Yeshiva University Undergraduate Student and Faculty Research Guidelines

Review of Proposed Faculty or Student Research/Student Curricular Activities:

All undergraduate faculty of Yeshiva University are required to notify the Office of the Senior Vice President for Academic Affairs of any proposed research activity to be conducted by either YU faculty, or research projects developed by YU students as part of their course curriculum – including activities that involve YU students as subjects.

The Senior Vice President for Academic Affairs, or designee, will review all proposed research activity and determine whether the activity is within the curriculum/academic content of the course structure, or whether the activity qualifies as research under federal regulations (45 CFR 46). If the determination is that the activity is not research, no interaction with the Einstein IRB is required. If the activity is considered to be ‘research’ as determined by federal regulations and institutional policy, the Senior Vice President for Academic Affairs will determine the review category (Exempt, Expedited, or Full) in compliance with 45 CFR 46. The following procedure applies:

Undergraduate Student Research: Applies only to research being done by students.
- All YU student research projects require direct supervision by a YU faculty member.
- The faculty member is required to be the Principal Investigator for the project.

YU Undergraduate Student Research Exempt Under Federal Regulations:
- The student together with the faculty advisor determines the exempt category under federal regulations (45 CFR 46.101(b)).
- The Senior Vice President for Academic Affairs confirms the ‘exemption’.
- The student is required to submit to his/her faculty sponsor (Principal Investigator) and the dean of the respective college the ‘Exempt Form,’ and a detailed protocol including a description of the recruitment plan. Both the faculty sponsor and respective dean are required to review and sign-off on the submission.
- The student is responsible for forwarding the materials to the Senior Vice President for Academic Affairs for review and signature. The Senior Vice President for Academic Affairs has the authority to review such protocols, in consultation with other parties as deemed necessary, and to recommend exemption verification to the Einstein IRB.
- The Senior Vice Present for Academic Affairs will forward the materials to the Einstein IRB.
- Upon verification by the Einstein IRB of the exemption status, written verification will be sent to the Principal Investigator with copies to the student.
- The transaction is recorded on the Einstein IRB agenda.

Additional Considerations for Exempt Research Protocols:
- Certain exempt research categories require anonymity (research participants cannot be identified in any way). In those instances, when anonymity is not ensured, the study requires Expedited Review by the Einstein IRB. The Exempt Categories and the Einstein IRB Research Application are available on the Einstein IRB website.
- Human research participants are required to voluntarily agree to enter a study. A description of the recruitment mechanism must be included in the detailed protocol and submitted with the ‘Exempt Form.’
• When applicable, to ensure anonymity, a 'Dear Participant' letter is recommended, rather than a signed informed consent document. The 'Dear Participant' letter should introduce the researcher to potential subjects, and include an explanation of each of the following points:
  o purpose,
  o procedures,
  o risks,
  o benefits,
  o alternatives to the study,
  o a statement that participants are under no obligation to participate in any research activity, and
  o that refusal to participate in the study will in no way influence their grades, or any services that they receive.

• For guidance in preparing a 'Dear Participant' letter, refer to the informed consent templates found on the Einstein IRB website. Prepare a separate letter. Submit the letter with the Research Application.

Research Requiring ‘Expedited’ Review:
Any research activity not eligible for exemption, and that involves only minimal risk to potential subjects, requires review by the Einstein IRB. Generally ‘Expedited Review’ guidelines apply. A Research Application and detailed protocol are required. The application forms and detailed instructions are available on the Einstein IRB website.

Research Requiring ‘Full’ Review:
Any research activity not eligible for exemption, and that involves more than minimal risk to potential subjects, requires review by the convened Einstein IRB. The application forms and detailed instructions are available on the Einstein IRB website. Protocols requiring ‘Full Review’ must be submitted by a specific deadline date. Refer to the Einstein IRB website for meeting and deadline dates.

YU Faculty Research:
Individual YU faculty research projects are to be submitted through the standard Einstein IRB review procedures (Exempt, Expedited, and Full Review). These include research projects in which YU students may be enrolled as research participants.