Office of Human Research Affairs (OHRA) and Institutional Review Board (IRB) Updates

Since March, the IRB and OHRA have released a number of updates to the iRIS software. Many of these have been in response to COVID-19. Others have been in response to policy updates as the Human Research Protection Program undergoes accreditation.

IRB Application

- Studies that are reviewed by an external IRB are now required to fill out the "Informed Consent Process" section of the IRB application. This allows the IRB to correctly complete our local context review process.
- The "Final Page" of the IRB application displays a list of required institutional approvals that apply to your submission.
- New COVID related questions have been added to the "Type of Application" section
    - COVID studies that involve secondary analyses of data/samples are sent to an abbreviated application
    - COVID studies that involve development of diagnostic assays are sent to an abbreviated application
    - COVID specimens (human tissues, fluids, and other products) that are to be used for research purposes, and taken to research laboratories or Shared Facilities at Einstein must have IBC review. For additional information, contact Delia Vieira-Cruz delia.vieira-cruz@einsteinmed.org or 718-430-3560.
    - COVID research involving Montefiore associates (or their data) as a target population requires review by Occupational Health Services. For additional information, contact Fran Ganz-Lord (fganzlord@montefiore.org) or Michela Catalano (mcatalan@montefiore.org).

Progress Reports

The progress report form has been updated to include detailed questions regarding the status of the study with respect to COVID-19. Questions include:

- Dates for periods during which the research was paused
- Details regarding changes to the study that were made in response to the pandemic (and reference numbers for the amendments that were sent to the IRB)

Approval Letters

Approval letters for new studies now include the following information to make clear to researchers the current workflow for releasing data at Einstein and Montefiore:
If you are releasing data to an external site/entity/collaborator, you are required to obtain a DUA (data use agreement). This may be obtained through the Research Agreement Request Portal (https://einsteinmed.co1.qualtrics.com/jfe/form/SV_8fgVaus0Bpcpeux).

Policies and Procedures

The OHRA has also actively been reviewing and revising its policies and. Here are some of our recent updates.

Federal regulations requiring Single IRB review for all federally-funded research recently took effect. The OHRA has published two new policies and procedures describing the requirements for Single IRB arrangements. **Single IRB Reliance Procedure** describes the Single IRB request and review process. **sIRB**

PI Responsibilities describes the additional responsibilities assumed by the PI when engaged in multi-site research under Single IRB review.

The OHRA has revised its compliance and reporting requirements into three separate SOPs: **Unanticipated Problems**, **Other Reportable Events**, and **Research Noncompliance**. "Unanticipated Problems" defines the types of events that federal regulations require to be reported to the IRB. "Other Reportable Events" described additional types of events that must be reported due to institutional policies. Finally, "Research Noncompliance" describes the process for investigating allegations of noncompliance.

Data and Safety Monitoring Guidelines did not change with respect what type of information to include in the plan, and whether or not a board is necessary. However, the section regarding the formation of "Data Monitoring Committees" was removed since it was largely out-of-date.

Institutional Approvals
The IRB process is also facilitating the following institutional approvals during the new study approval process.

COVID research involving Montefiore associates (or their data) as a target population requires review by Occupational Health Services. For additional information, contact Michela Catalano (mcatalan@montefiore.org).

IBC review of COVID samples: The IBC is supportive of research efforts involving SARS-CoV-2. Any research that includes handling samples with the virus or research with the virus may require IBC review. Please review the IBC policy (https://www.einstein.yu.edu/research/covid-19-collaboratory/biohazard-considerations/) for more information involving SARS-CoV-2. Call EH&S at 718-430-4150 if you have any questions.

COVID data governance: Montefiore maintains a large volume of clinical data of its COVID-19 patients. To ensure that our COVID-19 data are being used in retrospective, data review research in a manner that will produce high-quality results, each clinical department has established a COVID-19 data review committee. Effective immediately, all retrospective, data review research must be reviewed and approved by your departmental committee, prior to Chair sign off and prior to submission to the IRB. If you have questions about this review process, please contact your Department Chair or Division Chief.

If you have questions or concerns about recent updates to iRIS, the IRB review process or the OHRA's policies and procedures, please email irb@einsteinmed.org.