July 6, 2020

Dear Homewood IRB Investigators,

Across the university, efforts are underway to consider the re-opening of human-subjects research activities. It is important that you begin to formulate your plans for the return of non-COVID-19 related human-subjects research. The date when restrictions for human-subjects research will be lifted is unknown at this time; however, IRB researchers and staff have continued to facilitate research to a large extent. Many research teams have maintained remote contact with research participants, and we are waiting to restart their in-person work.

As we plan for the resumption of in-person research, careful consideration is needed to limit density and to ensure appropriate resource allocation. Our plan for restarting is based on the principles set forth in the university’s guidelines for phased reopening of research. This includes protecting all faculty, staff, trainees, and research participants, facilitating a gradual reopening, and synchronizing with requirements based on state and local regulations. Details about the human-subjects research restart plan and specific phases for restarting that research will be forthcoming.

Our goal is to increase research activity involving human participants in a safe, phased, systematic approach, providing a safe and supportive experience for our research participants, and creating a work environment where both social distancing and appropriate use of personal protective equipment (PPE) keep our research staff healthy.

Studies with no in-person interaction, studies that can be modified by submitting a change in research to the IRB to permanently alter the study so it may proceed without in-person interaction, and COVID-19 related research are exempt from this reopening process.

The following steps will be required to restart human-subjects research:

1. **Form a plan and secure departmental approval to restart human-subjects research.**
   
   This process is similar to the one that the lab research community is completing and requires that research teams submit a plan for staff to return to a safe work space when it is required to complete necessary research. Department chairs should approve these plans. This approval is required before research staff can return to the proposed workspaces. See the attached application.

2. **Apply to the Homewood Human Subjects Research Restart Committee (HHSRRC) for permission to restart research on a specific Homewood IRB protocol.**
   
   The HHSRRC will approve that the research team has developed a plan that protects research staff, protects research participants, and plans for coordinating with clinical and university resources. The committee will review and provide required approval to restart both ongoing research and new studies. More information on the submission process can be found on the IRB website.

3. **Once the HHSRRC has approved your study to move forward to the Homewood IRB, you must apply to the IRB for permission to restart human-subjects research if this is a new study or if an amendment (change in research) is required to your previously
approved protocol. Applications to the IRB will not be accepted until protocols have received approval from the HHSRRC.

The Homewood IRB must determine if any action is required related to changes to the conduct of the study that occurred during the COVID-19 reduction period and will assess if all necessary changes to minimize research participant risk have been implemented. Additional information about the submission process to the IRB will be forthcoming on the IRB website.

Next Steps

Research teams should start to contemplate their plans for safe return to research on campus and in the community. The Homewood IRB website will contain the links to the forms required for restarting. Please check the website regularly for updates.

Best regards,

John P. Toscano
Interim Dean
Homewood IRB Institutional Official