June 23, 2020

In-Person Non-COVID Research at BMC and BU Medical Campus

The institutions are taking a phased approach to resuming in-person non-COVID research that was stopped because of the COVID-19 pandemic (non-COVID research in-person interactions have been ongoing for those studies that are necessary to deliver a potential direct benefit or for safety).

Studies that do not need further approval to resume:

- Studies do not have to stop if 100% of interactions occur remotely.
- If a sponsor has stopped a study that is 100% remote interaction, study activities may resume as soon as the sponsor allows.
- Studies that formally had in-person visits that could be conducted remotely are encouraged to convert to 100% remote if approval is obtained from the sponsor, if applicable, and subsequently from the IRB where the protocol (and as necessary the budgets and contracts) can be modified (recruitment, consent and study visits via tele-health, IPS home drug delivery, VNA home visits, etc.).

Approval process for non-COVID studies that wish to resume in-person subject interactions with a member of the study team in BMC or BU Medical Campus space

Studies that are not focused on COVID-19 that wish to re-open with in-person subject visits in BU or BMC space must complete and submit the following BMC form: Returning Research Staff to BMC or BU Medical Campus. This form has basic questions about the research and requires the preparation of three attachments:

- Research Recovery Plan (describes the space where staff will work)
- Research Personnel Template (identifies the staff members)
- Resuming In-Person Subject Interactions (lists expected interactions with human subjects per project)

We will take a phased approach to restarting non-COVID studies on the medical campus (Table below). We will determine dates when the phases will start based on state requirements (clinical capacity, building occupancy, etc.), which the state will adjust depending on the course of the pandemic.

Research that obtained IRB approval on or before June 15, 2020 will start first in each phase. We are prioritizing studies approved on or before June 15, because we seek to support existing and ongoing studies before we begin to open new research projects in this environment of limited capacity.

The phases apply to both already-enrolled and new subjects. Subjects and research staff must comply with all BMC and BU requirements (staff training, use of PPE, cleaning, patient screening, movement within clinics, occupancy of dedicated research space, etc.). PIs are responsible for maintaining documentation of any additional required approvals for the spaces they will use.

Phase	Date	**In-Person Interaction** (recruitment, consent, study procedures; see below for specific examples)
Phase Ia – IRB approval by 6/15/20	Late June	• Occurs during a standard-of-care visit or inpatient stay, and o Clinic operations staff have determined that their staffing and patient volume capacity can accommodate, including any research-only procedures beyond the visit (e.g., imaging)
Phase Ib – IRB approval after 6/15/20	TBD	
Phase IIa – IRB approval by 6/15/20	TBD	• Occurs for research only (not during a standard-of-care visit or inpatient stay), and o Is therapeutic* OR • Inpatient admission for research only (not during a standard-of-care inpatient stay) OR • Does not qualify in the categories above but is prioritized because delay is likely to: 1. Damage professional or educational careers 2. Cause the loss of external funding 3. Prevent research with seasonal implications, e.g. Flu or RSV
Phase IIb – IRB approval after 6/15/20	TBD	
Phase III	TBD	• Occurs for research only (not during a standard-of-care visit or inpatient stay), and o Is non-therapeutic**
Phase IV	TBD	• Full operations (New normal) • No restrictions on study personnel (except in setting of COVID-19 + subjects)

*Therapeutic research: prospective clinical research involving a drug, biologic, surgery, or device that holds the prospect for direct benefit to subjects
**Non-therapeutic research: biological sample collection, surveys, prospective procedure for observational research, discarded tissue

Specific Examples:

Recruitment: Recruitment requires a warm handoff, that is, a treating clinician will ask a patient during an in-person or tele-health visit if they are OK with the study team contacting them. If the study team contacts the patient either remotely or as part of the in-person visit and all subsequent in-person consent discussions and research interactions occur during this or subsequent standard-of care clinic visits, the study can begin in Phase I. If the study requires an in-person consent and/or study procedures for research only, the study team may ask clinicians for a warm handoff during Phase I and contact the potential subject, including obtaining remote consent, but must wait for the in-person research-only consent and/or study procedures until Phase II if therapeutic (or prioritized) or until Phase III if non-therapeutic. PIs should make sure that they have IRB approval for their recruitment and consent process.

Biological sample collection: Non-therapeutic studies involving the collection of research-only samples or consent to obtain discarded tissue may begin in Phase I if the in-person consent and research interactions take place during a clinic or inpatient visit or if consent had been obtained remotely or at a prior visit. They may begin in Phase III otherwise (or in Phase II if prioritized).

Randomized routine care arms: Studies that involve randomization to different routine care arms when consent is obtained before or during a clinic visit and that do not involve any in-person research interactions (follow-up is only through chart-review data collection) may begin in Phase I.

Workflow Review Process:

1. Study team reviews protocol visits and re-develops protocol data collection to occur remotely as much as possible and submits re-start request noted above for in-person required work. Consultation with Research Operations, the PI's home department, IRB, clinic(s) location, and sponsor (when applicable) is recommended.

2. Form intake is managed by Research Operations, which may result in further conversations with the study team, and will be prioritized by phases noted above.

3. Study staff, or department assigned personnel, obtain a clinic operations manager approval email and provide to Research Operations.

4. Study staff, or department assigned personnel, obtain a Chief or Chair approval email and provide to Research Operations.

5. Research Operations requests Research Re-Start Task Force final sign-off.

6. Staff returning to campus complete Infection Control Education- TBD.

7. Study commences in-person research visits.

Research Re-start Task Force Members

Lead by: Grace Cashman
Members: Matt Ogrodnik, John Ennever, Steve Pelton, David Salant, Tyler Flack, Mike Porreca, Elizabeth Barnett, Nina Lin, Andy Taylor, Stephanie Wasserman, Fanny Ennever, Johanna Chesley, Christina Borba, Jamie Flaherty, Ben Linas, and Noah Goldman