NEW YORK INSTITUTE OF TECHNOLOGY

Updated August 12, 2021

Dear New York Tech Faculty, Students, and Staff,

In compliance with the New York State Governor's Executive Orders (or equivalent representative where your campus is located) and to safeguard the health and well-being of the New York Tech community, the Office of Sponsored Programs and Research (OSPAR) has issued 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, OSPAR is requesting that faculty members wishing to resume face-to-face research submit a Human Subjects Research Resumption Form to grants@nyit.edu for review.

The faculty member must:

- submit an Investigator Training Checklist.
- follow the guidelines in the Restart Plan for Clinical Research Activities.
- submit the certificate for the training module Covid-19: Back to Campus (Fall 2020), available at Citiprogram.org.
- submit a safety plan description detailing how research will be resumed on your protocol while keeping subjects safe.

Research subjects must also sign a Consent Addendum in addition to the regular Consent Form.

Additional Considerations for Human Subject Research
As restrictions are eased or lifted, investigators and IRBs need to appreciate that the parameters for what constitutes "normal" may have changed. Protocols that may have been considered "minimal risk" may need reconsideration as "greater than minimal risk" due to the risk of COVID-19 infection. The adequacy of provisions to minimize risk, monitor safety, and protect privacy and confidentiality may need to be re-evaluated. It may no longer be feasible to resume certain research as originally proposed, and modifications may be required.

Consider:

- Whenever possible, that studies that were modified to virtual/phone/remote formats continue to be conducted as modified.

- Studies being submitted to the Institutional Review Board for initial approval should include virtual/phone/remote formats for as many procedures as possible.
- For paused studies, whether it is possible to modify some or all face-to face procedures to virtual/phone/remote formats prior to re-starting the study.
- The security of virtual platforms (e.g. Zoom, Skype).
- Changes to data management (e.g. for remote access and use) and the security of these procedures.
- Whether research activities could be added to a routine care interaction instead of involving a separate visit.
- Whether PPE (masks, face shields, gowns, gloves) is needed and whether it is available for purposes other than clinical care.
- Whether consent forms and other materials need to be modified to address the risk of COVID-19 or to incorporate changes made to research activities.

Please note this guidance may change at any time.

Additional resources can be found at

- HRP COVID-19 Information
- Centers for Disease Control and Prevention

Sincerely,

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