PARTNERS HEALTHCARE | FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL AND MASSACHUSETTS GENERAL HOSPITAL

Policy on Conduct of Human Research Activities During COVID-19 Operations

March 16, 2020

(Updated: April 2, 2020; April 30, 2020 (marked "New" or "Updated")

In support of our mission to protect our patients and clinical and research community, we have been working with PHS leadership to develop our approach to the continued conduct of research in our clinical health environment. Effective immediately we are implementing the following requirements regarding research conducted in our PHS facilities and PHS research sites.

Points of Contact for Questions:
Martha F. Jones, Vice President, Human Research Affairs (mjones44@partners.org)
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Included in this document:

A. Policy on Conduct of Human Subjects Research including Clinical Trials

- Ongoing activities may continue only if they are commensurate with the PHS COVID-19 policy regarding staffing and remote work requirements. These activities cannot violate current PHS policy for research staffing.
- These requirements apply regardless of the IRB that oversees the ethical and regulatory conduct of these studies (including PHS, other institutional IRBs and commercial IRBs.) Researchers should follow the policies and procedures of the IRB that oversees the ethical and regulatory requirements of their research regarding how to report changes or obtain approval for changes that are needed to comply with the requirements below.

- **Therapeutic Research** (potential for direct benefit to subjects through therapeutic intervention)
    a. Recruitment of new subjects may continue ONLY for the following:
        i. Any COVID-19 research
        ii. Research that has the potential to be life-saving or is disease-altering AND there are no appropriate alternative clinical treatments for the patient. Do not enroll new subjects if there is risk they will have to come off of the therapeutic intervention due to lack of supplies or staffing.
        iii. Studies must also be conducted in accordance with the following:

1. The PI is available to maintain oversight appropriate for the study throughout the length of the study including from a remote location should that be required.
2. There are adequate and accessible supplies available to complete the study including the study treatment itself and all additional supplies to administer and monitor the study treatment.
3. There will be a sufficient number of trained study staff to support conduct of the study considering staff workloads and any requirement to work remotely or to cover other hospital needs.

    b. Ongoing conduct of active therapeutic studies may continue for subjects already enrolled in the study under the following conditions:
        i. The PI is available to maintain appropriate oversight including from a remote location should that be required.
        ii. There are adequate supplies available including the treatment itself and all additional supplies to administer and monitor the study treatment.
        iii. Study-specific procedures to maintain safety of subjects can be continued (labs, exams etc.)
        iv. There will be a sufficient number of trained study staff to support conduct of the study considering staff workloads and any requirement to work remotely or to cover other hospital needs.

> ***Contact the Partners Human Research Quality Improvement Program*** *if you need consultation or help in planning for the continuation of clinical therapeutic studies or planning for moving subjects to clinical care. Contact Pam Richtmyer at* prichtmyer@partners.org.

- **Non-Therapeutic Research** (no direct benefit to subjects through therapeutic intervention)
    a. Recruitment of new subjects may continue ONLY under the following conditions:
        1. Recruitment occurs completely remotely (e.g. by phone, videoconference)
        2. No in-person interaction with potential subjects is required.
        3. The research staff is working remotely

4. All study activities are currently approved to be conducted remotely or may easily be transitioned to remote activities (e.g. an internet-based survey study.)
5. If recruitment and study activities can occur with both staff and potential subjects operating remotely, the following must also be in place for recruitment to continue:
    a. The PI is available to maintain appropriate oversight from a remote location.
    b. There will be a sufficient number of trained study staff to support conduct of the study remotely and considering staff workloads and any requirement to work remotely or to cover other hospital needs.

b. Ongoing conduct of non-therapeutic studies may continue for subjects already enrolled in the study under the following conditions:
    b. No in-person interaction with subjects is currently required or visits can be changed to occur remotely.
    c. Study staff can work remotely to conduct all study activities.
    d. The PI is available to maintain appropriate oversight throughout the length of the study from a remote location.
    e. There is a sufficient number of trained study staff to support conduct of the study remotely and considering staff workloads that may include covering other hospital needs.

- **Suspension of Review of New Studies:**

  The IRB will not accept new study submissions (therapeutic or non-therapeutic) effectively immediately with the following exceptions:

  1. Any research on COVID-19 or related to COVID-19. These studies will be prioritized for review.
  2. Emergency Use requests
  3. Studies that have federal funding and receive Just-In-Time (JIT) notice. *Researchers must include a copy of their JIT notice as an attachment to their Insight application.*
  4. Any study with non-federal funding that already has an agreement in process in the Insight system as of 03.13.2020 and meets the requirements above for ability to recruit and conduct the study. Researchers that are approached after this date about participating in non-federally funded multi-site research that will be using an outside IRB should contact the IRB helpdesk at IRB@partners.org.

  Note: Any studies that were in the process of review with the IRB at the time of this notice will continue through the review process only as time allows considering other priorities. Studies that are approved are still required to follow the requirements above with regard to recruitment limitations and conduct of research.

