



Title	Policy on Rights and Welfare of Human Subjects
Approval Required	Baker College System President
Revision Level	1
Revision Date	June 11, 2015

**SCOPE**

- 1.1.1 This policy details Baker College’s commitment to protecting individuals involved in human subject research.

**1 POLICY**

1.1 It is the policy of Baker College to safeguard the rights and welfare of human subjects in research and other activities. Safeguarding the rights and welfare of human subjects in research is the responsibility of the Primary Investigator. Any project involving human subjects at Baker College is subject to review and approval by the IRB. In order to approve proposed research protocols, the IRB shall determine that all of the following requirements are satisfied:

- 1.1.1 **Risks to subjects are minimized** by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.
- 1.1.2 **Risks to subjects are reasonable** in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB shall consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of interventions subjects would receive even if not participating in research).
- 1.1.3 **Selection of subjects is equitable.** In making this assessment the IRB shall take into account the purposes of the research and the setting in which the research will be conducted.
- 1.1.4 **Unless waived by the IRB, informed consent will be sought from each prospective subject or the subject’s legally authorized representative,** in accordance with, and to the extent required by 45 CFR 46.116.
- 1.1.5 **Unless waived by the IRB, informed consent will be appropriately documented,** in accordance with, and to the extent required by 45 CFR 46.117.
- 1.1.6 **The safety of subjects will be ensured** through appropriate data monitoring methods provided in the research plan.
- 1.1.7 **Vulnerable populations may require special considerations.** Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, such as persons with acute or severe physical or mental illness, persons with disabilities, or persons who are economically or educationally disadvantaged, appropriate additional safeguards will be included in the study to protect the rights, welfare, and privacy of these subjects

- 1.1.8 Principles that assist the IRB in protecting the rights and welfare of human subjects include the following existing codes:
- 1.1.8.1 Ethical Principles in the Conduct of Research with Human Participants; adopted by the American Psychological Association, 1973.
  - 1.1.8.2 45 CFR 46, Code of Federal Regulations, Final Regulations for the Protection of Human Research Subjects; (Revised June 18, 1991 as the Federal Policy for the Protection of Human Subjects; Notices and Rules).
- 1.1.9 The Belmont Report – Ethical Considerations and Principles for the Protection of Human Subjects of Research.

REVISION LEVEL	REVISION DATE	REVISION COMMENTS
0	September 24, 2003	Initial Issue
1	June 11, 2015	Language Revisions

APPROVALS:

Approved By \_\_\_\_\_

Date \_\_\_\_\_

Latest Revision Approved By \_\_\_\_\_

Date \_\_\_\_\_

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