THE NEW SCHOOL INSTITUTIONAL REVIEW BOARD FREQUENTLY ASKED QUESTIONS

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Question 1: What is The New School Institutional Review Board (IRB)? What are its goals?

The New School's IRB is a university-wide faculty committee whose sole aim is to review research plans by New School faculty, students, and administrators in order to ensure that they properly consider the rights and welfare of human subjects involved in the research.

The IRB does not evaluate the quality of research projects; it exists simply to ensure that human subjects involved in research are protected in accordance with federal law.

Question 2: What are the regulations that govern IRBs and human subject protection?

IRBs are covered by federal regulation-which is an outgrowth of concern about human rights in research that began during the Nuremburg trials and was further sparked by several famous research studies, such as the Tuskegee experiments, that were injurious in some way to their participants. The federal mandates for protection of human subjects in research were codified in the Code of Federal Regulations, the "Common Rule" that can be found at 45 CFR 46 http://ohsr.od.nih.gov/guidelines/45cfr46.html

All universities, research facilities, etc. in the United States must adhere to these rules, whether they have an IRB or not; however the IRB is an almost universal entity in any institution engaged in research. TNS IRB functions under a Multiple Project Assurance (MPA-1445) granted by the Office for Protection from Research Risks (OPRR) of the Department of Health and Human Services (DHHS).

The University recommends that all researchers conducting human subjects research are required to complete the National Institutes of Health training tutorial and submit the certificate of completion with their IRB application to the IRB committee. This tutorial was updated on March 1, 2008. To complete the tutorial and obtain a downloadable certificate visit: http://phrp.nihtraining.com/users/login.php

Question 3: What are the definitions of "research" and "human subjects"?

Research is defined by federal regulations 45 CFR 46.102(d) as "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge".

Human subjects are defined by the regulations 45 CFR 102(f) as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information".

Intervention or Interaction includes physical procedures performed on an individual, manipulation, communication or interpersonal contact with an individual or manipulation of an individual's environment.

Private information includes information that an individual can reasonably expect will not be made public, and information about behavior that an individual can reasonably expect will not be observed or recorded.

Identifiable means that the identity of the individual is or may be readily ascertained by the investigator or associated with the information.

Question 4: What types of research must be reviewed and approved by the Institutional Review Board before the project can begin?

Any research proposal that involves human subjects and involves New School faculty, students or administrators as the researchers, is subject to IRB review. Please note that applications submitted for IRB review, should summarize proposed research protocols in a manner that is comprehensible to all members of the IRB committee. The IRB committee is a diverse membership (social scientists, biologists, education researchers, and psychologists) so disciplinary jargon should be avoided.

Question 5: What are some examples of research that must be reviewed and approved by TNS IRB?

Examples of projects that must be reviewed if they include living human subjects are:

- social sciences
- behavioral studies
- historical
- linguistic studies

- marketing analysis
- survey research projects
- undergraduate/graduate student projects
- dissertation research

Question 6: What about collaborative projects? Or projects run outside the United States?

Projects undertaken collaboratively with other institutions are also subject to IRB approval, usually from both institutions. Other institutions have different guidelines and the project will more likely be approved if there is a collaborator on site, or if The New School has approved the project. Please be aware that the timing of reviews varies from institution to institution. Researchers should review the protocols and submission schedule, and plan and sequences the reviews accordingly. Each institution is required to publicize general information on their IRB home page and a contact person for more information.

Projects undertaken outside of the United States are subject to IRB review. If the project is collaborative, both institutions should approve the project.

Question 7: What are some examples of projects that do not need IRB review?

Some data collection intended solely for the improvement of administrative or educational processes, services or policies at the University and not designed to contribute to generalizable knowledge are not considered research for the purpose of IRB review. Examples are student evaluations of teaching and administrative customer service surveys. Of course, in such cases it is expected that the privacy of the subjects is protected, the confidentiality of individual responses are maintained, and participation is voluntary.

Question 8: How does the IRB evaluate research?

There are three ways in which the IRB may approve a project. The researcher determines for which type of approval to apply, but the IRB makes the final determination of the type of review (if any) the project receives.

- a project may be declared exempt from review
- a project may receive an expedited review
- a project may need a full IRB review

Question 9: Some types of research are considered "exempt". What does this mean?

"Exempt" means a research plan or protocol does not require an extensive review. However, only the IRB can make a determination of exempt, so a researcher must still apply to the IRB for exempt status. To qualify as exempt, research must represent a low potential for risk to subjects. Risk is reduced through anonymity of responses, use of existing or publicly available data, or through the use of non-invasive methods that will not harm subjects.

Some common examples of exempt research:

- anonymous surveys or interviews
- surveys or interviews of non-vulnerable adults about non-sensitive topics
- research conducted in established or commonly accepted educational settings, involving normal education practices. Example: research on two different teaching strategies or research on curricular materials.
- passive observation of public behavior without collection of identities, unless information is recorded in such a manner that human subjects can be identified, or any disclosure of the human subjects responses outside the research could place subjects at risk of criminal or civil liability, or be damaging to the subject's financial standing, employability, or reputation.
- analysis of existing publicly available data with no identifiers.