B. Working with the IRB

1) Informed Consent Process and Documentation ★ **Updated 04.30.2020** ★
2) Changes to the protocol which DO NOT require prior IRB review and approval
3) Changes to the protocol which DO require prior IRB review and approval
4) Contingency planning
5) Home visits
6) Requesting priority review for novel coronavirus research

1. Informed Consent Process and Documentation

- **Minimal Risk Non-COVID Related Research**

  Minimal risk research which is not COVID related may NOT continue to recruit through an in-person process. Some minimal risk research may transition to a remote process for recruitment and informed consent. Research which is approved for written informed consent must submit an amendment to allow the IRB to document waiver of informed consent documentation. The researcher must follow procedures outlined above and in the PHRC Informed Consent policy for obtaining and documenting verbal consent.

- **Minimal Risk COVID Related Research**

  Federal regulations allow the IRB to approve a waiver of documentation of consent when the research is no more than minimal risk and involves no procedures for which written consent is normally required outside of the research context. If your minimal risk research does not currently have a waiver of documentation of consent, and it is eligible to continue recruitment remotely, you should submit an amendment to the IRB to obtain a waiver of documentation and revise recruitment procedures.

  Researchers approved for waiver of consent documentation, must follow the PHRC Informed Consent policy for obtaining verbal consent. The researcher is responsible for:

  - Providing the informed consent information to the prospective participant
  - Answering any questions
  - Obtaining the subject's verbal informed consent (agreement to participate.)

  The Partners IRB will require that the researcher provide the participant with a written statement regarding the research. Sample informational scripts are available on Navigator. This information may be mailed to potential subjects prior to the consent conversation with an IRB-approved cover letter, mailed to subjects after the consent conversation, or emailed to subjects to subjects after the consent conversation if that conversation includes, and the subject verbally agrees to transmission of information via email. (See FAQs for information on RODY participants.)

  Informed consent may be obtained by appropriately trained and qualified study staff as approved by the IRB. Physician involvement in the consent process (physician obtaining consent) is not required for minimal risk research. Revisions to who is obtaining consent should be submitted to the IRB as an amendment for approval prior to implementation. Importantly, the researcher must document the consent process in a note to file or

informed consent checklist.

- **More than Minimal Risk Non-COVID Related Research**

  By policy the ONLY studies that should be continuing to recruit with an in-person process are those that provide life-saving or significant disease-altering therapeutic intervention. We would expect a significant number of therapeutic studies would not meet this definition and should not be continuing to enroll unless it is done remotely. In response to COVID-19 infection control measures, the IRB will allow research teams to obtain consent remotely without prior permission as long as the researcher and patient both have the capability to finalize the consent process with a signed consent form. Researchers obtaining consent remotely must follow remote procedures outlined in the Informed Consent of Research Subjects Policy. For studies approved for in-person consent, the deviation log should document that consent was obtained remotely.

  The above steps may be followed for re-consents that require signed consent forms. **The Partners IRB encourages researchers to provide verbal notification of changes whenever possible.**

- **More than Minimal Risk COVID Related Research – See Table 1 ★ Updated 4.30.2020 ★**

  The Partners IRB is using flexibility wherever possible but is following the FDA's recently updated guidance on informed consent during the COVID-19 Pandemic. Consent of subjects in these studies can be very challenging. See Table 1 for consent options for these studies. Please contact the IRB helpline (**IRB@partners.org)** for questions on implementing these procedures in your study.

2. Changes to the protocol which DO NOT require prior IRB review and approval

- **Implementing mandatory COVID-19 screening of research participants prior to planned study visits.** All study teams should immediately implement the COVID-19 procedures to screen research participants before any interaction and incorporate mandatory telephone screening prior to planned study visits.
  - If a subject already enrolled in a study becomes symptomatic, study visits should be deferred if possible and the subject referred to appropriate clinical screening and care for COVID-19.
  - If a subject in recruitment/screening becomes symptomatic, they should be referred to appropriate clinical screening and care for COVID-19.

  The hospitals have provided specific procedures to conduct this mandatory screening and these may change over time. Please access your hospital-specific COVID sites for specific procedures.

- **Changes to protocols to prevent an immediate hazard to research participants.** The PI is responsible for making the assessment that there is a need for immediate action to protect the safety and wellbeing of the participant. If there is a need, the PI may make the change without first obtaining IRB approval. Note this option is only available for changes that would impact participants already enrolled in the study. It is not appropriate to make such a change in order to enroll a new participant (for example exceptions to inclusion/exclusion criteria.) We know we can rely on your flexibility and judgment in a making these decisions in this challenging environment.

  Follow the steps below if a change is made to prevent immediate hazard without IRB approval:
  - Submit an "Other Event Form" to the IRB via Insight within 5 working days of the change.

- The change and rationale for making it should be clearly documented in your research records (e.g. in a note to file.)
- This change may apply to one subject or a group/all subjects in the research study.

