This Procedure outlines the processes for implementing Board Policy 1095 and applies to all Human Subjects Research or institutional data collection at Schoolcraft College, including research involving minors.

Oversight: The Research and Analytics department has responsibility for dissemination and administration of Board Policy 1095, communications with external researchers, and review and approval/denial of research requests covered by Policy 1095 and this Procedure. All inquiries and requests regarding Human Subject Research or collection/use of institutional data should be forwarded to the Research and Analytics department.

Definitions:

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

Human Subject Research: For purposes of Policy 1095 and this Procedure, Human Subject Research is any systematic investigation using humans as subject, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge; a clinical investigation, meaning any experiment that involves a test article and one or more human subjects; or any other activities meeting the legal requirements of research involving human subjects or human participants.

Human Subject: Human Subject means a living individual about whom an investigator (whether professional or student) conducting research: (i) obtains information through intervention or interaction with the individual, and uses, studies, or analyzes the information; or (ii) obtains, uses, studies, analyzes, or generates identifiable private information.

Intervention: Includes both physical procedures by which information is gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

Interaction: Includes communication or interpersonal contact between investigator and subject.

Private information: Includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.
Identifiable private information: Is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

Limitation:

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.

Research Approval Process for Human Subjects Research:

The following steps must be taken to conduct human subjects research at Schoolcraft College, including research involving minors:

1. Prior to recruiting participants or collecting data, any individual, group or agency desiring to conduct research at the College; use students, faculty, staff, or data in research; or recruit research participants by any means, including on College property or at College sponsored events, must submit a Research Proposal to Research and Analytics. The Research Proposal must:
   a. Detail the purpose of the study, methodology to be used (e.g. participants, sampling, data collection, analysis), timeframe for research activities, target audience for participants, potential risks to study participants, format for the presentation/publication of results and intended audience, and expected outcomes/benefits of the study.
   b. Include documentation of Institutional Review Board (IRB) approval or appropriate IRB exemption from the researcher’s sponsoring institution. If evidence of approval or exemption is not available, an explanation must be provided.
   c. The informed consent verbiage that will be sent/read to participants.
   d. Affirm the researcher’s acceptance of all conditions of approval required by Board Policy 1095 and Procedure 1095.1.

2. Research and Analytics will review the proposal to determine if it meets the definition of Human Subjects Research.

3. If the proposal meets the definition of Human Subjects Research, it will be forwarded to an external IRB for review and approval.

4. The IRB will review the proposal and determine whether to approve the research.
5. If the research is approved, the researcher must follow the IRB’s guidelines for conducting the research.

Exempt Research and Institutional Data Collection:

Some research endeavors do not meet the definition of Human Subject Research and are therefore exempt from Institutional Review Board (IRB) review. Institutional data collection focuses on gathering information for the organization to improve its practices, processes, or programs. Unlike Human Subject Research, institutional data collection does not aim to draw broad conclusions that apply to a larger population beyond the organization itself. Examples of IRB exempt research include:

- Surveys or questionnaires administered in a classroom setting, such as surveys conducted by faculty to currently enrolled students in their classes as part of instruction;
- Student evaluations of courses and instruction;
- Student originated surveys as part of academic coursework;
- Research that is conducted as part of a normal educational practice, such as surveys for institutional improvement purposes or soliciting student feedback about a college event or service experience;
- Employee performance evaluations;
- Research that involves the use of focus groups or other qualitative methods;
- Observational research that does not involve any interaction with the participants;
- Research that uses existing data that is not personally identifiable, such as data from public records or data that has been aggregated in a way that makes it impossible to identify individual participants;
- Research that involves the use of non-invasive physical measures, such as blood pressure or heart rate measurements;
- Research that involves the use of non-deceptive psychological testing or assessment;

Minors:

Research involving minors must be conducted in a way that protects the minors’ rights and welfare. Parental permission must be obtained for all research involving minors, unless an exception is granted by the IRB. Assent must be obtained from all minors who are capable of giving assent, in addition to parental permission. Most exempt research on campus will not include anyone under the age of 18.
Research and Analytics Approval for Institutional Data Collection:

Research and Analytics will review research proposals that are exempt from IRB review. In addition to reviewing research requests, the Research and Analytics department offers support and guidance with research design, construction, administration, sampling plans, analysis, and reporting. Furthermore, when appropriate, the Research and Analytics department will facilitate information sharing across the College.

The review will consider the following factors:

- The purpose of the research;
- The potential risks to research participants;
- The benefits of the research;
- The use of best practices; and
- Regulatory and Legal Compliance.

IRB Exempt research projects which must be submitted to Research and Analytics Department for review include:

- Research that is conducted as part of a normal educational practice, including but not limited to, surveys for institutional improvement purposes or soliciting student feedback about a college event or service experience;
- All research that qualifies as human subjects research as explained on previous pages;
- Research that involves the use of focus groups, interviews, or other qualitative methods;
- Research that involves the use of non-invasive physical measures, such as blood pressure or heart rate measurements;
- Student evaluations of courses and instruction; and
- Research that involves the use of non-deceptive psychological testing or assessment.

IRB Exempt research projects that do not need to be sent to Research and Analytic department for review include:

- Surveys or questionnaires administered in a classroom setting, such as surveys conducted by faculty to current enrolled students in their classes as part of instruction;
- Student originated surveys as part of academic coursework;
- Employee performance evaluations;
• Observational research that does not involve any interaction with the participants; and
• Student coursework/applied practice (not research) using non-invasive physical measures, such as blood pressure or heart rate.

Approval:
Research proposals that are exempt from IRB review will be approved by Research and Analytics if they meet the following criteria:

• The research is compatible with the College's mission and purpose and does not duplicate other data collection efforts;
• The research is conducted in a way that protects research participants;
• The research uses best practices; and
• The research falls within regulatory and legal requirements.

Storage, Retention and Access:
Research data will be stored in a secure location and will only be accessible to authorized personnel. Records relating to Human Subjects Research shall be retained for three years after completion of the research.

Confidentiality:
Research data will be kept confidential to the extent possible. However, there may be circumstances where the college is required to disclose research data.

Research Misconduct:
Individuals conducting research activities in violation of Policy 1095 or this Procedure shall be subject to sanctions, including and up to dismissal from the College. The College may terminate or suspend any research, or take other action, whenever such actions are required to maintain the purpose of Policy 1095.