

Information for researchers in response to COVID-19 and Research at NJH 16 March 2020

While clinical research is critical to our understanding of disease and leads to life-saving therapies, at this time of increased risk of infection to our vulnerable patient population, severely limited access to personal protective equipment (PPE), and in the interest of the safety of our study teams, in person clinical research visits that do not have a potential benefit to patients (including all observational research, registry trials, and any other non-interventional trials) will be put on hold at this time. Please see below for additional details.

NJH's primary concern is the safety of our research participants and the research team members. We understand that the COVID-19 outbreak will affect the continuity and integrity of many research studies. We hope the following guidance is helpful in protecting our participants and staff and minimizing adverse impacts for research.

Mandatory Screening for COVID-19

Clinical Research Services (CRS) clinical research coordinators (CRCs) began screening for COVID19 per National Jewish Health (NJH) screening guidelines as of 4 March 2019. Kevin Smilor or his representative is attending the NJH institutional daily safety meetings, and will update CRCs on the changing/updated screening policy daily. Study teams should begin screening research participants at any interaction, whether in person or by phone. Screening should be an ongoing process with each subsequent encounter, subject to further notice from the CRS medical director. As this is clinical screening, the IRB does not need to be notified of, or approve, the incorporation of mandatory screening into research protocols.

Triage and management of participants who screen positive will be done per NJH guidelines.

Please review the NJH webpage on the Spyderweb for most up to date information regarding Coronavirus.

Deferral of On-Site Research Monitoring Visits

As of 10 March 2020, all planned in-person onsite clinical research monitoring visits were postponed until after 20 April 2020 or changed to remote monitoring when feasible. We will continue to reassess the need for this restriction or potential extension of the 20 April 2020 date.

Unanticipated Problems

Considering the broad public awareness of COVID-19, NJH would not consider the infection of a research subject or research staff member to be an unexpected event which required reporting to the IRB within 7 days. Researchers must remain compliant with other requirements to report adverse events to research sponsors and/or the FDA.

Changes to eliminate apparent immediate hazards to subjects

Federal regulations allow researchers to make changes to research to eliminate apparent immediate hazards to subjects without IRB approval. NJH policies are consistent with this regulation, as are most other IRBs.

Examples of changes to eliminate immediate hazards to subjects in response to COVID-19 include, but are not limited to, cancelling non-essential study visits, conducting phone visits in lieu of in-person visits, conducting additional screening of current and potential research subjects prior to in-person visits, and temporarily suspending enrollment.

Also, any new screening procedures or other policies implemented by the campus of any of our affiliate health care systems in response to COVID-19 are not policies or procedures that require IRB approval.

Deviations from the Protocol

If researchers deviate from their approved protocol to eliminate apparent immediate hazards to subjects, that does not require NJH IRB approval and does not fall under NJH 7-day reporting requirements assuming the deviations are considered temporary and are relatively minor.

Deviations that are necessary to comply with new policies issued by NJH, our affiliate health systems or public health directives also do not require NJH approval and do not fall under NJH 7-day reporting requirements.

Researchers should document these deviations and submit a single summary report to NJH at time of Continuing Review. For research that does not require Continuing Review, submit the summary report with a UPIRTSO submission at a reasonable point in the future (e.g., around the anniversary date of your approval or after institutional operations return to normal).

If deviations from the protocol are necessary which might result in potential new risks to subjects, these would need to be reported to NJH within 7 days. Examples include interruption of study drug prescriptions, or cancellations of study visits critical for subject safety. Please submit to NJH IRB using an Interim Event Report, selecting elimination of apparent immediate hazards to subjects.

Study Pauses/Revision of Study Activities

No new non-COVID-19 studies should begin at this time (study start-up activities such as budgets, contracts and IRB submission may continue), **and no new patients should be recruited for screening for studies that require in-person visits at this time.** Enrollment in an observational visit may occur if a patient can be enrolled by phone, and this consenting method for the study is IRB approved, WITHOUT need for additional in person tests or procedures (e.g. enrollment can be completed by phone and the visits and protocol screening window allows for visits after 20 April 2020 (or later if continued restrictions are necessary).

Observational studies

Please reschedule study visits. Discuss the recommended plan with your sponsor to determine whether:

- Rescheduled visits can take place out of window (if the subject is willing to return at a later date).
- If scheduling the study visit out of window is not feasible prior to the next regularly scheduled study visit, the RC can mark “not done” in EDC and specify reason not done as “COVID-19”, or mark based on the sponsor recommendations.
- During this time, protocol deviations will not be issued for any out of window visits and missed study visits due to COVID-19. Work with the sponsor or within the data capture system to record any out of window or missed visits.
- The later study visits may have important endpoints, so please encourage your subjects not to withdraw completely from the study.
- If a subject is being seen in clinic for clinical purposes, the observational visit may occur, but should not include any research procedures that will use PPE and/or increase exposure to research staff through aerosolization (e.g. bronchoscopy, induced sputum, spirometry, multiple breath washout, nasal scraping, nasal potential difference measurement).

