Principia College Human Subjects Research Policy

1. **Introduction.** Research is essential for discovering, validating, or extending knowledge—and a hallowed part of educational institutions and the educational process. While research often entails studying purely inanimate objects, it can also involve living people with intrinsic human rights and the expectation of fair treatment. The pursuit of knowledge, while normally beneficial, can also be deleterious if done unethically with or to people. While there can also be ethical issues involving animals as research subjects, this policy only concerns research involving human subjects to ensure ethical processes are used during and after research. Researchers at Principia College using human subjects must uphold our highest ethical standards while conducting research, and this policy explains those ethical standards and the processes that must be followed.¹

Our research work involving human subjects should keep in view the discussion of true scholarship provided by Mary Kimball Morgan (Education at The Principia, pg. 68): “A true scholar is always a gentleman or a gentlewoman. Refined speech, delicacy of thought, unobtrusive manners, unselfish consideration of others, and exquisite courtesy, the result of real love for others, are some of the graces of spirit that distinguish the scholarly individual.”

2. **Responsibilities**
   a. The Dean of Academics is responsible to the President for maintaining these policies and ensuring they are followed by Principia College academic researchers. The Dean of Academics will work with and seek advice in these matters from Principia’s legal counsel.
   b. The Dean of Academics will appoint at least two faculty members and one academic staff member to an Institutional Research Board (IRB). The IRB will be charged with implementing and managing Principia’s human subjects research policies, including granting administrative approval to human subjects research proposals. Appeals of IRB decisions can be made to the Dean of Academics, and that appeal decision is final.
   c. All Principia College employees and students, when intending to conduct research involving human subjects, must understand and follow these policies as applicable.

3. **Definitions**
   a. Research. Systematic, intentional investigation to uncover generalizable knowledge. The two key concepts are **systematic** and **generalizable**. Adhoc questions of students or staff are not research questions. Systematic surveys of limited groups for only limited information results not applicable to wider groups are not considered research because they are not meant to be generalizable. For example, answering questions in class or doing academic course evaluations and assessments such as exams or papers are not considered research under this policy since they are necessary for evaluating the course outcomes of individuals or a specific group of students in a specific course. In these latter situations, however, the spirit of this policy should still be followed.
b. Human Subjects Research. Human subject research entails using people as the subjects of research—examining and recording their thoughts, motives, actions, characteristics, abilities, skills, or knowledge.

c. Confidentiality and Anonymity. Confidentiality ensures that specific collected data associated with a particular person will not be publicly associated with that individual subject. Anonymity ensures that collected data is never associated with a particular individual subject—even to the researchers.

4. Principles

a. Research involving humans must consider personal respect, beneficence, and equity.¹  
   i. Respect. People should be treated as autonomous beings, and those with limited practical autonomy should be protected. People should have a voluntary choice about what they do and say, while those with less choice or lesser abilities of self-determination should be protected from exploitation.
   ii. Beneficence. Researchers have an obligation to minimize possible harm to human subjects, while maximizing the possible public benefits of research.
   iii. Equity. Human subjects ought to be treated equally; each person receiving equal potential benefits and burdens for participating.

b. Voluntary Participation. All human research subjects should feel free to decline or terminate participation at any time without retribution. Coercion—direct or indirect, stated or implied—should not be used to gain subject consent. Encouragement by offering minor or inconsequential gifts or benefits, however, may be used. Monetary compensation for time, research-related inconveniences, or research-related hardships may be offered—but not as an intended benefit of the research.

c. Informed Consent. Informed consent is complete and accurate knowledge by the subjects of the research purpose and methodologies, how personal data will be kept secure, the risks involved, and the ultimate use of the collected data. Deception for research methodology purposes shall not be used during the consent process but may be used during data collection (see 4.d.). Informed consent involves:
   i. The identity of all researchers and any third party sponsors
   ii. The purpose of the research and the data collection methodologies that will be used
   iii. How collected data will be protected, and how confidentiality or anonymity will be ensured
   iv. Any likely risks of harm to the human subject
   v. Any use of electronic or mechanical recording devices
   vi. Parental or guardian consent when human subjects are minors
   vii. How collected data will be shared with others in papers, presentations, or on an informal basis.


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d. Deception. While deception is intrinsically unethical and disempowers human subjects to some degree of their natural rights, deception may be used during data collection if researchers can reasonably make the case that human subjects would likely withhold or distort important information and not respond naturally or with total honesty during the data collection phase without some deception. In this case, subjects must be informed in advance that some features of the research will not be revealed to them until afterwards. All forms of human research deception must be specifically approved by the IRB and must be based on written informed consent. Deceived human subjects must be informed after data collection of all deceptions used, but they may not consequently retract their data.

e. Expected Benefits and Burdens. The expected benefits of human subjects research must outweigh the expected burdens—physical or mental. Researchers, human subjects, and the IRB must understand the expected benefits and burdens of any human subjects research. When research plans change, researchers are responsible for re-evaluating the benefits and burdens balance, and terminating the research when overall burdens outweigh benefits.

5. Procedures

a. If human subjects will be used in a research effort (per 3.b.) not previously IRB-approved, researchers must request approval of the IRB before using any human research subjects. The request, submitted by the lead researcher, will address all the topics listed in paragraphs 4.b. through 4.e. If the researchers are enrolled students, the request must be submitted by an overseeing Principia College faculty member. Recurring research associated with academic courses can be approved in general but must be re-submitted if there are substantive changes (paragraph 5.f.) or at least once every three years.

b. The IRB will speedily consider research proposals in light of this policy and other salient Principia policies and procedures. The IRB, in approving or disapproving the request, may suggest ways to improve the treatment of human subjects. IRB discussions shall be transparent to the lead researcher and the Dean of Academics.

c. The IRB will notify the lead researcher and the Dean of Academics in writing of their decision, and will keep a record of the decision.

d. If denied, the lead researcher may appeal to the Dean of Academics, or alter the research plan and resubmit a revised request to the IRB.

e. After IRB approval and before initiating any human subject research, researchers will obtain informed consent in an appropriate way from all human subjects. Consent must be in writing for minors and those at risk (4.c.) and when deception is involved (4.d.), and copies of that written documentation must be sent to the IRB. The IRB will maintain the written informed consent documents with the lead researcher’s IRB request.

f. During and after the research effort, researchers should act consistently with their approval request to the IRB. Because of unforeseen reasons, however, conditions and methodologies may change during the course of the research. In those circumstances, researchers must be alert for possible effects on human subjects, and use sound judgment in deciding when to notify the IRB of significant changes and ask for re-validation of the original approval.
Researchers are always responsible for bringing significant changes to the IRB in the spirit of 4.a. When research involves minors or intentional deception, however, re-validation due to changes is mandatory.

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