- **Minor protocol deviations which do not have the potential to negatively impact participant safety or integrity of study data (ability to draw conclusions from the study data), or affect subject's willingness to participate in the study.** Minor protocols deviations could include conducting a study visit virtually (by remote means) or outside of window, omitting a specific research procedure or collecting questionnaire/assessment data over the phone instead of in person. Minor protocol deviations are reported to Partners IRB at time of Continuing Review through submission of the Minor Deviation Log.

3. Changes to the protocol which DO require prior IRB review and approval

Changes to the protocol and requests for protocol exceptions that may impact participant safety or the integrity of the study data require prior IRB review and approval. This may include dispensing study drug without performing a key safety lab or procedure, or failure to capture endpoint assessment data. PI and study teams submitting Amendments related to COVID-19 must complete the COVID-19 specific questions on the Amendment Form. Amendments related to COVID-19 are automatically prioritized for review. Study teams may email the IRB helpdesk with questions on Amendments: **IRB@partners.org.**

4. Contingency Planning

PI and study teams should begin planning now for potential disruptions of supplies, study visit schedules, temporary reduction in research staff etc. Closely monitor clinical advice from the hospitals and Partners to assess how disruptions in research could impact safety and welfare of research participants.

- **Investigational Drugs**: If research participants are on investigational drugs, work with the research pharmacy and your sponsor (as applicable) to determine what the plan would be if the investigational drug could not be dispensed to the research participants. If the investigational drugs cannot be dispensed to the research participants, the PI should make plans to transition research participants to the most appropriate clinically available treatments. This transition should include consultations with the investigational drug service, research sponsor(s) and the clinical team caring for the research participants.

- **Research Procedures:** PIs need to assess whether any reduction in staff makes it unsafe to complete the planned research procedures (e.g. specimen collection may not be safe if the study does not have appropriately trained staff to conduct the specimen collection.)

- **Review of research data:** If research team members are not available, completion of research-required procedures such as reviewing lab results in a timely manner might not be possible and will require special attention under the direction of the study PI.

- **Conference Call/Video Conference**: If medically appropriate, PI and study teams should consider alternative study visit options to allow participants who cannot or do not want to come to the hospital to complete study visits.

If you have specific questions on research contingency planning, please contact the Partners IRB helpdesk: **IRB@partners.org.**

5. Home Visits

Any study that is currently approved to conduct home visits should suspend these visits. If you believe home visits are required to maintain the safety of subjects on therapeutic trials as provided in Part A of this policy, please contact the IRB for consultation prior to visiting the home. (jripton@partners.org)

6. Requesting priority review for COVID-19 research

Some Partners researchers have already started conducting COVID-19 research. We expect that many more studies are being planned. Such research needs to consider exposures to staff and clinical needs, and we recommend that you consult Infection Control before crafting your protocol. Due to expected shortages in PPE, and to avoid exposure of staff, clinical care visits to infected patients may be limited or "bundled." For us to prioritize the review and consult on the regulatory and ethical issues we ask that the PI provide the following information by email (**IRB@partners.org**):

- PI Name
- Protocol No.
- Protocol Title
- Funding (if any)
- 1-2 sentence summary on the proposed work
- Identify any local agencies working on the study

C. Working with Sponsors

The PI and research team are responsible for working with their sponsors to address changes needed to accommodate any disruptions in the approved research protocol. *The requirements set out in this document as well as any other PHS requirements take precedent over sponsor approaches unless the sponsor is requiring more restrictive changes.*

1. **Contact study sponsors** (e.g., federal, industry, private) and/or the coordinating center for study-specific information related to procedures to address the following as indicated:
    - Anticipated delays in recruitment for new participants
    - How delayed or missed participant contacts/visits for participants may impact on-going study participation (e.g., whether a missed safety assessment might impact the ability of the participant to receive the next round of therapy)
    - If the sponsor anticipates any drug shortages or delays in shipping and the subsequent impact on study conduct
    - Any changes to biospecimen/sample storage and shipping requirements
    - Changes in any reporting requirements to the sponsor

2. **Changes in monitoring** (implementation of remote monitoring procedures.) All sponsor monitoring or audit visits must be conducted remotely or in accordance with current PHS guidance.
   The process for giving monitors access to Epic is already in place. Monitors can get access to Epic via the Physician Gateway and study coordinators may facilitate this. Study coordinators who have not already done so should submit a request on behalf of the monitor to set up the account on Physician Gateway. The Epic Research may create an account and provide login information and a temporary password to the monitor, and the monitor must sign the confidentiality agreement when they log in to the system for the first time. Once the monitor has an account, any study coordinator on that study can give the monitor access to records for their study subjects. The coordinators determine which subjects and the time span for the access which may be 24 hours or longer. Directions for giving monitors access are available on the Partners eCARE site.

