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The below list of resources was created to assist study teams with the new IRB application requirement for investigator-initiated, single-site clinical trials. The INSPIR application has been updated to collect quantitative data about the potential eligible subject pool in order to confirm that fulfilling the sample size is feasible. The new requirement aims to minimize the likelihood that a study involving human subjects and is greater than minimal risk will be approved when there is a very low probability that the required sample size will be reached. To read the full guidance and for more information regarding this new requirement please visit Fulfilling Your Sample Size: What is Required and Why.

If you need assistance with the new question or require additional resources to comply with the new requirement, please see below for a list of useful resources.

For general questions about the BU CTSI please email Helia Morris @ hmorris@bu.edu. For questions regarding BMC Clinical Trials Office, email clinicaltrialoffice@bmc.org.

Resource	Contact Information
BU CTSI	
The BU CTSI Research Navigator Team helps to educate research teams about the many BU CTSI resources which include tools and services for clinical investigators to maximize the impact of discoveries and speed the translation of research into improved patient care and population health. Example of services include: • Community Engagement • Regulatory Consults Regulatory consults from the Clinical Research Resources Office-See below for more information or contact ctsisvcs@bu.edu • The Biostatistics, Epidemiology, and Research Design (BERD) • Protocol Implementation • Recruitment Assistance • BMC/BU Clinical Research Informatics and Technology Consultation (CRITC) Service. Assist them with use of information technology and informatics to facilitate clinical studies. Please visit the BU CTSI resources page for a more comprehensive list of resources @ https://www.bu.edu/ctsi/support-for-research/ctsi-offerings-and-resources/	ctsisvcs@bu.edu
BMC Clinical Trials Office (CTO) Share Service Resources	
BMC CTO oversees the Clinical Trial Management System (CTMS)- Velos- which: 1) Is CTO's trial intake and process management tool, 2) Enables central study enrollment reporting, and 3) Ensures research billing compliance by integrating study and participant information with BMC's Electronic Medical Record System (EMR) - Epic. Please visit BMC CTO resources for Velos system training to gain access and for refreshers:	clinicaltrialoffice@bmc.org

https://www.bmc.org/research-operations/clinical-trial-office and visit Velos / Epic live training for a research billing compliance training https://www.bmc.org/research-operations/clinical-trial-office In addition, the Clinical Research Network (CRN) at BMC is working in collaboration with CTO and CTSI to develop an index of fee categories to support equitable recruitment practices that can be included within study budgets. These fees will capture the time and effort associated with enrollment of a diverse patient population and reduce financial barriers to research participation. Please contact the Clinical Research Network team to request a copy of the fee index (ryan.schroeder@bmc.org).	
Clinical Research Resources Office	
The CRRO provides consultations for PIs and research staff at any point during the life of the study. Get assistance with: • IRB application preparation and submission, including pre-reviews of IRB applications before submission to the IRB. The CRRO can work with you to spot potential issues and provide advice on how to address them, facilitating review and shortening review time. • Study implementation: when the study is in progress often questions come up about the conduct of the study, such as effective processes related to documentation, consenting, eligibility determination, and AE monitoring/reporting, etc. To request a consultation, please complete the Request CRRO Services form and/or email Mary-Tara Roth at mtroth@bu.edu.	mtroth@bu.edu
Additional BU/BMC Resources	
The Boston Medical Center and Boston University Medical Campus **Institutional Review Board** (IRB) provides ethical review of human subjects research to protect the rights and welfare of human subjects of research and to assure that human research is conducted according to applicable federal, state, and local laws and regulations and the relevant policies of the Human Research Protection Program, Boston Medical Center, and Boston University. **Website:** http://www.bumc.bu.edu/irb/	http://www.bumc.bu.edu/irb/
The Clinical Data Warehouse consolidates patient data from the BMC Electronic Medical Record Systems and other health system-related data streams to create a repository of data to support research. With appropriate approvals, researchers may request data through a CDW analyst. Researchers are not allowed direct access to the CDW.	cdw@bmc.org

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The CDW can provide count data for feasibility analysis or proposal/grant preparation without IRB approval (so called prep-to-research). With HIPAA and /or IRB approval, analysts can identify patient cohorts that meet study eligibility criteria and provide de-identified data sets, limited data sets, or identifiable data sets for retrospective and prospective research studies **Website**: https://www.bumc.bu.edu/ohra/using-bmc-and-chc-data-for-research-purposes/	
Sponsored Programs specializes in assisting faculty and administrators in proposal review and submission, award negotiation and acceptance and University policies and procedures. Sponsored Programs is the coordinating office for all pre-award and non-financial post-award needs. **Website:** http://www.bu.edu/researchsupport/profile/sponsored-programs/	ospera@bu.edu
Tools	
REDCap (Research Electronic Data Capture)- a secure web-based application for building and managing online surveys and databases for research.	rchelp@bu.edu,
TriNetX is a dynamic, data driven platform that leverages the i2b2 data warehouse and Cerner PowerChart (EHR). Employing a clean and easily user interface, a researcher can easily generate a query to perform study feasibility and cohort discovery through aggregate data. Additionally, TriNetX has the ability to perform analysis of the identified cohort and "estimated rate of arrival" projections. For more information and to view an instructional video: https://www.youtube.com/watch?v=trDGSWPpeH8 https://www.youtube.com/watch?v=e22eECt-UDA	Nicholas.Trombley@bmc.org
Additional Resources	
The Trial Innovation Network (TIN) is a collaborative initiative within the Clinical and Translational Science Award (CTSA) Program.The vision for the TIN is to innovatively address critical roadblocks in multi-site clinical trials and accelerate the translation of novel interventions into life-saving therapies. It features a single IRB system, master contracting agreements, quality by design approaches, and a focus on evidence-based strategies to recruitment and patient engagement. The below website contains several recruitment resources, webinars and other clinical trial recruitment information. **Website:** https://trialinnovationnetwork.org/	ctsisvcs@bu.edu
Other useful sites and resources: • **MRCT Toolkit:** https://mrctcenter.org/blog/resources/mrct-center-diversity-inclusion-and-equity-in-clinical-research-guidance-document-and-toolkit/ • **Trials Today:** https://www.trialstoday.org/ • **ResearchMatch:** https://www.researchmatch.org/	

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- **Community Engagement Alliance Resources: https://covid19community.nih.gov/communication-resources**
- **University of Michigan Recruitment Toolkit**: https://michr.umich.edu/resources/participant-recruitment-toolkit