



Title	Policy on Processing of Research Protocols
Approval Required	Baker College System President
Revision Level	1
Revision Date	June 11, 2015

## 1 SCOPE

- 1.1 This policy details procedures for processing protocols submitted to the IRB for review. The purpose of this policy is to
  - 1.1.1 Identify when a protocol will be returned to a researcher without review.
  - 1.1.2 Create timelines to ensure timely processing of materials.
  - 1.1.3 Define responsibilities of individuals involved in the review process.
  - 1.1.4 Detail notification procedures to inform investigators of actions the board has taken.

## 2 POLICY

- 2.1 The initial step in the review of all submitted protocols will be a “Technical Review.”
  - 2.1.1 The technical review of the protocol will be conducted by the Chair of the IRB, or his/her designee.
    - 2.1.1.1 The Chair may appoint any current voting member of the IRB to complete the technical review of any or all protocols.
  - 2.1.2 The purpose of the technical review is to ensure that the protocol is complete according to the guidelines set forth by the Baker College IRB. This includes ensuring that all forms have been completed, that all supplemental materials required have been supplied, that the correct number of protocols have been submitted including one electronic copy in MS Word format, and that at least one hardcopy of the protocol contains original signatures in blue or black ink.
  - 2.1.3 Any protocol found to be incomplete as a result of the technical review will be returned to the principal investigator, along with written notification that the protocol is not in compliance with established policies of the Baker College IRB. Such notification will include details about documentation that is incomplete or missing, or other problems noted with the protocol.
    - 2.1.3.1 Written notification, including identification of explicit problems with a protocol, shall not be construed to be all of the problems or potential problems with a protocol. Investigators may respond to all of the identified problems in the written notification, and still be out of compliance because some problems may be overlooked in the initial review, particularly in the case of protocols that have major omissions, misinformation, or incorrect completions.

- 2.1.3.2 Investigators will be encouraged to resubmit their protocol once it is in compliance with established policy. Resubmitted protocols will be treated by the IRB in all manner as new protocols, including timelines, review processes, and final disposition.
- 2.2 It is the policy of the Baker College IRB to process all materials in an expeditious manner, to aid investigators in the conduct of their work, and to avoid creating obstacles that unduly delay action.
  - 2.2.1 Technical reviews will be completed on all protocols by the end of the week following submission of the protocol to the Chair of the IRB.
  - 2.2.2 All protocols will be reviewed at the next regularly scheduled meeting of the IRB, providing the technical review has been completed at least 1 week in advance of the regularly scheduled meeting. Generally, this means that a protocol should be submitted approximately 3 weeks prior to the regularly scheduled IRB meeting. This early submission will help to ensure that a technical review can be completed, and that copies of the protocol can be made available to all board members for review prior to the scheduled meeting. Protocols not submitted in time for review at any regularly scheduled meeting will be held over for review at the next scheduled meeting.
  - 2.2.3 Once a protocol has been reviewed, whether by the Chair for a technical review or by the full board, a response detailing the action will be drafted for delivery to the principal investigator within 48 hours of the board's action. If the PI has provided an email address, contact will be made by email. If no email address has been provided, contact will be made by U.S. post.
    - 2.2.3.1 The 48-hour timeline is intended to provide guidance for action to be taken by the board. It is not intended to be seen as a guideline by when the PI must be contacted. The board takes no responsibility for the time involved in delivery of any communication, whether by email or U.S. post.
- 2.3 Primary responsibility for the processing of protocols will be with the Office of the Dean of Research as well as the Chair of the IRB. However, every member of the board maintains some role in ensuring the timely processing of all materials.
  - 2.3.1 The Chair of the IRB will be responsible for accepting all submitted protocols, for recording their receipt, and for assigning a tracking number, not later than the end of business on the Friday of the week the material arrives, provided the material arrives prior to 12:00 noon on Friday. Material which arrives after this time will be held for processing during the following week.
  - 2.3.2 The Chair of the IRB will have prepared for pickup by 10:00 am on every Monday, all protocols needing technical review by any IRB member that have been received and registered during the previous week.
  - 2.3.3 The Chair of the IRB will be responsible for ensuring that a technical review of all protocols available for pickup on any Monday are completed by the close of business on Friday of the same week.
  - 2.3.4 The Chair will be responsible for ensuring that all protocols that have passed a technical review, and are to go on to a full board review are available for pickup by the primary reviewer, as well as all other board members, no later than 10:00 am on the Monday of the week following the completion of the technical review.
  - 2.3.5 All board members are responsible for picking up their copy of every protocol to be reviewed no later than the end of business on Friday in the week prior to the scheduled board meeting.
  - 2.3.6 Deadlines for preparation of material for pickup will be extended by 24 hours if the Baker College System, or the individual campus of the responsible party is closed on the day of the deadline.

