



Title	Policy on Maintenance of IRB Records
Approval Required	Baker College Institutional Review Board
Revision Level	1
Revision Date	June 11, 2015

1 SCOPE

1.1 This policy is designed to clarify:

- 1.1.1 Records that will be maintained for the benefit of the IRB
- 1.1.2 Who has responsibility for maintenance of records
- 1.1.3 Where records will be maintained.

2 POLICY

2.1 The IRB shall prepare and maintain adequate documentation of IRB activities, including the following:

- 2.1.1 Copies of all research protocols reviewed; scientific evaluations, if any, that accompany the protocols; approved sample consent documents; and progress reports submitted by investigators;
- 2.1.2 Minutes of IRB meetings which shall be in sufficient detail to show attendance at the meetings; actions taken by the IRB; the vote on these actions including the number of members voting for, against, and abstaining; the basis for requiring changes in or disapproving protocols and a written summary of the discussion of the issues and their resolution;
- 2.1.3 Records of continuing review activities;
- 2.1.4 Copies of all correspondence between the IRB and the investigators;
- 2.1.5 A list of IRB members as specified in 49 CFR 11, Section 103.b.3;
- 2.1.6 Statements of significant new findings provided to subjects.

2.2 All records required by this policy shall be retained for at least three (3) years, and records relating to research which is conducted shall be retained for at least three (3) years after completion of the research. All records shall be accessible for inspection and copying by authorized representatives of the department or agency at reasonable times and in a reasonable manner.

2.3 The Chair of the IRB will house and maintain IRB records

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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