FAQS FOR HUMAN SUBJECTS RESEARCH AND COVID 19

Are there any new research studies that will be prioritized by the IRBs?
A. Yes. Tier 1 studies that involve COVID 19, whether or not the studies provide a direct personal benefit to study participants, will be prioritized and may be submitted through all Phases. The IRB will not approve any COVID related study for which the risk/benefit ratio is not reasonable and will consider the risks of data collection in that analysis.

Are there any restrictions on human subjects research activities?
A. Yes. In order to ensure the safety of our research participants and our community, Johns Hopkins University has adopted a tiered approach to research which outlines the types of activities that may occur or must be paused based on the type of research. Please click here for detailed information. Principal Investigators should consider each of their protocols, and decide which tier each falls into. If you have questions, please consult with the IRB.

Can I enroll new participants in my research?
A. No Tier 2 or 3 protocols may enroll new research participants until further notice. PIs must pause on enrolling new research participants for Tier 1 studies unless it is a COVID-19 study or there is a compelling reason. PIs may petition the IRB if they have a compelling reason for not following this new policy. Requests will be reviewed in order of priority. These guidelines must be followed for studies seeking an appeal until such time as an appeal is granted.

Do I need to submit an Amendment to implement the changes required by the new Tier Plan?
A. Because Johns Hopkins University is directing its researchers to execute emergency changes in response to the national COVID-19 state of emergency and local health care directives to reduce all but essential research interactions, so long as you abide by the Tier Plan, and the changes do not increase risk to participants, you need not seek a prospective change in research from your respective JHU IRB and may report these as deviations from protocol in accordance with our JHU IRB’s deviation reporting policies. You should record these emergency Protocol Deviations and report them as protocol deviations as part of your next Continuing Review; documentation should indicate these deviations were required by the COVID-19 emergency. For temporary changes in the protocol for active participants you are not required to report these changes now via an Amendment. IRB staff/committees are ready to respond to questions.

Please Note: Amendments not specifically related to the directives of the Tier Plan still require approval by the respective JHU IRB. You must submit Amendments to change consent procedures, as they potentially require waiver of signature determinations and approval of telephone or other remote scripts.

Should I consider delaying or cancelling any research procedures at this time?
A. Please consult the Contingency Plan for Human Subjects Research to determine if your research procedures must be delayed or cancelled at this time. If your study falls
within a Tier that does not require that research procedures be stopped/cancelled please carefully consider the specifics of the study population and the potential risks and benefits to the participants and research staff before conducting the visits. Special consideration should be given to populations that may be particularly vulnerable such as older adults or those with compromised immune systems. For industry sponsored studies, study teams should communicate the mandatory tier structure and consult with the sponsor or CRO when making changes to research procedures.

Do I need to indicate in my new application, amendment or protocol event if the submission is related to COVID-19?

A. Yes. It is important the IRB is able to accurately track all new applications, protocol events and changes in research related to COVID-19. Please insert the following phrase in each COVID-19 related application “COVID-19 RELATED SUBMISSION”

See below for specific instructions for each application type:

- For new applications include this phrase in the study title
- For Amendments please include this phrase in the summary of changes in PHIRST 2.0 Amendment Submission, Question 1.
- For protocol event reports, please include this phrase in PHIRST2.0 Problem Event Report Submission, Question 2.

What should I do if I have a new application, amendment or protocol event that is related to COVID-19 that may need to be reviewed urgently?

A. If you need urgent IRB review of a new application, amendment or protocol event related to COVID-19 reviewed by the IRB urgently, please send an email to the IRB help desk at jhsp.irboffice@jhu.edu with “Urgent” in the subject line prior to submission. If available, please include your IRB study number in the email. Please cc Joan Pettit at jpettit@jhu.edu.

Should my research administration office be notified when sponsored studies are put on hold due to COVID-19?

A. Yes. Please notify your research administration office if a study, funded by a sponsored award is placed on hold. Notification may be sent to: ORA@jhmi.edu (SOM including for industry funded clinical trials); Bara@jhu.edu (KSAS); or JHURA@jhu.edu (JHSPH and all others).

What kind of changes do I have to submit for IRB review prior to implementation?

A. Except for the changes permitted under the Tier Plan (see A. to Q. 3 above), all changes require prior IRB approval before implementation. An additional exception
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includes changes designed to eliminate an apparent immediate hazard to subjects (45 CFR 46.103(b)(4); 21 CFR 312.66). If the investigators change the research in order to eliminate apparent immediate hazards to subjects without prior IRB approval, they should report those changes to the IRB within 10 days. This change must be documented in the research file. For studies that are FDA regulated, you should promptly notify the study sponsor.

