Johns Hopkins School of Medicine Clinical Research Restart Update
June 19, 2020

While clinical research has never totally stopped during the COVID-19 epidemic period, we are officially reopening our broader clinical research activity in the School of Medicine on Wednesday, June 24. Our reopening committees are meeting regularly and have started reviewing proposals. For the process to go as efficiently as possible, it is helpful if research teams follow the guidelines for the types of protocols that will be reviewed first. The first protocols to be reviewed include therapeutic trials where there is a potential for direct benefit to the research participants. While it may not be possible for a research team to open all of their therapeutic clinical trials at the same time (ex, sponsor has trial on hold), the applications are easier to review if similar clinical trials from a research team are submitted at the same time.

Updates

Please note that the numbers of protocols reviewed by the various committees listed below reflect experience with refining the process. They do not reflect the number of protocols that will be reviewed as we switch to full capacity. We are carefully monitoring the length of time any protocol might be waiting for review, and will adapt if necessary.

Clinical Research Space Review and Approval

Almost 200 plans for research staff to return to a safe work space have been submitted and are under review by Departmental Research Restart Review Committees. The form and FAQ are posted at the ICTR website. https://ictr.johnshopkins.edu/coronavirus/researchrestart/ Review of plans has not uncovered any major unanticipated issues. Initial guidance emphasized staff members being at least 6 feet apart. We now provide updated, simpler guidance that for shared spaces/offices, the occupancy should not exceed 1 person/100 square ft.

Clinical Research Protocol Review and Approval

The Human Subjects Research Protocol Restart Committee (HSRPRC) has completed review of 26 submissions and is currently reviewing an additional 27 submissions. In parallel, the designated Sidney Kimmel Comprehensive Cancer Center restart subcommittee has prioritized 86 studies for clinical research restart. More information on the HSRPRC, including access to the application form, can be found on the IRB website at: https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/index.html

IRB Protocol Review and Approval

The IRB has posted new petition forms to submit requests to resume in-person activities/new enrollment for previously approved research and new applications. Study teams may now begin to submit these forms as part of a request to resume in-person interaction/new enrollment for previously approved research and new applications. These forms may only be submitted after a
The protocol has been approved by a designated Human Subjects Research Restart Committee. Links for these forms are below:

- Petition to Resume In-Person Human Subjects Research Activities and New Enrollment in a Previously Approved Study (https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/PetitiontoResume_CIR.docx)

The IRB has also implemented an update to the Change in Research (CIR) application to allow study teams submitting a petition for previously approved research to indicate that their CIR includes a petition to resume research activities. This will enable the IRB to easily identify these applications and help expedite the review process.

Please visit the IRB’s website (https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/index.html) for FAQs and helpful resources for submitting a petition for in-person interaction/new enrollment.

IRB approval is required before in-person interaction/new enrollment may begin.

Summary

Each of our committees have met and we have outstanding leadership that is committed to expanding clinical research in a safe manner. Gail Daumit has been working every day on the space approval process. Ellen Mowry and Sumati Murli are dedicated to making certain the HSRPRC is efficient and effective in their reviews. Megan Singleton and all of our IRB committees continue to work overtime to make certain our research participants have a safe experience and feel they have been partners with the research team.

We are well aware that research teams are concerned that important observational protocols not be delayed too long before fully restarting. We are working on ways where research teams could prioritize their most essential protocols for early approval either because of funding issues, participation in multicenter studies, or because these protocols might be the only research activity, like for junior faculty on K awards. We expect to make announcements on how this will work as soon as we evaluate our early experience with the therapeutic research protocols.

Finally, please be supportive of our research coordinator community. They have an essential role in whether our clinical research is successful and they will have new challenges. Many research coordinators stepped up and helped us with our emergent COVID-19 protocols and are just transitioning back to their primary position. Research coordinators will have to become comfortable with use of PPE and they will be communicating with patients who still have many questions about whether it is safe to volunteer to join research studies.
Through this transition period we will be sending out a weekly email on our progress. The latest information you need to know will be on the ICTR website (https://ictr.johnshopkins.edu/coronavirus/) and the JHM IRB website (https://www.hopkinsmedicine.org/institutional_review_board/news/covid19_information.html/index.html)

Sincerely,

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