REMOTE STUDY DESIGN: OPTIMIZING FEASIBILITY DURING COVID-19

BMC Research Operations and the Clinical Trials Office strongly encourages principal investigators and their study teams to adopt as many remote options in designing new funded or unfunded studies as is reasonably possible. Promoting remote design optimizes feasibility of studies continuing through the COVID pandemic. Two goals need to be balanced — ensuring patient safety and also ensuring study integrity. This document provides information on remote options that should be considered as part of study design. For additional guidance, review the CR Times article on "Planning Studies to Minimize Visits to BMC/BU Medical Campus".

New studies will need to complete the BMC Clinical Research Feasibility Survey and submit to Research Operations for review before commencing. Contact michelle.irick@bmc.org for questions or additional information.

Benefits of Remote Interactions

- Studies that have 100% of interactions occurring remotely will be able to continue without stopping, barring unforeseen circumstances.
- If 100% of the study interactions are remote, but the study sponsor stops the study, the study may resume as soon as the sponsor lifts the stoppage.
- Support our community by minimizing risk to your colleagues and to patients.

Designing a Protocol During a Pandemic – Quick Tips

(1) Recruitment

Can you utilize remote methods of recruitment, as opposed to in-person recruitment? Consider using:

- MyChart portal communications
- Online or phone screening questions: consider if it would be possible to screen for eligible participants electronically
- TriNetX: is a data analytics platform that assists in optimizing protocol design and feasibility, site selection, and patient recruitment. For access or questions, contact the CTSI Research Coordinator at nicholas.trombley@bmc.org and the Senior Research Compliance Manager at michelle.irick@bmc.org.
- Introducing study during telemedicine visit and collecting contact information
- Posting opt-in promotional materials in clinics
- Mailing opt-out letters that reference a treating provider
- Social media strategies with BMC Communications and Marketing

(2) Remote Consent (including e-consent)

Implementing a remote consent process can help to reduce in-person contact and can include e-consent, a hardcopy remote consent process, or a combination of a remote discussion with an in-person signature. There are many ways to do this and your methods will depend to a large extent on specifics of your study and your study population and whether your study is FDA regulated or not.

- Please consult the guidance on remote and e-consent http://www.bumc.bu.edu/crro/tools/e-consent-tools-and-guidance/

- View the December 2020 Clinical Research Seminar on Remote and E-Consent: http://www.bumc.bu.edu/crro/training-education/past-seminars/
- Schedule a consultation with the Clinical Research Resources Office (CRRO) to review options for your study: http://www.bumc.bu.edu/crro/
    - **Contacts**
        - Contact the Clinical Research Resources Office (CRRO) at http://www.bumc.bu.edu/crro/ for more information on best practices for e-consenting:

(3) **Regulatory Binder**:
- **Storage:** Use your BMC corporate account of Box for storage and restrict access to only appropriate users/viewers.
- **E-Signatures:** Use DocuSign, wet signature if needed.

(4) **Source Documentation**: attributable, legible, monitorable, auditable.
- Currently entered into Epic.
- For study monitoring please see Section 11 below.

(5) **Virtual Study Visits**: FDA does not support any particular video conferencing platform, but more generally states that the investigator/study personnel should be trained such real-time video conferencing visits, that the investigator should institute procedures to protect the participant's privacy, that each party should confirm their identities, and that the date and time of these virtual visits should be noted
- FDA considers real-time in video interactions, including telemedicine, a live exchange of information between trial personnel and trial participant. These interactions are not considered electronic records and therefore not subject to 21 CFR Part 11.
- BMC encourages use of the BMC-corporate account of Zoom for video conferencing and virtual study visits.
- You may not record the study visits on Zoom.

(6) **Secure Delivery of Investigational Products**: FDA suggests that investigational products, especially those for self-administration, may be provided through "alternative secure delivery methods". For investigational products normally administered in a health care setting, FDA had recommended consulting FDA review divisions on plans for alternative administration – for example, "home nursing or alternative sites by trained but non-study personnel". VNA services may be an option for interactions with subjects. Contact CTO and the IRB for more information.

(7) **Alternative Methods for Safety Assessments in Clinical Trials**: The FDA has stated that alternative methods for safety assessments such as "phone contact, virtual visit, alternative location for assessment", and determination if in-person visits are necessary to fully assure the safety of trial participants may be necessary. Contact CTO and the IRB for more information.

(8) **Remote Clinical Outcome Assessments (COAs)**: Remote assessments should be performed in a manner as similar to in person assessments as possible while protecting trial participant safety and privacy. For certain COAs, other considerations such as the appropriateness of remote assessment, need for special training, and the risk of missing data, and risk of score bias, should be considered.

(9) **<u>Surveys and Questionnaires</u>**: With the approval or input of the IRB, some data collection tools may be used remotely. To avoid direct contact with subjects, consider if surveys or questionnaires can be utilized electronically in your study design.