Question 10: What determines if a project can receive an expedited review?

To qualify for expedited review, research must fall into any of regulated expedited categories. These categories can be seen at http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm. Expedited categories involve collection of samples and data in a manner that is not anonymous and that involves more than minimal risk to subjects. (Note: Expedited does not mean an emergency review due to time constraints.)

Some common examples of expedited research:

- Studies including moderate exercise by healthy volunteers
- Analyses of video and voice recordings (such as those taken in the investigation of speech defects)
- Research on individual or group behavior or characteristics of individuals, such as studies of perception, cognition, game theory, or test development, where the research investigator does not manipulate subjects' behavior and the research will not involve stress to subjects.
- Education or ethnographic research that includes identifiers of any kind (video recording is a form of identification)
- Ethnographic research that included identifiers of any kind

The IRB determines if a project falls into this category.

Question 11: What categorizes the need for a full review?

Proposed human subject research that does not qualify for exemption or expedited review must receive a full review. Protocols that represent more than a minimal risk to the subjects are reviewed rigorously for compliance with all applicable federal, state, local and university regulations.

Many factors can trigger a full review, including the type of research subject, the topic of research, and/or the methodology of research. Some common examples are:

- Research on Substance Abuse
- Research on Sexual and Physical Abuse
- Research on Depression and Suicide
- Research Involving children and adolescents
- Research on Race, Sexuality, and Gender
- Research involving subjects with diminished capacity

- Research involving institutionalized subjects (e.g., prisoners, state hospital patients)
- Research involving data gathered from a clinical database of human subjects
- Research on perception of clinical procedures that could cause depression, anxiety (i.e. genetic knowledge, reproductive technologies)
- Research conducted in a clinical setting (genetic counseling, doctor's office, hospital)

It is especially important for researchers who are contemplating the use of minors or people in situations in which they do not have complete control over their actions (such as prisoners, hospital patients, etc.) to consult the IRB. Use of subjects with constrained choices, such as the homeless, or subjects for whom incentives to participation may be construed as coercive, such as students or employees of the University, may also present issues that must be considered by the IRB before proceeding.

Question 12: What is the process for obtaining IRB approval?

1. Go to http://www.newschool.edu/admin/provost/irb.html and download the appropriate application form.
2. E-mail the application to the IRB at IRB@newschool.edu or mail it to: IRB Assistant, 80 Fifth Avenue, 7th floor. If the form is emailed, please fax the first page with your signature to 212-989-0846. The IRB will notify you if your project is exempt, or requires an expedited or full review. The IRB will advise you if modification or a different form is required.
3. Your project will either be approved, or a modification required pending approval.

Applications should be submitted to the IRB as early as possible, especially if outside funding is being sought. The review process takes approximately one month.

Question 13: Can a researcher submit a proposal for external funding before receiving IRB approval?

Most external funders-public and private--will allow you to submit a funding proposal pending IRB approval. However, The New School's Office of Grants and Sponsored Projects will withhold authorization for submission until you have at least submitted your application to the IRB. Also note that external funders will require final IRB approval prior to any formal award.

Question 14: What is the procedure for ongoing or multi-year projects?

In the case of projects that re-use the same protocols year after year-you must advise the IRB annually that the protocols have not changed. The applicant should indicate on the first page that the proposal has been previously accepted.

If the protocols for the project change, you must inform the IRB immediately and should not proceed with revised protocols until IRB approval is received.

Question 15: What are the researcher's obligations if there is an adverse effect to a participant in the research project?

In addition to any standard notifications required by law or common sense, you must advise the IRB within

72 hours, or if it is an emergency situation, 24 hours.

Question 16: What happens if a researcher does not comply with IRB policies?

In addition to the risk of adverse effects for the subjects and ethical implications for the investigator, bypassing IRB review incurs the following risks:

The University
If the university does not fulfill its responsibility under the IRB regulations it may be subject to civil liability claims, loss of federal funding and ineligibility to apply for further federal funding. In addition, private funders often will not fund projects unless the university certifies IRB compliance and the project director adheres to the regulations.

Faculty and Staff
External funding may be withheld: Federal sponsors, and most private sponsors, require IRB approval as a condition of funding for relevant projects. Sponsors may postpone review of proposals for which review is not complete/pending at the time of proposal submission. Some sponsors will not release funds to the University for the investigator's use without IRB approval. The University will not support unapproved research: Liability issues arising from unapproved research become the responsibility of the investigator. Persons conducting unapproved research are deemed to be acting outside the scope of authority granted them by the University.

Students
Credit may be withheld: The University may, at its discretion, refuse to grant students course credit for research conducted without IRB approval. Degrees may not be awarded for work based on non-IRB-reviewed projects.

Question 17: Where do I go for more information?

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