director of Institutional Excellence, Research, and Grants. Surveys and protocols will be mutually agreed upon and the President's Council will be asked to approve the research. Surveys of HCC employees will also be reviewed by the Human Resources department.
 - b. Participation in any institutional research conducted by the College must be voluntary and anonymous.
- (2) Activities, demonstrations and exercises designed solely for educational or teaching purposes, including surveys and information collecting, that do not present more than a minimal risk and do not result in generalizable research.
 - (3) Information or data gathered generally for class discussion.
 - (4) Collection of information for an oral history or biography.
 - (5) The use of publicly available data (e.g. census information, labor statistics, etc.).
 - (6) Case Studies or case histories limited to three or fewer human participants.

To determine if an activity is research that should be reviewed by the RRC, apply the following questions:

- Does the research involve human subjects?
- Does the research collect or use individually identifiable information?
- Does the research involve any interaction or intervention with human subjects on the part of the investigator?
- Is the project designed to study, evaluate, or examine public service programs?

Any researcher or investigator uncertain of whether their research requires approval of the RCC should contact the director of Institutional Excellence, Research, and Grants.

Research as Part of a Class Activity

Students conducting research as part of a regular class activity that is common to the discipline and involves no risk to the subjects will receive an expedited review by the director of Institutional Excellence, Research, and Grants. If there are questions regarding the nature of the research study, the director, at his or her discretion, may forward the request for permission to the Research Review Committee for a full review. Instructors must provide copies of each of the research requests with the appropriate Dean and also inform them that the class is conducting discipline-specific research activities.

Research Using Animals

All research conducted using animals must be done so under the guidance of a College faculty member. It is expected that all such research will be conducted as part of a college course and will follow the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, the Animal Welfare Act and the USDA Animal Welfare Regulations.

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