3. **Develop study-specific plans** for each active study considering the following:
    - Sponsor provided information (from prior section)
    - Need for continuity of the research intervention during the study period
    - Feasibility of changing from protocol-mandated visits to home visits or telemedicine (or telephone visits)
    - Need for active assessment for Adverse Events (AEs)
    - Facility availability
    - Study team and clinical staff availability
    - Identify emergency contacts within the study team
    - Develop a communication plan with the study team and participants (i.e., assure participants are kept informed if clinic visits or administration of study intervention is canceled or delayed)
    - Orderly withdrawal of subjects if indicated or necessary

4. **Contact PHS CTO** (https://cto.partners.org/contact/) for contract or budget considerations on industry sponsored projects

D. Guidance on Developing Your COVID Protocol and Application ★New 04.30.2020★

The Partners IRB is making every effort to prioritize COVID research reviews and review them as quickly as possible. We have developed a Guidance (link once posted) identifying key areas that frequently require modifications during the IRB review process or have caused protocols to be deferred for subsequent review. Researchers are encouraged to use this Guide in preparing their IRB application. COVID research occurring at MGH or BWH must be submitted and approved by the appropriate COVID Oversight Committees prior to IRB submission. Comments from the hospitals' Oversight Committee reviews are shared with the IRB. The PI should incorporate changes and address all comments/issues raised by hospital committee in the protocol summary and detailed protocol. Contact the Partners IRB helpdesk (**IRB@partners.org**) with questions on preparing COVID research applications.

E. Proposed Workflow for SARS-CoV-2 Serological Testing of Health Care Workers (HCWs) Participating in Research Protocols at Partners HealthCare ★New 04.30.2020★

There has been increased interest in research involving SARS-CoV-2 Serological testing of Health Care Workers (HCW). Dr. Ravi Thadhani, Chief Academic Officer at Partners HealthCare, convened the Partners Serology Research Oversight Committee to harmonize the approach to use of serology tests and return of results in this research. The committee developed guidelines (link to guidelines) which we will now be implementing across all research studies involving SARS-CoV-2 Serological Testing of HCWs. These guidelines will be revisited and updated as new data on serological testing emerge.

Key information addressed in the guidance include:

- The information indicating the uncertain interpretation and implications of serologic testing result must be provided to participants in the consent form and at of results Partners IRB have developed consent form language (link to consent form language) to address these issues.
- SARS-CoV-2 serological test used in this research must be developed and validated consistent with FDA requirements.
- All research studies must have a defined mechanism to ensure NP PCR testing is conducted for any positive antibody (IgM or IgG) result and that positive results are immediately communication to occupational health.

The IRB office will coordinate review by this ancillary committee.

F. FAQs

1. **Is my COVID-19-related project considered research?**

   It depends. In some cases, IRB approval may not be required for COVID-19-related activities. For example, the activities may consist solely of public health surveillance activities, clinical care, or diagnostic testing for which an FDA emergency authorization has been obtained. Contact Jesse Ripton (jripton@partners.org) for consult on this issue.

2. **Do I need IRB approval to communicate a pause in recruitment and study activities to research participants?**

   No. These messages to participants do not require IRB approval. In addition, messages about changes to study visits, like administering questionnaires over the phone or video conferencing, do not require IRB approval.

3. **Based on PHS requirements my study will pause to recruitment, is submission to Partners IRB required?**

   No.

4. **The PI has decided to suspend the ongoing study due to COVID-19, do I need to notify the IRB?**

   It depends. If this is a non-therapeutic or Minimal Risk study (expedited study) where the temporary suspension would not impact the safety or welfare of research participants, this would be considered a minor deviation and would not require prior approval by the IRB.

   If the study is a therapeutic study and More than Minimal Risk (Full Board study), submission of an Amendment is required to the IRB and should contain information on contingency planning related to interruption or changes in investigational product and/or safety monitoring.

5. **My research study is reviewed by an external IRB, do the restrictions apply to my study?**

   Yes. The PHS policy and requirements regarding research restrictions applies to all research conducted in our PHS facilities/sites, regardless of the IRB that oversees the ethical and regulatory conduct of these studies.

6. **I am pausing recruitment and/or study procedures on a project reviewed by an external IRB of Record, should I notify that IRB?**

   It depends. You should follow the requirements of the IRB that oversees your research regarding reporting changes and whether any review/approval will be needed prior to resumption of study procedures.

7. **Do I have to submit an amendment to change an in-person visit to one conducted virtually or by remote means?**

   It depends. If the approved procedures to be conducted at that visit can be done remotely without compromising the safety of the research participant or the scientific validity of the study, this would be considered minor deviation and would not require prior approval by the IRB. However, if there are procedures that cannot be conducted because an in-person visit cannot occur AND those procedures impact the safety of the participant or the scientific validity of the study, this should be submitted to IRB for approval as described above.

8. **Should consent forms be revised to include the risk of contracting coronavirus at the hospital or during a study visit?**

   No. Research teams should carefully consider the risks of participants attending study visits in light of the factors discussed in this document.

9. **Do I need to report risk of contracting coronavirus at time of continuing review in response to the question "Since the last continuing (or initial) review, have the risks to subjects changed?"**

   No. The PI should not include the risk of contracting coronavirus in the continuing review progress report form.

10. **Do I need to report to the IRB if a subject or member of the research tests positive for COVID-19?**

    No. The PI and research teams should follow applicable hospital policy for reporting all new COVID-19 infections. The IRB does not require Other Event reporting for COVID-19 infections or deaths unless determined to be unexpected and related to the protocol.

