



RUTGERS

Office of Research and
Economic Development

IRB & RESEARCH PREPARATIONS FOR COVID-19

The Rutgers IRB is heeding current guidelines from University leaders in response to the COVID-19 outbreak.

RUTGERS IRB WILL BE FULLY OPERATIONAL.

IRB Staff will be working remotely. All IRB staff will receive voicemails and can return calls or respond to emails.

RESEARCHERS NEED TO PREPARE THEIR STUDIES FOR POSSIBLE INTERRUPTION OR COMPLICATION IN CONDUCTING PROCEDURES.

Because of public and institutional self-isolation efforts, as well as possible quarantine of exposed individuals, it may be necessary to alter research plans to keep study team members and research participants safe. Please see the University's guidance on the [COVID-19 website](#) and consider the following:

1. **Additional clinical services, testing, and screening related to COVID-19 that need to be performed for research participants do not need IRB approval prior to initiation.** Such procedures would be considered usual care outside of the research context.
2. **Consider whether your study or parts of your study may be placed on hold during this time.** The decision to place a study on hold needs to be made on a study by study basis in consultation with your department leadership and in accordance with University guidance. **You are not required to report study holds to the IRB; however, you must document them in your research records and report them to sponsors as necessary.**
3. **Any changes to your protocol or the conduct of your research procedures still requires an amendment with the IRB.** The IRB does not pre-approve deviations from protocol outside of the amendment process.
4. There may be an urgency to deviate from the protocol or the conduct of research procedures before an amendment can be approved by the IRB. **All deviations must be reported according to the [IRB's reporting policy](#).**

The IRB acknowledges that the COVID-19 outbreak and isolation/quarantine requirements may result in deviations that are intended to eliminate apparent immediate hazard to a research participant. **Though a deviation may not pose a conceivable threat or possible harm, it may represent possible continuing non-compliance if an amendment is not pursued with the IRB. All deviations must be documented in the research record, regardless of whether they meet the IRB's reporting criteria.**

5. **Do not store electronic research data on unsecure devices while working remotely.** The IRB encourages the use of University-approved cloud services and VPN

access while working at home instead of storing data directly on your devices. Do not take home physical research records or data (paper consent forms, case report forms, questionnaires/surveys, etc.). **All physical records must continue to be stored in IRB-approved, secure locations.**

6. For additional guidance, see:

- [HRP-322 - WORKSHEET - Emergency Use](#)
- [HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process](#)
- [HRP-411 - CHECKLIST - Waiver of Written Documentation of Consent](#)
- [Use of Electronic Informed Consent FAQ - Dec 2016](#)
- [Oral Consent Guidance](#)