

**April 1, 2020**

**Dear New York Tech Faculty, Students, and Staff,**

In the context of rapidly evolving circumstances regarding COVID-19 and the university's compliance with the New York State Governor's Executive Orders (or equivalent representative where your campus is located) as well as the health and well-being of the community, the Office of Sponsored Programs and Research has issued these revised standards related to human subjects-related research visits:

**Research Activities Involving Human Subjects**

To ensure the safety of our researchers, staff, and research participants and to be aligned with the most recent National Institutes of Health guidance, the Office of Sponsored Programs and Research is requesting that research involving person-to-person contact or gatherings of human research participants be paused as soon as possible unless needed for participant safety. The duration of the pause is unknown, but to reduce disruption to the extent possible, this decision will be reviewed frequently. Therefore, we are implementing the following restrictions on research involving human subjects:

**Restriction 1: Human Subjects Research**

- During this period of remote work, there should be minimal contact with human subjects involved in research. Contact with human subjects should be limited to remote methods (e.g. email, phone, Zoom, RedCap, Qualtrics) to the extent possible. Please email [grants@nyit.edu](mailto:grants@nyit.edu) if you need to revise or amend your IRB protocol to conduct remote interviews or surveys.
- In those instances in which human subjects research cannot be performed remotely and are not essential to a participant's health, researchers should work with their teams to develop revised/alternative plans to enable continued progress on research or should delay projects.
- Researchers who need to have physical interactions with human subjects in clinical trials should follow the guidance of the facility, hospital, or clinic in which those studies are taking place. If human participants in a study are at risk of harm from the research suspension, please document a plan to safely discontinue protocol activities and submit the plan to the IRB. This is recommended to ensure the safety of subjects, and the IRB may not have the time to review and approve before necessary steps need to be taken.
- If pausing your activities requires a permanent change in your protocol, please submit an amendment to the IRB and notify your sponsor.
- If you have a human subjects research protocol that has been submitted for approval, please review this guidance and contact the IRB coordinator to update your research and recruitment plan in order to address the items listed above.
- If you are considering a new research protocol, please review this guidance and determine if you should instead delay your research plans due to the current restrictions due to COVID-19.

Our federal sponsors recognize the significant effects this emergency is having on funded projects, clinical trials and other human subject studies. The NIH has published guidance to assist researchers during these times and it can be found at [grants.nih.gov/grants/natural\\_disasters/corona-virus.htm](https://grants.nih.gov/grants/natural_disasters/corona-virus.htm). The NSF has created a similar webpage with resources at [nsf.gov/news/special\\_reports/COVID-19/](https://nsf.gov/news/special_reports/COVID-19/).

**Restriction 2: Students**

**Undergraduate Researchers:** Undergraduate students are not permitted to be on campus to carry out any research activities. All human subject activities need to be limited to remote methods (e.g. email, phone, Zoom, RedCap, Qualtrics) to the extent possible.

**Graduate Student Researchers:** Graduate students conducting research for their thesis/dissertation or as part of a research assistantship are not permitted to be on campus to carry out any research activities. All human subject activities need to be limited to remote methods (e.g. email, phone, Zoom, RedCap, Qualtrics) to the extent possible. Where research activities in associated research facilities are necessary, additional practices dictated by those facilities should be adopted to keep health and safety a priority.

**Research Program Milestones:** It is recommended that you review your Research Program Milestones and assess the impact of COVID-19 on your research. In addition to the guidance published in this document, **please also consider the guidance for investigators from your external funder, campus location (where appropriate), or external facility where you are performing the research.**

#### **Scenarios in Which to Consider These Impacts:**

- What will the impact be to my research and sponsored programs due to the Governor's Executive Orders as it relates to your specific research location?
- What will the impact be to my research and sponsored programs if more than one of my research staff contracts COVID-19 or needs to self-isolate for an extended period of time?
- What will the impact be to my research and sponsored programs due to New York Institute of Technology's directive for all faculty and staff to work remotely?
- What will the impact be to my research and sponsored programs due to New York Institute of Technology's directive of partially reduced campus operations?
- What will the impact be to my research and sponsored programs due to New York Institute of Technology's directive that all in person research activities will be limited to remote methods (e.g. email, phone, Zoom, RedCap, Qualtrics) until the end of the semester (or longer)?

#### **Ways to Begin Assessing the Impact of COVID-19 on Your Research in Any of the Above Scenarios:**

- Are there any studies involving participants, animals, ingredients, or experiments that would be adversely affected? If so, what plans are you putting in place to allow for them to continue or allow for them to be stopped and later resumed in the least impactful way?
- What standing purchasing orders or human resource issues if any will be impacted?
- Will data collection/analysis/storage be impacted?
- Are there costs associated with these impacts?
- What regulatory approvals will expire soon and might be impacted if they are not renewed? Can they be renewed early?
- Are there any collaborators that need to be notified?
- What sponsor reports or deadlines might be due during this time period?
- Will the impact of these actions warrant a for-cost or no-cost extension request for any of my sponsored projects?
- What notice might I need to give sponsors or regulators if the research is going to be paused or significantly delayed beyond a couple of weeks?

#### **Additional Considerations for Human Subjects Research:**

- Is the location of the study remaining open and available for participants to be present?
- Has the location implemented any procedures to slow the spread of the COVID-19 that will affect participation in your study or the ability of your study to proceed?
- Does your protocol require in-person participation or treatment? Can it be modified for remote participation?
- Does your protocol require in-person monitoring? Can it be modified for remote monitoring?

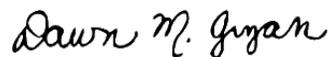
- Should your participants be screened for COVID-19 as part of your inclusion/exclusion criteria? Do you have the capability to get them tested?
- Would your data or results be affected if your participants had to self-quarantine or if they contracted COVID-19?
- Do any modifications made to your protocol and approved by the IRB due to the COVID-19 also need to be reflected in ClinicalTrials.gov?
- Remember, any modifications you make to your protocols as a result of the impact from the COVID-19 need to be submitted to the IRB and approved before implementation.

**Additional Resources:**

- PRIM&R COVID-19 and COVID-19 Updates for the Oversight Community: <https://blog.primr.org/covid-19-and-covid-19-updates-for-the-oversight-community/>
- A listing of agency guidance is available on the COGR website: <https://www.cogr.edu/institutional-and-agency-responses-covid-19-and-additional-resources>.

**Once you have considered the impact of this guidance, please take appropriate steps to make sure your research program is prepared.** If you have any questions, please contact [grants@nyit.edu](mailto:grants@nyit.edu).

Sincerely,



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