11. **Do I need to report to the IRB if a participant is hospitalized or dies due to COVID-19?**

    No. Unless the hospitalization or death is determined to be unexpected and related to the research protocol.

12. **I am the Lead PI on a study where Partners IRB serves as the central IRB for external research sites. Do these requirements apply to the external sites?**

    It depends. The requirements apply to research conducted at PHS facilities and are based on the situation in Boston. External research sites may have different requirements based on the local situation. As the IRB of Record for research conducted at the external research site, we require the Lead PI assess whether the study can continue for recruitment and participants already enrolled in the study under the following conditions:

    - The PI is available to maintain appropriate oversight.
    - There are adequate supplies available including the treatment itself and all additional supplies to administer and monitor the study treatment.
    - Procedures to maintain safety of subjects can be continued (labs, exams etc.)

- There are a sufficient number of trained study staff to support conduct of the study considering staff workloads and any requirement to work remotely or to cover other responsibilities at their health care facility or institution.

13. How can I flag my Amendment related to COVID-19 for priority review?

Email the IRB helpdesk (IRB@partners.org) AND answer the COVID-19 specific questions on the Amendment Form.

14. I need to make a change to study visits for multiple participants, should I submit this an Amendment or a Protocol Exception?

Amendment. Changes to study visits or procedures which require IRB approval prior to implementation should be submitted as an Amendment. Include an attachment as an addendum to the study protocol that provides a detailed description of the revised study visits or study procedures noted as temporary changes during the COVID crisis. You do not need to revise the Protocol Summary or the Detailed Protocol. The study team must document in the research record by a Note to File or on their Deviation Log the participants who will undergo the revised study visit or study procedures, the dates of visits impacted, and the rationale for the change.

15. I am conducting FDA-regulated research for which I am the sponsor of an IND or IDE. Do I need to notify the FDA if I pause my study?

Yes. The FDA will need to be notified as soon as feasible. Please contact the Partners Human Research Affairs Quality Improvement Program for questions (Pamela Richtmyer, prichtmyer@partners.org)

16. I submitted an initial review to the IRB before the effective date of the temporary suspension of new research studies, will the IRB still review my study?

Yes. The IRB will continue to review and approve submissions submitted before the effective date. For studies that are approvable but subject to additional PHS restriction on recruitment and study activities, the IRB will approve the study but explicitly note all research conducted at PHS facilities must comply with current restrictions on human subject activities.

17. Will the IRB continue to accept and review Amendments, Other Events and Continuing Review?

Yes. The IRB will continue to review and approve these submissions. The IRB will approve submissions but explicitly note that all research conducted at PHS facilities must comply with current restrictions on human subject activities.

18. My new study is assigned to an upcoming IRB meeting, will it still be reviewed?

It depends. The IRB is prioritizing research related to COVID-19 and last minutes changes made to accommodate essential research.

19. Has the process for single patient emergency use been changed?

No. The procedure for Single Patient Emergency Use of an experimental drug or device remains the same during the COVID-19 situation.

20. Is the IRB help desk still functioning?

Yes. The Partners IRB is fully functioning, and the research community is encouraged to contact the help desk with any questions:
Tel: 857-282-1900
Email: IRB@partners.org

21. I am working on a therapeutic trial with the potential for direct benefits to participants and we have paused recruitment. Can in-person study activities continue for our enrolled participants?

It depends. In- person study activities may continue under any of the following conditions:

- COVID-19 research that involves treatment or diagnostic activities or requires collection of biospecimens.
- Research that has the potential to be life-saving or is disease-altering AND there are no appropriate alternative clinical treatments for the patient
- Research where stopping the study could be harmful to the participant (i.e. monitoring is needed to ensure participant safety)

The IRB expects that this research will, for the most part, be conducted during a clinical visit to avoid additional exposure risks. In addition to meeting conditions noted above, the PI must be available to provide oversight, the study must have adequate supplies and adequate staffing given requirements for remote work and other clinical responsibilities.

22. My study will be conducting recruitment remotely, what methods can I use to contact potential participants?

IRB submission and approval is required for changes to recruitment methods or materials. Researchers must follow all IRB policies on recruitment and email communication with participants. Current recruitment policies do allow for direct electronic communication with patients who have elected "YES" to RODY Researchers may send an electronic (e.g., email) recruitment letter directly to RODY YES patients via Patient Gateway or Send Secure. The IRB would need to approve the text of these letters/emails.

23. What should I do about study visits for subjects already enrolled in my Phase I study?

Only study activities related to monitoring the safety of already enrolled participants should continue if the PI is available to supervise the conduct of the study and the study has adequate supplies and staffing. The

IRB anticipates that some safety procedures could be performed remotely such as collection of adverse events and reactogenicity symptoms. Changes to the protocol to address safety monitoring should be submitted to the IRB for review as an Amendment.

24. I am the PI on a study which is being conducted entirely at an international site and my study is approved by the Partners IRB and the local IRB, does this policy apply to me research study?

