NYCDOE IRB COVID-19 FAQ (03.22.2020)

**General:**

1. **My study was under review by the NYCDOE IRB but was not approved before the closure of schools and the shift to remote work. Is the NYCDOE IRB continuing its work during this time?**

Yes, but we are presently prioritizing amendments and research that aims to address the COVID-19 pandemic and its impact on NYCDOE families and staff.

1. **Why must some human subject research studies or specific activities be paused?**

The COVID-19 pandemic has altered the risk/benefit ratio for in-person contact associated with research activities. Ethical principles of research as well as federal regulations for the protection of human participants in research require an acceptable risk/benefit ratio.

1. **Can the study team conduct home visits to collect data?**

No.

1. **Which studies or study procedures** must **be paused?**

Studies or study procedures involving face-to-face interaction with participants that have no direct therapeutic benefit must be paused or modified.

Procedures such as telephone contact or remote communication or remote data collection may continue.

1. **What previously approved human subject research activities may continue?**

On-going research that does not entail in-person interaction or intervention may continue.

Researchers are asked to voluntarily suspend their research if they can do so safely and if the suspension will not jeopardize the scientific integrity of the research. Note that NYCDOE schools are presently closed.

1. **My study involves observations on classroom activities, but now classroom activities have been moved to a virtual platform. May I continue observations of, for example, a Google classroom?**

These requests will be considered on a protocol-by-protocol basis and must be submitted to the IRB for consideration via protocol amendment.

1. **Does modifying from in-person to remote (e.g. phone, Teams, Zoom, etc.) data collection require prospective review and approval from the IRB?**

Yes, review and approval from the IRB for all changes to previously approved data collection procedures is required. The exception to this is a change implemented to reduce or remove immediate risk to research participants. These changes must be reported to the IRB using the Unanticipated Event xform within 10 business days of the implemented change.

1. **For an approved and ongoing study, can the study team collect data and follow-up with previously enrolled subjects by telephone or through other electronic communication platforms?**

Yes, but only after this change to data collection has been reviewed and approved by the NYCDOE IRB through the submission of a protocol amendment.

1. **My research (e.g. timeline for data collection) has been directly impacted by closure of NYCDOE schools. Do I need approval from the IRB to reflect the impact/change this has had on my previously approved data collection and enrollment targets?**

Researchers must submit amendments to reflect the necessary changes they will be required to make to their studies. These amendments may be submitted at the researcher’s discretion.

1. **Does a change to the consent process to enroll new study subjects (e.g. from in-person to electronic) require prospective review and approval by the NYCDOE IRB?**

Yes. Among other considerations, consent determinations correlate with previous risk determinations. Further, changes to the previously approved consent process may require changes to previously approved consent forms.

1. **If I revise my study to migrate data collection to an electronic platform, will I need to reconsent my study subjects?**

These determinations will be made on a protocol-by-protocol basis. Generally, an information letter will suffice.

1. **What do I need to know about conducting research with students/children online?**

Conducting remote or online research with children is subject to additional laws, regulations, policies, ethical principles. and administrative safeguards. This includes, but is not limited to, COPPA, numerous NYS and city laws, as well as applicable NYCDOE regulations. For guidance, please email mazar@schools.nyc.gov (additional formal guidance is forthcoming).

1. **How do I open a new research study related to COVID-19?**

Email mazar@schools.nyc.gov with the subject line “COVID-19 research study”. All requests will be reviewed on a case by case basis but will be prioritized if demonstrated to be of importance to the NYCDOE or to the wellbeing of NYCDOE families and/or staff.

1. **Can new study subjects be enrolled in protocols that are already ongoing?**

To minimize the burden on NYCDOE families and staff, it is recommended that new study subject enrollment be halted for the time being, but requests to enroll new subjects in ongoing research will be considered by the NYCDOE IRB on a case by case basis. Please email mazar@schools.nyc.gov for guidance.

1. **Do I need to notify the IRB if I pause my research?**

No, unless the research is federally-funded.

**Federally-funded studies:**

1. **What about federally-funded studies with mandatory progress report and other deliverable deadlines?**

For suspended or paused studies with federal funding (e.g. IES, USDE, NIH, NSF, HHS, etc.) for which the NYCDOE IRB is serving as the IRB of record, the following information must be emailed to Marianna Azar at mazar@schools.nyc.gov immediately:

1. Name of PI
2. Protocol number
3. Name of Sponsor
4. Grant award number
5. Contact information for your grant officer or point person
6. **I have a progress report due in the near term and my study has been impacted by the COVID-19 pandemic and/or closure of NYCDOE schools. Should I include information relating to this pause/impact in my progress report?**

Yes. You should also work with your grant officer to determine the agency-specific requirements that may have been put in place to address the pandemic and its impact on ongoing research.

1. **My study is going to expire in the coming weeks or months. Should I submit a renewal request even if I cannot continue the research during this time?**

Yes. Studies that are allowed to expire will not be renewed and will necessitate the submission of a new initial submission detailing all research to be carried out moving forward.

 **Data Requests:**

1. At this time, the NYC DOE External Data Request Committee will continue processing requests, but we are currently working with severely limited capacity to fulfill approved requests, so it will take substantially longer to complete requests at this time. We will continue to update this page with additional guidance when available. Please contact RPSGResearch@schools.nyc.gov with any questions, thank you for your patience.