(10) **<u>Secondary Research</u>**: Studies using identifiable information or using identifiable information that is either publicly identifiable or has been recorded in such a way that is not re-identifiable may be able to use remote methods for such research.

- *Storage*: All BMC data should be stored securely in compliance with BMC policies.
    - *Data Retention*: In addition, research data must be retained in compliance with BMC policy limits or contractual limits (if applicable), whichever is longer.
- *Transmission*: Any data shared between colleagues or collaborators must be shared in a secure, approved method.
- *Sharing/Access/Transfer*: any sharing or providing access (also including viewing, not just actual transfer) must first be reviewed by Research Counsel (DUA.MTATransfer@bmc.org) to determine if an agreement is needed to permit the sharing or access with a non-BMC collaborator.
- *Questions*?: Contact Michelle Irick, Senior Research Compliance Manager at michelle.irick@bmc.org.

(11) **<u>Remote monitoring and Auditing.</u>** BMC strongly encourages virtual / remote research study-related monitoring/auditing ("Monitoring/Auditing Visits"). Any and all Monitoring/Auditing Visits, including for study initiation, study monitoring, and study closeout, whether conducted by the study sponsor ("Sponsor") or the study Contract Research Organization ("CRO") (collectively such entity conducting a Monitoring/Auditing Visit, whether from the Sponsor or CRO, hereinafter referred to as the "Monitor") personnel, should be conducted remotely to the extent possible.

- **Remote monitoring and auditing involves generally involves planning in three steps:**

    1. Schedule Zoom, password protected, virtual meetings to display scanned documents or view spaces where the study is conducted. The screen-share function may be used to facilitate this.
    2. Provide access to a secure Box file housing study-related documentation
        - Non-FDA regulated studies: REDCap
        - FDA regulated studies: DocuSign
    3. Request ChartLink access for Monitors requiring Epic access

- **Exemptions**. In certain situations, for example trials that involve a <u>significantly large number</u> of enrolled subjects, a research study may be exempted from remote monitoring/auditing.
    - **Contact** BMCRemoteResearch@bmc.org for more information on exemption.

- If an in-person Monitoring/Auditing Visit must occur, justification / rationale must be provided by the Sponsor, and visitors must adhere to the following guidelines:

1. In-person Monitoring/Audit Visits will only be permitted when:
    - Sponsor has provided in writing an acceptable justification for why the Monitoring/Audit Visit cannot be done remotely, AND
    - Boston Medical Center and the department approval for non-clinic space allows visitors, AND
    - Study has been approved by Research Operations for activation, AND
    - The Monitor permits staff travel AND
    - The state of Massachusetts or the city of Boston at the time of the requested visit either (a) has not prohibited or restricted any travel associated with or required by the Monitoring/Audit Visit or (b) the Monitor has complied with any such state or local restrictions, including mandatory quarantining after entering the state of Massachusetts, if any, and shall sign and furnish to BMC, prior to the Monitoring/Audit Visit, a certification of compliance with such restrictions that BMC provides to Monitor AND
    - The Monitor agrees to and is prepared to comply with any BMC policies, including but not limited to those relating to personal protective equipment (PPE).
    - Monitor acknowledges it and its personnel travel at their own risk, and that BMC is not responsible for Monitor personnel who may contract COVID-19 infection or COVID-19-like symptoms at any point during its travel to and from BMC.

2. In-person Monitoring/Audit Visits should be:
    - Limited to as few visitors as possible;
    - Limited to visitors who are able to and agree to comply with any applicable BMC policies, including but not limited to those relating to health screening at entry, use of face mask, social distancing, hand sanitizing, and disinfection of common equipment after use.
    - Monitors should not be working in clinical care areas. Appropriate conference rooms and offices located a distance away from patients will be designated for the Monitor's use.

3. In-person Monitoring/Audit Visits should be planned in advance to allow sufficient time to identify a location that will allow for social distancing and minimize the number of staff the Monitor will directly interact with, as well as the duration of direct interaction. For additional information, visit: https://www.bmc.org/visiting-us/visitor-policies

4. Study teams should keep a log of any Monitoring/Audit Visit to record contact information of the visitor and list of staff that the visitor interacted with.

5. BMC reserves the right to cancel or modify at any time logistics of the onsite Monitoring/Audit Visits depending on the evolving COVID-19 environment.

(12) **External Collaborators**: If your funded or unfunded study includes collaborators, plan for using compliant methods to share data electronically whenever possible, avoiding sharing data physically or in person. However, if you require sharing BMC data or receiving outside data, see the recent guidance documents on transferring data, which provides relevant information as a refresher on what steps you should take to transfer any BMC data. See the other

recent guidance document on transferring biological materials for a refresher as well if this is relevant to your study.