The policy applies to research conducted at PHS facilities and is based on the situation in Boston. International research sites may have different requirements based on the local situation. The local IRB should be contacted to determine what restrictions are in place at the international site.

25. I am working on a study where we will transition to remote study visits. What video conferencing platforms are approved for research use? ★Updated 4.30.2020★

Partners has a Zoom corporate account which can be used to conduct remote study visits. Study teams must follow all standard procedures for maintaining privacy. Be sure to also consider that the research team member needs to be in a private setting when using these tools. A complete listing of Partners approved video platforms can be found at https://rc.partners.org/it-services/collaboration#web-video-conferencing.

Information security guidelines for Zoom can be found at https://pulse.partners.org/hub/departments/emergency_preparedness/coronavirus/virtual_care.

26. Can I use video conferencing to record study visits and communications?

It depends. You cannot use these tools to record study visits or communications unless the IRB has already approved recording for your study and the subject has provided consent. Typically visits and communications that are not normally recorded for research, should not be converted to being recorded simply because they are happening remotely. If you believe it is necessary to record any communications or visits, you will need to submit an amendment to the IRB and receive approval prior to implementing this practice.

27. I am the Responsible Party on a Clinical Trials.gov record, do I need to update the Recruitment Status on the record due to restrictions on clinical research recruitment activities due to COVID-19?

You only need to update the Recruitment Status on the Clinical Trials.gov record if, based on the IRB guidance, your study was required to stop recruitment activities temporarily due to the COVID-19 restrictions. If you are continuing to follow enrolled subjects remotely but have stopped recruiting new subjects, then you should update the Recruitment Status to 'Active, not recruiting".

28. Due to COVID-19 restrictions my study timeline has been affected. Do I need to update anything on my Clinical Trials.gov record?

You should check the Primary Completion and Study Completion Dates on the record and update as appropriate. Please remember that the Primary Completion Date entered on the record is what determines when results reporting is due.

29. My Clinical Trials.gov record is due for results reporting now, do I still need to report results during the current COVID-19 situation?

Yes, if you are due to report results on your Clinical Trials.gov record, you must do so.

Contact the Partners Human Research Quality Improvement Program for questions or additional information on Clinical Trials.gov: QIProgramCTgovTeam@partners.org.

30. There were some changes to my protocol, but they did not require an amendment, how should I document this in my study files?

Write a Note To File for the Regulatory Binder/Essential Documents outlining any changes to study conduct as a result of the COVID-19 restrictions with the effective date and file a copy of the Partners IRB COVID-19 guidance with the Note To File. It will be important to document in a Note To File when usual study activity resumes as detailed in the IRB-approved protocol once the restrictions are lifted.

31. Changes to my protocol required an amendment which I submitted, is there any other documentation required?

Write a Note To File for the Regulatory Binder/Essential Documents outlining the changes to the study as a result of the COVID-19 restrictions with the effective date and file a copy of the Partners IRB COVID-19 guidance with the Note To File. It will be important to document in a Note To File when usual study activity resumes as detailed in the IRB-approved protocol once the restrictions are lifted.

32. Are there special documentation requirements related to the COVID-19 restrictions for my PI-initiated (interventional or observational) study?

Yes, it is important that investigators and study staff do the following for all human subject research studies (interventional and observational):

- Identify and track all subjects whose enrollment, procedures, or other study activities were affected by the COVID-19 restrictions. Suggestions:

    - Add a column to the Enrollment Log to flag any subjects affected by COVID-19 restrictions to easily identify these subjects during data analysis or for reporting to the sponsor
    - Maintain a separate log listing the subjects affected by the COVID-19 restrictions with visit dates and study procedures completed
    - Add a column to the Deviation Log to indicate which deviations are associated with the COVID-19 restrictions
- For any study visits conducted during the COVID-19 restrictions document on Case Report Forms or Data Collection Forms that the visit was conducted during the COVID-19 restrictions. Suggestions:
    - Add a field to Case Report Forms or create a separate case report form to identify if a study visit was conducted during the COVID-19 restrictions.

33. My study involves an investigational product and during the COVID-19 restrictions we provided the investigational product to the study subject using an alternate method, how do I document this?

Investigational product accountability must be documented and maintained as required by research regulations. If alternate methods of distribution and/or administration are used due to COVID-19 restrictions, please make certain you have approval from the sponsor and IRB if required. Suggestions:

- If alternate methods of distribution and/or administration are used, write a Note To File outlining the changes to process to file in the Regulatory Binder/Essential Documents.
- On the Investigational Product Accountability Log identify which distributions were made during the COVID-19 restrictions

34. I am a Sponsor-Investigator (hold an IND/IDE) and the Monitoring Plan for my PI-Initiated protocol (single site or multi-center) includes in-person monitoring visits that cannot be completed during the COVID-19 restrictions.

As the sponsor of the study you are required to ensure that monitoring of the study data is completed regularly. The FDA recommends that sponsors utilize remote or central monitoring to ensure appropriate oversight. Suggestion:

- Revise Monitoring Plan, if necessary, to outline how remote or central monitoring of study data will be completed and how often it will be done. Ensure all monitoring activities are documented to demonstrate oversight.

