

Saint Louis University
IBC Protocol Review Procedures & Reviewers' Guidelines

(Effective April 8, 2005)

PREAMBLE

To facilitate timely yet thorough and complete review of protocols submitted to the IBC, the following procedures have been promulgated and adopted by the IBC and by the University Administration. As an additional aid, the Reviewer's Guidelines, inclusive of a Reviewer's Checklist, have been developed to help assure uniformity of critique among reviewers and across all protocols submitted for review.

PROTOCOL REVIEW PROCEDURES

A. PROTOCOL SUBMISSION & PROVISION TO IBC MEMBERS

1. All protocols must be submitted to the University Biological Safety Officer (BSO), Caroline Building C307.
2. Only protocols that are timely submitted will be reviewed by the IBC.
3. In order to be considered a timely submission for review, the protocol should be received at least 14 days prior to the next regularly scheduled IBC meeting in order to be considered for that meeting.
4. The BSO will attempt to provide copies of all applications to be reviewed to the IBC members NO LATER THAN 10 days prior to the IBC meeting to facilitate adequate time for review.

B. PRIMARY REVIEWERS

1. Assignment:

- a. The BSO will assign two in-house technical IBC members as primary reviewers for each protocol. The assignment will be based roughly upon area of expertise if feasible, but with priority given to equal rotation among technical reviewers. The BSO will communicate the assignment of primary reviewers in the application packet to the entire IBC membership.
- b. External IBC members (i.e. members of the general public) will not be assigned responsibility as a primary reviewer. External IBC members may volunteer to be primary reviewers for protocols involving areas in which they may have special expertise.
- c. Administrative IBC members, (i.e. Ex-Officio members, the IBC Chairperson, the Director of Environmental Safety, the Director of Employee Health,) will not be assigned responsibility as a primary reviewer.

2. Primary Reviewer Responsibilities:

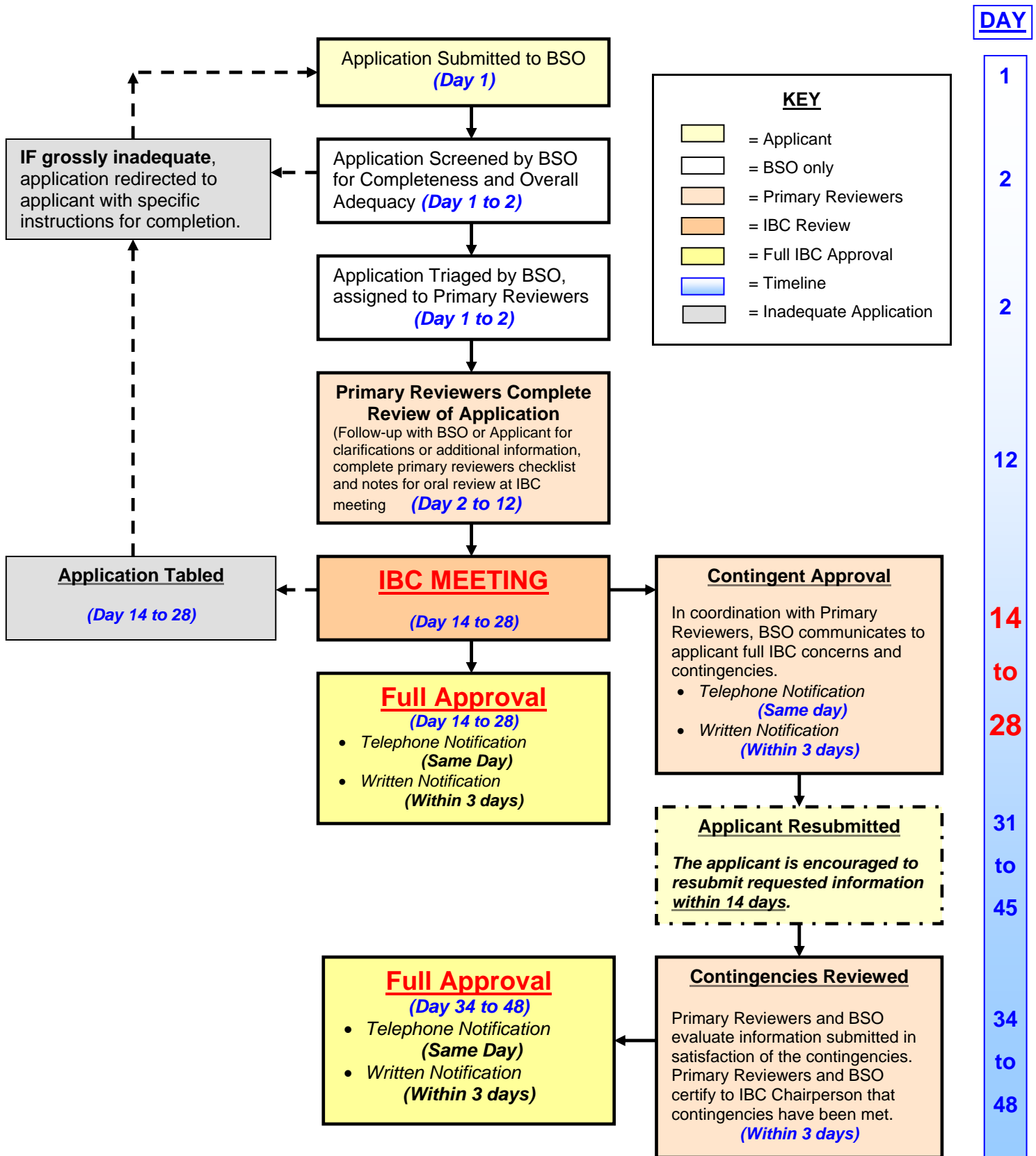
The primary reviewers will be responsible for the following:

- a. Thorough and complete review of IBC protocol submission, and supporting documents.
- b. Using the IBC primary reviewer's checklist, assure a comprehensive safety review of the applicant's protocol and procedures.
- c. Prior to the IBC meeting, communicating to the BSO any concerns, potential contingencies, or requests for follow-up information. In coordination and through the BSO, the primary reviewers will communicate to the investigator their concerns and requests for additional information.
- d. Deliver an oral report of their review findings at the IBC meeting.
- e. In coordination with and through the BSO, communicate to the investigator full IBC concerns and contingencies immediately following the meeting.
- f. In coordination with the BSO, review items submitted in satisfaction of the contingencies.
- g. Providing written signed certification, cosigned by the co-primary reviewer and the BSO, to the IBC Chairperson that the contingencies have been met.

C. IBC CHAIRPERSON

Upon receipt of certification that all contingencies have been met (as certified by signature of the primary reviewers and BSO), the chairperson will provide full approval of protocol.

IBC PROTOCOL FLOWCHART & TIMELINE*



** Based on an initial submission occurring at mid-cycle between meetings (just prior to submission deadline) to maximum 4 weeks prior to next meeting (day after most recent IBC meeting).*