I. Purpose of this SOP

The purpose of this SOP is to set forth the responsibilities of the Brandeis University IRB staff.

II. Scope of this SOP

This SOP applies to Brandeis University IRB staff members in the execution of their duties.

III. Statement of SOP

It is the standard operating procedure of Brandeis University that its IRB office exists to support investigators in their activities with regards to the IRB, as well as the IRB.

IV. Procedures

The overriding responsibility of the IRB staff is to support the IRB in its safeguarding the rights and welfare of human subjects in research. In so doing, the IRB staff:

- Ensures their availability to investigators in need of guidance regarding the application for human subjects research, as well as its continuing review and termination
- Assures compliance with the Brandeis University Federalwide Assurance
- Participates in ongoing training and stays informed of current events related to human subjects research
- Understands and provides interpretation of federal regulations and institutional policies related to human subjects research
- Acts as liaison between the IRB and principal investigator/student researcher
- Follows all applicable written procedures
• Pre-reviews all submitted research applications
• Determines the level of review for all submitted research applications
• Reviews all submitted non-limited IRB review exempt research applications for approval
• Recommends reviewers for expedited and limited IRB review exempt applications to IRB chair
• Forwards each expedited and limited IRB review exempt application (including the assurance; protocol; consent documents; recruitment materials; study instruments; translation certifications, when applicable; permission letters; grant proposal, when applicable; and international research addendum, when applicable) to selected IRB member for review
• Forwards non-limited review exempt continuation and modification requests to IRB reviewer of initial application or other IRB member as designated by the chair
• Maintains documentation of IRB activities:
  o Complete files on all research applications, including (but not limited to):
    ▪ The initial and all revised protocols
    ▪ Approved consent documents
    ▪ Recruitment materials
    ▪ Scripts
    ▪ Study instruments
    ▪ Permission letters
    ▪ Continuation requests
    ▪ Modification requests
    ▪ Termination and final reports
    ▪ Correspondence related to the project
    ▪ Statements of significant new findings
    ▪ Reports of unanticipated problems and instances of non-compliance
  o Detailed minutes of IRB meetings including
    ▪ Committee member attendance
    ▪ Names of consultants, investigators, or other guests present
    ▪ Details of non-review related committee discussions
    ▪ Determinations of conflict of interest of committee members
    ▪ Details of committee discussions related to reviewed applications, including:
      • Risk level
      • Results of determination votes
      • Approval period
    ▪ A list of applications reviewed as expedited since the last convened meeting
    ▪ Any additional business discussed
    ▪ Date of next meeting
• Coordinates monthly IRB meetings, ensures a nonscientific member will be present, and ensures a quorum will be reached and maintained
• Compiles all relevant materials for monthly IRB meeting and distributes to IRB members one week prior to meeting:
  o Agenda for upcoming meeting
- New and revised applications to be reviewed (including cover sheet; assurance; protocol, including all revised versions, if applicable; consent documents; recruitment materials; study instruments; permission letters; grant proposal, when applicable; and any other relevant documents)

- Continuation and modification requests to be reviewed, including all previous applications and requests

- Minutes from previous meeting

  • Attends and takes minutes for every convened IRB meeting

  • Forwards all allegations of investigator misconduct and instances of unexpected serious harm to participants to IRB chair and institutional official, when appropriate

  • Keeps confidential all documents and other information acquired as IRB staff

  • Conducts training and education for prospective principal investigators and student researchers

V. Applicable Regulations and Guidance

The US government code of federal regulations for the protection of human subjects (45 CFR 46) contains the following requirements involving the IRB office responsibilities:

1. An institution, or when appropriate an IRB, shall prepare and maintain adequate documentation of IRB activities including the following [§46.115(a)]:

   a. Copies of all research proposals reviewed, scientific evaluations, if any, that accompany the proposals, approved sample consent documents, progress reports submitted by investigators, and reports of injuries to subjects. [§46.115(a)(1)]:

   b. 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 research; and a written summary of the discussion of controverted issues and their resolution. [§46.115(a)(2)]

   c. Records of continuing review activities, including the rationale for conducting continuing review of research that otherwise would not require continuing review as described in §___109(f)(1). [§46.115(a)(3)]

   d. Copies of all correspondence between the IRB and the investigators. [§46.115(a)(4)]

   e. A list of IRB members in the same detail as described in §46.108(a)(2). [§46.115(a)(5)]

   f. Written procedures for the IRB in the same detail as described in §46.108(a)(3) and (4). [§46.115(a)(6)]

   g. Statements of significant new findings provided to subjects, as required by §___116(c)(5). [§46.115(a)(7)]
h. The rationale for an expedited reviewer’s determination under §___110(b)(1)(i) that research appearing on the expedited review list described in §___110(a) is more than minimal risk. [§46.115(a)(8)]

i. Documentation specifying the responsibilities that an institution and an organization operating an IRB each will undertake to ensure compliance with the requirements of this policy, as described in §___103(e). [§46.115(a)(9)]

2 The records required by this policy shall be retained for at least 3 years, and records relating to research that is conducted shall be retained for at least 3 years after completion of the research. The institution or IRB may maintain the records in printed form, or electronically. All records shall be accessible for inspection and copying by authorized representatives of the Federal department or agency at reasonable times and in a reasonable manner. [§46.115(b)]