35. What should I do if there are individual instances of efficacy endpoints not collected due to COVID-19 restrictions?

Document the reasons for not obtaining the efficacy assessment making certain to identify the specific limitation caused by the COVID-19 restrictions that resulted in not completing the protocol required assessment. Suggestions:

- Document the missed assessment on the Deviation Log and reference the specific COVID-19 restriction that caused the missed assessment.
- Write a Note To File regarding the missed efficacy assessments and identify the specific limitation related to the COVID-19 restrictions involved.

36. I think I may need to revise the data management plan and/or statistical analysis plan outlined in the protocol due to the COVID-19 restrictions, what do I need to do?

Review the data management plan and/or the statistical analysis plan in the protocol to determine what, if any, revisions are needed. Remember to consider the impact of protocol deviations resulting from the COVID-19 restrictions on these plans and how these will be handled. Before revising the protocol, you may need to consult with the study biostatistician or appropriate FDA review division to discuss. If the protocol is revised, then an amendment will need to be submitted to the IRB.

37. I am a Sponsor-Investigator (hold an IND or IDE), do I need to include information in my Annual Report to the FDA or in the Clinical Study Report (final report) about the impact of the COVID-19 restrictions on the conduct of the study and/or the data?

Yes, you should include appropriate information related to the impact of the COVID-19 restrictions on the conduct of the study in the Annual Report to the FDA. The FDA asks that you include the following in the Clinical Study Report:

- Outline of steps taken to manage study conduct during the time of COVID-19 restrictions.
- List of all study participants by unique subject number and investigative site with a brief explanation of how the subject's participation was altered.
- Analysis and explanation of the impact of the changes made as a result of COVID-19 on the safety and efficacy results reported.

Contact the Partners Human Research Quality Improvement Program for questions or additional information regarding documentation requirements for human research studies and/or reporting to the FDA: *humanresearchqi@partners.org*

Table 1
Consenting in COVID Research
that is
More than Minimal Risk
04.06.2020
Updated: April 30.2020 (Marked in red "Updated")

Condition	Consent Process	Subject (Updated 4.30.2020)_	PI/designee Obtaining Consent (Updated 4.30.2020)_	Impartial Witness
COVID Subject is Inpatient/Isolation	Electronic system available that is 21 CFR Part 11 compliant.	Subject reads, has consent conversation with PI/designee and signs electronically.	Conducts consent conversation with patient, signs electronically and documents consent process in a note to file or in a COVID-19 Informed Consent Checklist.	Not required
	Consent form provided via email or other electronic means but does not include ability to sign electronically. When sent by email a copy of the email should be retained in the subject file. OR Paper consent can be transported to the patient during a clinical team visit to the room.	1. Patient reads, has 3-way phone conversation with person consenting and the witness. 2. Patient signs the hard copy consent and the consent form is removed from the patient's room following established hospital infection control procedures.	Conducts consent conversation with patient, signs consent form and documents consent process in a note to file or in a COVID-19 Informed Consent Checklist	Not required
		1. Patient reads, has 3-way phone conversation with person consenting and the witness. 2. Patient signs the hard copy consent and it is retained in the room. 3. Patient takes a picture of the consent signature page, any pages with	1. Conducts consent process in person or via phone conversation with subject. 2. Prints and signs their own copy of the paper consent document as person obtaining consent. 3. Documents in a note to file or in the COVID-19 Informed Consent Checklist that the consent form was provided to the participant, consent was obtained, the method used to obtain consent, that the	

Condition	Consent Process	Subject (Updated 4.30.2020)_	PI/designee Obtaining Consent (Updated 4.30.2020)_	Impartial Witness
		optional checkboxes and send electronically to the research team	subject signed a separate copy, and date/time. A compiled copy of the consent including the document with PI/designee signature and the subject signature consent document is retained in the study record and a copy of the compiled consent form is uploaded to EPIC. 4. Study record must also include attestation by the person entering the photograph into the study record that states how that photograph was obtained and that it is a photograph of the informed consent signed by the patient. 5. A compiled copy of the consent including the document with PI/designee signature and the subject signature consent document is retained in the study record and a copy of the compiled consent form is uploaded to EPIC.	
		1. Patient reads, has 3-way phone conversation with person consenting and the witness. 2. Patient signs the hard copy consent, provides verbal agreement to participate and verbal confirmation of signature. 3. Due to COVID-19 transmission risk the paper consent is retained in the room.	1. Conducts consent process via 3-way phone conversation with patient and witness. 2. Prints and signs paper consent document as person obtaining consent. 3. Documents in a note to file or in a COVID-19 Informed Consent Checklist that the consent form was provided to the participant, consent was obtained, the participant signed the consent form which was retained in the isolation room due to COVID transmission risks, the method used to obtain consent, date/time, and witness name. 4. The *COVID-19 Attestation/Witness Form is stored with the signed consent form in	Required. Witness signs the *COVID-19 Attestation/ Witness Form. ***Note IRB approval is not required for use of COVID-19 Attestation/Witness Form**.

