Introduction to the IRB
What is the IRB?

- The Institution Review Board (IRB) is composed of New School faculty and one external reviewer. The committee reports to the Office of the Provost.
- The IRB is geared towards reviewing and approving research involving humans with the aim to protect the rights and welfare of the research subjects.
- The Department of Health and Human Services regulations have empowered IRBs to approve, require modifications in planned research prior to approval, or disapprove research.
- Some funders require evidence of IRB approval, but all relevant research projects must be reviewed whether funded or not.
History of IRBs

- IRBs were developed in direct response to research abuses that took place early in the twentieth century.

- Notorious studies that reflect abuses include experiments of Nazi physicians that became a focus post-World War II & the Tuskegee Syphilis Study, a project conducted between 1932 and 1972 on black men in rural Alabama as well as similar studies of prisoners of all colors.
IRB Purpose

- To assure, in advance, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in research studies.

- IRBs review research protocols and related materials (e.g., informed consent documents and study measures) to ensure this protection.

- Chief objectives of the IRB protocol review are to assess research methods in relation to human subjects, to promote fully informed and voluntary participation by prospective subjects who are themselves capable of making such choices and to maximize the safety of subjects.
IRB Responsibilities

- To safeguard the rights, safety, and well-being of all study subjects and communities
- Special attention should be paid to research that may include vulnerable subjects and communities, such as pregnant women, children, prisoners, the elderly, or persons with diminished comprehension
- The IRB may only approve research for which there is a bona fide informed consent process for participants, for which the risks to subjects are balanced by potential benefits to society, and for which the selection of subjects presents a beneficial distribution of risks and benefits to eligible participants
- For additional detailed information, the ethical principles in human subjects review are outlined in the Belmont Report
The IRB should obtain and review the following documents: research protocol(s)/amendment(s), informed consent form(s) and consent form updates that the investigator proposes for use in the study, subject recruitment procedures (e.g., advertisements), written information to be provided to subjects, available safety information, information about payments and compensation available to subjects, and any other documents that the IRB may need to fulfill its responsibilities.

- The IRB should conduct continuing review of each ongoing trial at intervals appropriate to the degree of risk to human subjects, but at least once per year.

- The IRB should feel free to request additional information if it would add meaningfully to the protection of the rights, safety and/or well-being of the subjects.
IRB Exemptions

While all human subjects research must be initially reviewed by the IRB, the IRB can declare it exempt from further review. Exempt status means the researchers are free to conduct their research but also is exempt from approval and renewal processes.

1) Research conducted in established or commonly accepted educational settings, involving normal educational practices.

2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior.

3) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
The IRB Process Here at The New School

- The applicant turns in their application to the IRB Administrator via e-mail (irb@newschool.edu)

- After checking to ensure all requested application materials are included, the application is passed on to the reviewer via e-mail

- The reviewer independently reviews the application within 2 weeks

- When the review is completed, the reviewer passes their feedback back to the IRB administrator

- Feedback includes: Approval, Exemption, or the specific corrections/additions needed in order for Approval to be obtained
The IRB Process Here at The New School
Continued

- If Approval or Exempt status is given, then the IRB Administrator passes this information onto the applicant by email and, if applicable, an Approval Letter is distributed.

- If corrections or additions are needed, the IRB Administrator passes these specifics onto the applicant and receives these corrections/additions before granting approval (If the reviewer wishes to see the corrections/additions that were required they should make the IRB Administrator aware of this).

- All projects require repeated review for purposes of continued approval after one year.
Online Training Resources

- Collaborative Institutional Training Initiative (CITI) Public Access Course in the Responsible Conduct of Research is available to the public without charge. Register here: [https://www.citiprogram.org/enroll/courseregistration1b.asp?language=english&institution=100](https://www.citiprogram.org/enroll/courseregistration1b.asp?language=english&institution=100)

- The NIH Office of Extramural Research also offers basic online training in the protection of human research participants. Information is available here: [http://phrp.nihtraining.com/users/login.php](http://phrp.nihtraining.com/users/login.php)
Questions?

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