

IRB Project Number
(Obtain from IRB Approval Letter)

_____ - _____

New Jersey Institute of Technology

HUMAN SUBJECTS REVIEW FORM FOR ANNUAL REVIEW

Fill out the form completely. Annual review cannot be accomplished unless this application and the self-audit are completed and submitted with current consent form.

PRINCIPAL INVESTIGATOR(S):

Mailing Address:

E-Mail Address:

Telephone Number:

Fax Number:

FACULTY SPONSOR, if applicable:

Students, including doctoral candidates, applying for continuation of IRB approval must submit written documentation from their faculty advisors (via e-mail) stating that they are aware that the research is still being conducted under their supervision.

DEPARTMENT:

PROJECT TITLE:

I. PROJECT DESCRIPTION

A. Project activity STATUS is (check one):

- CONTINUING with NO CHANGES in procedure, risks, or number of human subjects since the last review.
- REVISED with minor changes as indicated on this form. (For substantial changes, a new Human Subjects Review Form must be completed, indicating the manner in which the project was revised, and returned with this form.)

Please indicate minor changes below (such as those in procedures, risks, or number of subjects). Attach additional pages if necessary.

B. This project is being conducted at the following SITE(S):

- NJIT
- OTHER (specify): _____

II. PROGRESS REPORT

A. NUMBER OF SUBJECTS STUDIED TO DATE: _____

NUMBER OF SUBJECTS YET TO BE STUDIED: _____

B. Have any ADVERSE REACTIONS been noted since the last review?

YES NO

If YES, describe and state how many.

Were any of these UNANTICIPATED REACTIONS? ("unanticipated" being defined as not having been anticipated in the protocol nor stated in the consent form)

YES NO

If YES, describe below.

C. Please attach a copy of your **CURRENT CONSENT FORM**.

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Submit to:

Dawn Hall Apgar, PhD
NJIT Institutional Review Board Chair

(973) 642-7616
(973) 596-8443 (fax)
dawn.apgar@njit.edu

**Institutional Review Board
Self-Audit**

The following self-audit should be completed by Principal Investigators annually for protocols involving minimal risk (i.e., those approved by expedited review). This form should be turned in to the IRB with the continuation applications for these protocols.

Principal Investigators of projects involving more than minimal risk (i.e., those approved by full review) should complete this form six months after being granted initial approval and every six months thereafter for as long as the research is being done. Completed self-audits for these projects should be submitted to the IRB within 5 working days of completion for review.

The full IRB will be informed about the timely submission of these forms and the findings of these self-audits.

Failure to perform self-audits according to the procedure outlined above may result in revocation of IRB approval.

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Name of Principal Investigator(s): _____

Completing the Self-Audit: _____

Date Self-Audit Completed: _____

Signature: _____
(ORIGINAL SCANNED, FAXED, OR HARDCOPY SIGNATURE REQUIRED)

Yes No

 1. Have there been any changes to research staff, including Principal Investigators, since obtaining IRB approval?

If Yes to Q1, have these changes been reported to the IRB?

Yes No

If Yes to Q1, have new staff completed the on-line human subject protection course and copies of their certificates been submitted to the IRB?

Yes No

 2. Are all subjects are at least 18 years of age?

If No to Q2, is written permission also obtained from their legal guardians/parents?

Yes No

 3. Do subjects include pregnant women or prisoners – special populations classified by federal regulations?

 4. Have there been changes to research procedures and/or instruments since obtaining IRB approval?

If Yes to Q4, have changes been approved by the IRB?

Yes No

Yes No

5. Have subjects signed, dated, and received copies of their written consent forms? (The IRB recommends examining several randomly-selected participant files to ensure that consent forms are signed and dated before completing self-assessment of this item.)
6. Are original signed written consent forms stored in a secure location (i.e., locked file cabinet)?
7. Is the consent form which was approved by the IRB still being used?
8. Have all participant recruitment materials (i.e., flyers, ads, etc.) been approved by the IRB?
9. Have there been any adverse events?
If Yes to Q9, have they been immediately reported to the IRB?
Yes No

For Student Projects:

10. Have there been any changes in faculty advisors since obtaining IRB approval?
If Yes to Q10, have they been reported to the IRB?
Yes No

For Research Reviewed by Full IRB (i.e., those involving more than minimal risk):

11. Are emergency procedures for handling adverse events posted in the lab?
12. Have staff been trained in emergency procedures prior to starting work?
13. Are emergency procedures regularly reviewed with staff after their initial training?