Condition	Consent Process	Subject (Updated 4.30.2020)_	PI/designee Obtaining Consent (Updated 4.30.2020)_	Impartial Witness
		*Note if patient is unable to sign the consent document, they will be asked to make their mark and provides verbal agreement to participate.	the study record and a copy of the consent form is uploaded to EPIC.	
Subject is in Outpatient setting OR Consenting Remotely	Electronic system available that is 21 CFR Part 11 compliant.	Subject reads, has consent conversation with PI/designee and signs electronically.	Conducts consent conversation with patient and signs electronically.	Not required.
	Consent form provided via email or other electronic means but does not include ability to sign electronically. When sent by email a copy o of the email should be retained in the subject file. OR Hard copy consent can be given to subject.	Subject reads, has consent conversation with PI/designee and signs document. Subject can scan or take a picture of the consent signature page, any pages with optional checkboxes and send electronically to the research team.	1. Conducts consent process in person or via phone conversation with subject. 2. Prints and signs their own copy of the paper consent document as person obtaining consent. 3. Documents in a note to file or in the COVID-19 Informed Consent Checklist that the consent form was provided to the participant, consent was obtained, the method used to obtain consent, that the subject signed a separate copy, and date/time. 4. Study record must also include attestation by the person entering the photograph into the study record that states how that photograph was obtained and that it is a photograph of the informed consent signed by the patient. A compiled copy of the consent including the document with PI/designee signature and the subject signature consent document is retained	Not Required.

Condition	Consent Process	Subject (Updated 4.30.2020)_	PI/designee Obtaining Consent (Updated 4.30.2020)_	Impartial Witness
			in the study record and a copy of the compiled consent form is uploaded to EPIC.	
Non-English Speaking Subjects: In normal circumstances the IRB does not allow for remote consent of non-English-speaking participants when the short form process is used; however, COVID -19 transmission concerns necessitate alternative procedures. **For subjects participating in a COVID-19 study <u>ONLY</u>, the following short form procedure may be used when a remote interpreter is used:**				
	Short Form Consent provided to Subject either in paper or electronically.	1. Patient reads, has 3-way phone conversation with person consenting and the witness/interpreter. 2. Signs the Short Form and returns to the research team by email, fax or mail. The subject may scan or take a picture of the consent. If the subject is mailing the Short Form back, either two copies must be provided the subject initially and the subject signs both, keeping one for themselves, or the research team returns a copy of the signed document to the subject.	1. Provides the subject with the IRB-approved Short Form in their native language 2. Conducts a 3-way call with subject and interpreter/witness. 3. Confirms that a. The interpreter is also willing to serve as the witness b. The investigator/designee may sign on behalf of the interpreter by recording their name and ID# on the Consent and Short Form 4. Conducts consent conversation with interpretation. 5. Signs the Consent Document. Records the interpreter's name and ID# on the Consent Document and Short Form. 6. Documents in a note to file or in the COVID-19 Informed Consent Checklist the use of a remote interpreter/witness, that the short form was provided to the subject, consent was obtained, the method used to obtain consent, that the subject signed a separate copy of the short form, and date/time. 7. A copy of the consent and compiled short form including the short form with	Required. May use interpreter as witness if the interpreter agrees. May also use a different witness who speaks both English and the subject's language and is not a member of the research team or a family member of the subject.

Condition	Consent Process	Subject (Updated 4.30.2020)_	PI/designee Obtaining Consent (Updated 4.30.2020)_	Impartial Witness
			interpreter/witness name and ID and subject signature short form is retained in the study record and a copy of the consent form is uploaded to EPIC.	
**** In situations where the subject is inpatient and not able to return a signed copy of the Short Form due to COVID-19 transmission risks, the investigator must also confirm that they may sign on behalf of the interpreter/witness on the COVID-19 Attestation/Witness Form. The COVID-19 Attestation/Witness Form is stored with the consent, compiled short form in the study record.**				

Partners HealthCare System

COVID-19 Witness Signature & Attestation Page

Protocol Title:
Principal Investigator:
Site Principal Investigator:

This witness signature page is intended to be used when an original copy with the participant signature could not be obtained because of physical COVID-19 transmission concerns. Consent was obtained verbally and the participant kept the original signed consent document.

Delete red text, insert protocol title, PI and site PI as applicable

IRB Approval is NOT required for use of this form.

WITNESS STATEMENT:
A signed consent document (original or copy) from the participant or their legally authorized representative was not able to be shared with the study team due to COVID-19 transmission concerns.

Participant's Name:_____

- I confirm that I am an impartial witness who is not a member of the study team.
- I confirm that I was present as a witness for the consent process for this study.
- I confirm that the participant named above was given the information in the consent document, had an opportunity to ask questions, and that the participant verbally agreed to take part in the research study.
- I confirm that the participant signed their copy of the consent document and that the document could not be returned to the research team due to COVID 19 transmission risk .

_____
Print Name of Witness

_____ _____
Signature of Witness Date