From: irb@umassmed.edu
To: Blodgett, Allison
Subject: COVID19-related IRB Updates
Date: Thursday, March 12, 2020 11:47:51 AM
Attachments: COVID 19 Clinical Research Memo March 12 plus UMMHC and IRB.pdf

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Dear Research Community,

The UMMS IRB Office remains open, and our electronic submission system, eIRB, remains accessible via the web. Our Ask-An-Expert sessions will not be held this month.

Because of COVID-19, researchers may need to implement changes to research studies in order to eliminate apparent immediate hazards to subjects. For example, study teams may need to conduct scheduled visits by phone instead of in-person, arrange for blood draws at commercial labs in order to minimize potential exposure to COVID-19, or add research personnel who are not yet CITI certified in order to ensure staffing levels and provide for back-up coverage. **Changes to eliminate apparent immediate hazards to subjects can be made without prior IRB review and approval. However, they must then be reported to the UMMS IRB within 5 days in accordance with HRP-801 INVESTIGATOR GUIDANCE: Prompt Reporting Requirements** (https://www.umassmed.edu/ccts/irb/investigator-guidance/). If your study is reviewed by an external IRB, please check the applicable SOPs as timelines and reporting processes may be different.

For step-by-step instructions on **How to Submit a Reportable New Information** (RNI), visit the eIRB Job Aids: https://www.umassmed.edu/ccts/irb/eirb2/job-aids-ii/ If you are submitting an RNI to report a change to eliminate an apparent immediate hazard, please describe the hazard, the changes implemented, and any additional information that may inform the IRB's risk assessment.

Study teams should actively plan for coverage of research-related business in the event that staff and colleagues may be out of work due to travel-related quarantine, illness, or the need to care for a loved one who is ill. For IRB approved studies, coverage must take into account the skills and training needed to conduct research procedures. Appropriate personnel should be added in eIRB and added to delegation logs in anticipation of changes.

Study teams do not need to report to the UMMS IRB that they have implemented institutionally mandated COVID-19 screening procedures prior to in-person visits. However, all interactions with research participants should be documented in the study binder.

The IRB will continue to work with UMMS leadership to assure the health and safety of our community.

Sincerely,

Allison Blodgett, PhD, CIP

Director of IRB Operations