The deadline for completion of all work will be similarly extended by 24 hours for any campus or system closing that directly impacts the responsible party.

### 3 PROCEDURE

- 3.1 Upon receipt of a protocol, the Chair of the IRB will record the submission in a continuous log of all submissions, and assign the protocol a tracking number that uniquely identifies the protocol.
- 3.2 The Chair of the IRB will retrieve all protocols available for review on a weekly basis, and will provide the technical review as detailed in IRB policy. Upon completion of the technical review, the Chair will either:
  - 3.2.1 Determine the protocol is not in compliance with IRB policy, in which case the Chair will prepare a written letter for the PI detailing the problems found in the protocol. The letter will be completed and sent for delivery within 48 hours.
  - 3.2.2 Determine the protocol is in technical compliance with IRB policy. The Chair will then assign a primary reviewer from among the regular members of the IRB, and contact that member via email to request that he/she provides primary review of the protocol. This request will be made within 24 hours of the completion of the technical review, but should be made as soon as practical to allow the primary reviewer adequate opportunity to pick up and review the protocol.
    - 3.2.2.1 The Chair may choose to assign himself/herself responsibility for primary review. However, it is the intention of IRB policy to involve all members in the review process, and in most situations the Chair will not assume primary reviewer responsibility.
    - 3.2.2.2 If the request for primary review is declined, the Chair will be responsible for contacting another member of the board to act as primary reviewer.
    - 3.2.2.3 Under exceptional circumstances, the Chair may request that an outside consultant act as the primary reviewer of a protocol. This will occur when it is clear that members of the board do not possess the expertise to adequately review the protocol and determine its proper disposition. In such a circumstance, the outside reviewer will not be considered a voting member of the board.
- 3.3 The Chair will provide notification that the protocol has been reviewed and is being moved forward for a full board review. The Chair will also provide notification of who has been assigned primary reviewer responsibilities.
- 3.4 The Chair will notify all board members via email that one or more protocols are available for pickup and review prior to the next scheduled IRB meeting.
- 3.5 Upon agreeing to act as primary reviewer of a protocol, the individual board member will be responsible for obtaining a copy of the protocol from the Chair.
  - 3.5.1 The primary reviewer will be responsible for a careful review of procedures outlined in the protocol and preparing to present at the board meeting a synopsis of the protocol along with any reservations or concerns. The reviewer will be responsible for knowing enough detail about the protocol that he/she will be prepared to answer questions from other board members. If the PI is not in attendance at the meeting, the primary reviewer will have the responsibility of adequately representing the protocol to the board in an unbiased manner. In this role, the primary reviewer acts as a representative of the PI, not to persuade, but to help board members understand the proposed research in its entirety.
- 3.6 All board members will obtain copies of all protocols for review prior to the scheduled meeting of the IRB, and will review each protocol so that they are prepared at the meeting to discuss the proposed research. Protocols will be available from the Chair of the IRB.

- 3.7 Following review of a protocol by the board, the Chair will prepare a written letter to be sent to the PI detailing the board's action and including any special concerns or notes of the board. This letter will be prepared within 48 hours of the board's action.
- 3.7.1 If the proposal is approved, the PI will be informed, and reminded of Baker College IRB policy concerning continuing review, changes in the protocol, or adverse impact of human subjects.
- 3.7.2 If the proposal is approved with conditions, the conditions of approval will be carefully documented for the PI, along with timelines and specific procedures, if appropriate.
- 3.7.3 If the proposal is denied, a written statement summarizing the reason for denial will be included, along with any further action that the PI may take if appropriate.

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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