Do I have to call all participants before they come in for a permitted scheduled research visit?
A. Yes, all individuals coming in for a permitted visit, whether clinical or research related, must be pre-screened prior to the visit. We urge all research teams to call participants prior to their visit to screen them before they arrive and cancel visits for those that give positive responses to the phone screen. Participants should be screened again when they arrive on site. If prior phone screening is not achievable, screening should be done prior to commencing the research visit.

Do I have to submit an Amendment application to add the COVID-19 screening questions to my protocol?
A. No, this is an enterprise-wide screening procedure, not limited to human subject research. The screening can be implemented without approval by the IRB.

Where can I get the most up-to-date phone screen algorithm for calling participants?
A. For studies in Baltimore and likely the rest of the US, use this link to the ICTR website https://ictr.johnshopkins.edu/coronavirus, click on Tips for Research Teams and use your JHED credentials to log in. The latest phone screen algorithm can be accessed on this page.

If a participant is coming in for a visit that is primarily for clinical care and may incorporate research procedures, can the research team defer to the clinical team for the screening?
A. Yes, where the clinical team will perform screening already it is appropriate to defer to the clinical team and not repeat the screen.

If patients are at the clinic for clinical purposes and a study team member approaches them afterward, do we have to ask them the screening questions before proceeding with further conversation?
A. Duplicate screening for research is not needed if clinical screening has occurred in the same visit.

For JHM located studies: for teams that do not use EPIC, can they simply document the results of a negative screening in the research record? Should it be documented somewhere else since the screen was not directly part of the research protocol?
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A. The screening results should be documented in EPIC, if the individual has an EPIC record for which you have access. If EPIC documentation is not possible, a brief note documenting the screening took place should be made in the research record. However, the results of the screener should not be formally incorporated in the research record as this screening is not being performed for research.

Do we need to move non-clinical follow up appointments to zoom or telephone calls now?
A. The safety of your study team members and the research participants should be first priority. If your research is categorized as tier three, you must follow the phased guidance. In the US as of March 16, you should not conduct face-to-face visits for tier 3 and many tier 2 studies. Study teams should consider other alternatives (such as Zoom, Skype or phone calls) that will allow the research to continue while limiting potential exposures.

How can I get study drugs to participants who can’t come in to pick it up?
A. If home visits are not practical or possible, you should develop an alternative plan for getting study drug to the participant. Please note that shipping study drugs to participants is subject to state and federal laws.

Are there any restrictions on research home visits already included in your approved research protocol?
A. Check the Tier assessment for your study. If there are currently no restrictions on home visits for research purposes, consider the specifics of the study population and the potential risks and benefits to the participants and research staff before conducting the visits. If you are doing home visits, you must conduct the COVID screening prior to and at each visit.

My study receives scheduled monitoring visits from outside monitors from the study sponsor or contract research organization (CRO). What should I tell the CRO or sponsor monitors about visiting Johns Hopkins Hospital or other JHU location?
A. All external monitor onsite visits for clinical research protocols must be postponed until at least April 20th. We will inform the research community if the date for this requirement needs to be extended.

Are there any alternatives to in-person monitoring visits?
A. First, refer to any existing contingency plan established by the sponsor or CRO. Check with the CRO or sponsor to discuss how the monitoring visit can be postponed to a later date, no earlier than April 20, 2020, or arrange with the CRO or sponsor to implement interim remote-monitoring procedures, where study data and other materials can be securely reviewed electronically.
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What will happen if I can’t meet my accrual goals due to COVID-19 restrictions?

A. The IRB will keep this in mind when reviewing future continuing review/progress reports applications. You should include a detailed explanation as to why you were not able to meet the accrual goals.

Are there any considerations for moving school-based educational research online?

A. You must first consult each school system where the research is taking place, as each system may have different requirements and guidelines on contact of previously enrolled participants, re-consent, study-specific data collection procedures, and data protections. Some school systems may have paused all human subjects research activities or only certain types of activities. Based on the new information, you must submit a change in research (amendment) application that includes, at minimum, acknowledgement to follow any relevant local school-system requirements, revised school/principal permission letters, updated consent, assent, and parental consent forms, modified data collection instruments, an updated data security plan, and other IRB approval letter(s), if applicable.