**NYC DOE IRB**

**Guidance on Resuming or Starting Research During the 2020-2021 Academic Year**

**Effective Date: 10/06/2020**

**Background:**

The purpose of this guidance is to outline criteria for conducting research in NYC DOE physical and/or virtual sites and/or with NYC DOE staff, students or families during the 2020-2021 academic year.

In the interest of minimizing the burden on NYC DOE staff, students and families during this challenging time, the NYC DOE IRB will require all researchers conducting non-essential or non-COVID-19-related research to demonstrate an anticipated tangible direct benefit associated with their study or to otherwise offer a justification for conducting the research during this academic year. It is recommended that research designated as non-essential, non-COVID-19-related, or that does not carry a direct tangible benefit to participants be postponed until the resumption of normal operations.

In the interest of ensuring an equitable selection and inclusion of subjects and sites, the NYC DOE IRB will also require accommodation of students and families attending both partially in-person and fully remote as well as DOE staff teaching in-person and fully-remote. All studies seeking initial approval or renewal approval will be required to demonstrate procedures for accommodating all participant groups during the 2020-2021 academic year.

**Research Renewed or Approved before October 6, 2020:**

Researchers who received initial approval or annual review/renewal approval from the NYC DOE IRB for in-person or remote data collection prior to October 6, 2020 are required to submit an Amendment to the NYC DOE IRB to present a plan for conducting their research under the hybrid school reopening model and to offer a justification for conducting the research in these challenging circumstances (see criteria below). Specifically, researchers will be required to detail the recruitment, consent, and data collection procedures for both teachers, students and families attending or teaching partially in-person or fully remote and to justify their study as either essential, COVID-19-related, as carrying a direct tangible benefit for participants, or related.   
  
Researchers who wish to postpone their study until resumption of normal operations are not required to take any action at this time.

**New submissions and requests for continuing review/renewal (including those already under review):**

Researchers seeking approval for new studies or continuing review/renewal for previously approved but expiring studies will be required to demonstrate that their research falls into one or more of the following criteria:

1. The research is essential and must be carried out to satisfy a city, state, and/or federal mandate or other funding or agency requirement.
2. The research is COVID-19-related and aims to address a time-sensitive COVID-19-related matter.
3. The research carries a direct tangible benefit to research participants. Note that compensation, monetary or otherwise, is not a benefit of research participation.
4. Another substantive justification for conducting the research during the 2020-2021 academic year.

In the case of renewal requests, an Amendment must be submitted in conjunction with the Continuing Review xform to offer the applicable justification/explanation, as outlined above. If a study expires before it can be reviewed and renewed, a new protocol detailing any/all outstanding research procedures will be required.

**NYC DOE assistance of external research efforts:**

The NYC DOE IRB recognizes the logistical challenges for conducting research under the hybrid-reopening model.

Research not conducted by or on behalf of the NYC DOE or in direct formal collaboration with the NYC DOE is not permitted to utilize DOE offices, staff, or other resources for recruitment, consent, data collection, or other activities that support the external study team. This includes, but is not limited to, seeking email lists for recruitment, asking DOE staff to collect informed consent signatures or send recruitment or consent forms to staff, students, or parents, or utilizing DOE staff to administer research measures or facilitate research interventions or interactions.

All external research must aim to minimize the burden on NYC DOE sites, staff, students and families.   
  
External studies that are deemed essential, COVID-19-related, as presenting a direct tangible benefit to participants, or related, will be required to offer recruitment, consent, and data collection plans that do not rely on assistance from the NYC DOE or its staff for implementation or execution.

**For additional guidance, please see:**

[DOE Engagement Guidance.](https://nycdoe.my.irbmanager.com/Attachments/6cbee051-374c-4f09-9cc9-57089d98baef)

[DOE PI Role and Responsibilities Guidance .docx](https://nycdoe.my.irbmanager.com/Attachments/8377890f-6dcc-4efd-ac4d-72786421c6e9)

[NYCDOE IRB Guide for Virtual interactions and Interventions with Research Subjects.docx](https://nycdoe.my.irbmanager.com/Attachments/defe1fbc-b596-43ef-a312-16491a3a9e8d)

[Digital Recording Guidance NYC DOE IRB FINAL ma.doc](https://nycdoe.my.irbmanager.com/Attachments/fd72abc1-e764-4398-be7a-92b177d58cdd)

[Recruitment Guidance NYC DOE IRB 05042020.doc](https://nycdoe.my.irbmanager.com/Attachments/372c9eba-afb1-456d-ad90-b9b4d70c498f)

[New York City Department of Education Data Security Guidance 05062020.docx](https://nycdoe.my.irbmanager.com/Attachments/bcd2ae28-7ef5-4b22-b930-48f92b4c6c15)

[NYC DOE IRB e-Consent Guidance.docx](https://nycdoe.my.irbmanager.com/Attachments/d64e69bd-1e74-4ab3-a8c7-ca4cad8426fb)

**In-person research activities:**

Requests for conducting or resuming in-person research will be considered on a case-by-case basis using the following criteria:

1. The research must be demonstrated to require in-person interactions or interventions with research subjects.
2. The research procedures/research participation must present a direct tangible benefit to participants.
3. External researchers will be required to provide documentation from their IRB of record explicitly detailing permission to conduct in-person research in DOE sites during the COVID-19 pandemic.
4. Researchers will be required to detail completion of training in COVID-19-safety and other related risk-mitigation efforts. It is expected that all external institutions will make such training available for researchers aiming to conduct in-person activities in DOE sites.
5. Researchers will be required to provide documentation of recent COVID testing and follow all other applicable DOE site building safety policies and protocols. Additional information will be provided by sites and is also available here: <https://healthscreening.schools.nyc/>
6. All applicable informed consent documents will be required to detail the risk of COVID-19 infection as a risk associated with in-person research activities.
7. Researchers will be required to address their plan for protecting the privacy of research subjects while adhering to applicable Track & Trace requirements.

\*\*\*This guidance is subject to change at any time without notice.