Interventional studies with direct benefit to patients (e.g. interventional phase III studies)

This research will continue because of its potential to benefit patients. However, please consider the following:

- CRCs will call the subject to screen them for COVID-19 using the NJH guidelines prior to their visit and again when they arrive for their visit. Subjects who screen positive will be triaged per NJH guidelines.
- Where feasible, discuss the possibility of remote visits with shipping of IP to avoid an in-person visit.
- Discuss modification of protocols with sponsors to avoid conducting procedures that will use PPE and place research staff at increased risk because of aerosolization (e.g. bronchoscopy, induced sputum, spirometry, multiple breath washout, nasal scraping, nasal potential difference measurement).

Changes to the Protocol

If researchers change their protocol (e.g., to make deviations permanent) to eliminate apparent immediate hazards to subjects, they can do so without prior IRB approval but should report the protocol change to NJH within 7 days and submit an amendment for review and approval of the revised protocol. NJH will review and approve those amendments quickly but since prior approval is not required, researchers are not out of compliance in the interim.

Limitations:

The conduct of research must otherwise remain in compliance with human subjects’ regulations, NJH policies and the terms of NJH’s approval. The following are some examples where prior IRB approval should be obtained.

Informed Consent: If signed consent is required for research participation, changing to verbal consent would not be an acceptable deviation or protocol change without IRB approval. If circumstances make obtaining signed consent impractical, researchers should consider slowing or suspending enrollment. Contact NJH if you wish to discuss whether conducting a consent process over the phone is feasible. NJH approval would be required before implementing the new consent procedure.

Visit Locations: Carefully consider any changes before implementing them. For example, moving study visits from a clinic to the subject's home in the current environment would need to involve new screening procedures for the subjects, the household members, and for your research staff. Such a change may also require additional staff training and protective gear, which is in very short supply at this time. Moving study visits from clinical locations to campus non-clinical locations is not advisable. Contact NJH if you wish to discuss whether some study procedures could be moved to new locations. NJH approval would be required before implementing these changes to make sure risks are minimized.

Sponsor/Funding Notifications

In light of the temporary suspension of any parts of your study (enrollment, interventions, data/safety monitoring) due to COVID-19 (multiple bullets may apply), please contact the sponsor:

- For federally funded studies, please contact your grant officer;
- For all externally-funded studies, please contact the funding source and/or the overall PI;
- For any studies for which a NJH PI holds the IND/IDE, please contact your FDA

External IRB: If your research is under the purview of an external IRB, there may be some slight differences in IRB policies but these would not impede a researcher's responsibility to make immediate changes eliminate apparent immediate hazards to subjects.

WIRB

https://www.wcgclinical.com/changes-to-research-made-in-response-to-covid-19/?mkt_tok=eyJpIjoiWkRKAk9XVXhPR1kyWW1ZeCIzInQiOiJDOHhDSWNORFNfVEJ6VWVvUXhhcEQ5WIZNSnNjbWlYeGZmMEZ3N0NPWXFLMXpMcE5tdUd1WGROSDBYY3R3OWd0dUNHTVAybVNHQUQyZWpGUxdWQlF3VDJ1U0c4dEJ1aG90eXVTWWJSNUJoUSrbGhTVU43TDhLRkFPME51UFwvXC9CTCJ9

Advarra

https://www.advarra.com/about-advarra/news/impact-of-coronavirus-outbreak-on-protocols-under-advarra-irb-review/?utm_source=slidein&utm_medium=website&utm_campaign=impact-of-coronavirus-outbreak-on-protocols-under-advarra-irb-review&utm_content=impact-of-coronavirus-outbreak-on-protocols-under-advarra-irb-review

Requirements from Sponsors: If sponsors issue updated protocols, or require evidence of IRB approval of changes, researchers should submit an amendment to NJH as usual.

COVID-19 Research Studies

New Data and New Objectives: If researchers wish to collect additional data for their studies or add research objectives to approved research in response to COVID-19, an amendment should be submitted to NJH IRB for prior approval.

Should NJH investigators wish to submit NEW research studies specifically focused on COVID-19, please email IRB@NJHealth.org.

CONTACT NJH IRB/HRPP Office

Contact us at NJH IRB/HRPP Office for any questions or assistance: IRB@NJHealth.org

We are readily available to answer any questions, to consult, and to provide assistance. We are happy to set up conference calls and/or virtual meetings.