# BMC Clinical Research Feasibility Determination

**Instructions:** The form below is required to complete for research involving in-person recruitment, consent, and/or study visits in BMC space. Please fill out a separate form for each project. Note: Save the completed version of this document to your computer with the PI name and include nickname for the project to identify it, e.g., “First name, Last name\_BMC\_Clnical\_Research\_Feasibility\_Determination\_Nickname”. Attach one document for each study to the “BMC Clinical Research Feasibility Approval” webform.

Once you have submitted the form to BMCRemoteResearch@bmc.org, a reviewer will review your submission and get in touch with you for follow-up questions. Depending on the state of the pandemic, government restrictions or guidelines, and available BMC resources, your submission will be accepted with a plan to move forward, or will be returned to plan for additional modification or alternatives where possible. Next steps will be determined in conjunction with the input of clinic operations managers and/or department heads, who will provide information on the availability or scarcity of BMC resources. BMC Research Operations will provide a Final Approval notice via email once a determination has been reached.

**Project Identification**:

Name of PI:

PI Email:

Department:

Project Title:

IRB H number (if available):

Project InfoEd Number (if available):

Anticipated Start Date:

Does this study fit either COVID-19

exception category (direct benefit or safety): YES/NO

Is this a [COVID-19](file:///C%3A%5CUsers%5CMiIrick%5CDocuments%5CResearch%20Restart%5C1.a.%09If%20) related study: YES/NO

Type of COVID Study — please describe (i.e. chart review, survey study, interventional with treatment etc.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Required BMC Resources: Please check any boxes for BMC resources you will need for your study.

* Radiology
* Pathology
* Investigational Pharmacy Service
* Investigational Device (IDE) implants
* Infusion services
* Lab medicine
* Cardiology
* Opthalmology
* Performing physical exam in BMC space
* Drawing blood in BMC space
* Other

If “Other” please describe: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Feasibility Determination Steps**

1. **Designing the Project for Feasibility:** For new studies, or for modifying studies in progress, consider how project design could promote feasibility while creating your study protocol. To minimize risk of viral transmission and avoid overwhelming clinic capacity, each PI should strategize conducting as much of the study remotely as possible (e.g. using visiting nurse associates (“VNA”), conducting remote exams, sharing data via Box, etc.). For more information on working in remote options into studies see the [Guidance: Remote Study Design - Optimizing Feasibility During COVID-19](https://www.bmc.org/sites/default/files/Research/Remote_Study_Design_Optimizing_Feasibility_During_COVID-19.pdf).
	1. Can you conduct **some or** **all** study activities remotely? Yes/No
		* + 1. **Activity/Visit Description**: If yes, please describe your plans for conducting study activities. Describe remote plans\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
				2. **Sponsor Approval and IRB protocol**: Ensure the sponsor approves of the plans to conduct the study using some or all remote methods. Sufficiently describe the remote plans in the protocol to be submitted for IRB review. Be prepared to provide documentation if requested by reviewer.
				3. If some or all activities must be in person, onsite at BMC, go to Step **(2)**.
2. **Piggyback research onto routine care visits:** If certain study activities or visits must be conducted in person, onsite at BMC, with no remote option possible, then such research activities or visits should be piggybacked onto routine, standard-of-care clinical visits whenever possible.
3. Can you piggyback some or all necessary onsite research activities or visits onto routine, standard-of-care visits? Yes/No
4. If no, please describe in detail what your research-only visit will entail\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
5. **Activity/Visit Description**: If yes, please describe the current or future piggybacked activity\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
6. **In Person Participants**: Who will be involved in the onsite piggybacked activity or research visit?
	1. Only Employees/research staff/clinical staff (e.g. techs, phlebotomy, etc.) Yes/No
		1. Please describe\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. Both Subjects and employees/research staff/clinical staff: Yes/No
		1. Please describe­­\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
7. **Space:** Where will the onsite activit(ies) or visit(s) take place? Provide full addresses including floor and suite where possible\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
8. If some activities or visits cannot be piggybacked onto routine/standard-of-care visits, move on to Step **(3)**
9. **If you must conduct any research-only activities or study visits onsite at BMC (that are not “piggy-backed to standard of care visits), describe these activities or visits**:
10. **Activity/Visit Description**: Please describe the research-only activities or study visits.
11. **In Person Participants**: Who will be involved in the onsite activity or study visit?
	1. Only employees/research staff/clinical staff: Yes/No
		1. Please describe the activities/visits\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	2. Both subjects and employees/research staff/clinical staff: Yes/No
		1. Please describe the activities/visits\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
12. **Space**: Where will the onsite activit(ies)/visit(s) take place? Provide full addresses, including floor and suite number when possible\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
13. **Supplies:** Describe your plans for decontaminating before and after research activities and study visits to protect research staff and subjects\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
	1. Describe any issues concerning obtaining sufficient cleaning and PPE supplies\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
14. **Describe considerations for prioritizing this study:**
15. **Grant/Contract Support:** If any, describe considerations concerning grant and contract support, including concern over loss of funding, or any timeline constraints such as seasonable restrictions around the research study?\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
16. **Potential for direct Benefit to subjects:** If any, describe any potential direct benefit to the subject or concerns over loss of direct benefit to subject if study suspended (e.g. study drug, study device, etc.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
17. **Harm to reputation or career?**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
18. **Other considerations?** (e.g. research with seasonal implications, expiring samples, etc.)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_