Beth Israel Lahey Health
Beth Israel Deaconess Medical Center

Clinical Research Response during COVID

Gyongyi Szabo, MD, PhD, Andi Hernandez, Tanya Santos, Michelle Beck, Kim Chun, Chris Botte, and Angela Lavoie
BIDMC

Introduction/Problem

Research Operations needed to quickly prepare a coordinated and safe response to the reduction of hospital activity in the early response to COVID. It was important to ensure that the safety of research participants on ongoing therapeutic trials while enabling a rapid implementation of COVID-related therapeutic trials. Clinical research is conducted across the medical center. Implementing change would need to be coordinated with department leadership and communicated through different mechanisms. With guidelines being instituted from hospital leadership, statewide restrictions, and a developing understanding of SARS-CoV-2, it was essential to have a working group to understand the impact on clinical research and create guidelines that would align with developing institutional policies.

Aim/Goal

The goal was to effectively manage conducting research during a period of constrained resources and a statewide lock-down. To address this, research operations instituted several measures to protect participants and research staff and support important initiatives for COVID research. Just as important as the response to reduce the research activity to focus on therapeutic trials and COVID was the resumption of activity in a staged way to allow for a controlled return and coordinated with departments, clinics, and research teams.

The Team

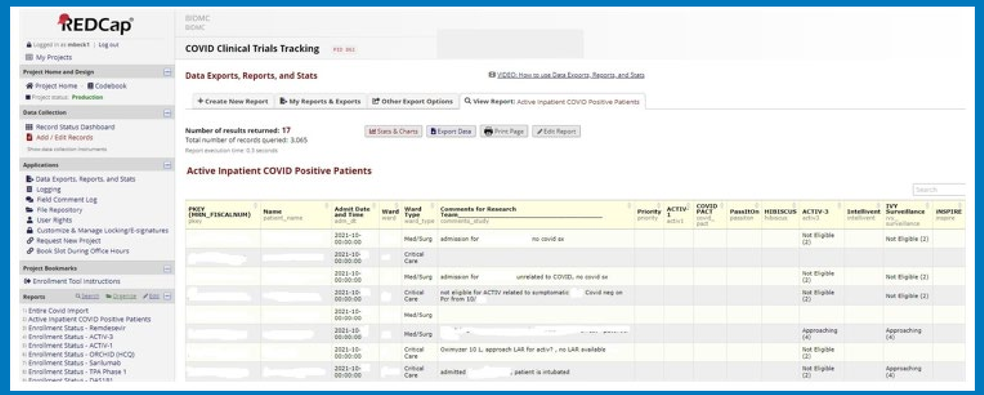
Gyongyi Szabo, MD, PhD, Chief Academic Officer, BIDMC and BILH
Andi Hernandez, Vice President of Research Operations
Tanya Santos, Director, Research Operations
Michelle Beck, Administrative Director, Clinical Research Programs
Kim Chun, Project Manager, Research Operations
Chris Botte, EDC Support Specialist, Academic and Research Computing
Angela Lavoie, Director, Human Research Protection Program

The Interventions

- Development of guidelines for the restriction of research activities on-site during the COVID lockdown
- Creation of an Urgent IRB Committee for rapid review of COVID research.
- Establishment of a Scientific and Institutional Research Review Committee to review the impact of PPE, lab, nursing, and other clinical resources from research activities.
- COVID-19 Steering Committee was established to review new COVID research proposals to promote collaboration and reduce duplicative efforts and maximize data and biospecimen collection.
- Creation of a Return to Clinical Research workgroup to develop a phased re-opening for non-COVID research. The group was charged with developing a staged plan to reopen clinical research.

Results/Progress to Date

Creation of a COVID dashboard to eliminate patients from being repeatedly approached to participate in research studies. The dashboard provided real-time updates with impatient data and whether the participant was approached and/or enrolled into a COVID research study.



REDCap dashboard created with Academic and Research Computing to facilitate recruitment communication between different study teams.

For more information, contact:
Andi Hernandez, Vice President of Research Operations

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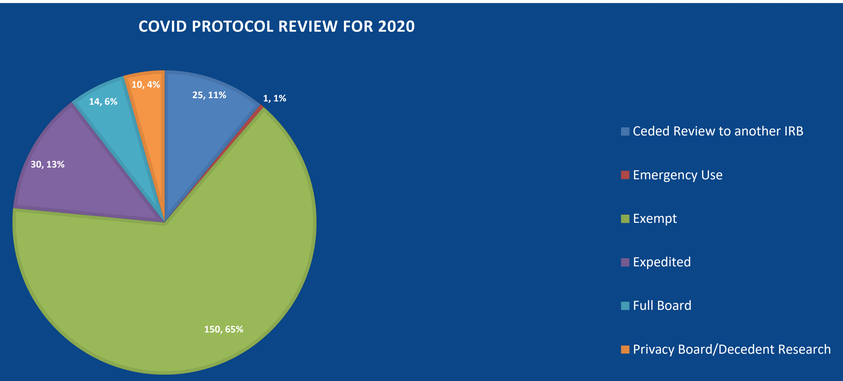
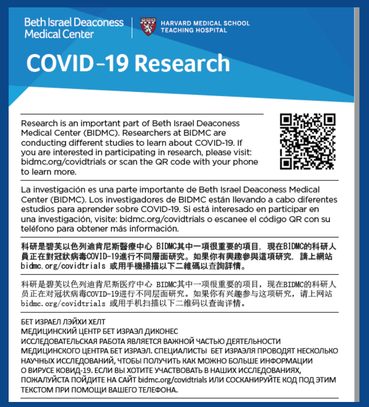
More Results/Progress to Date



During 2020, the IRB reviewed 230 new research protocols about SARS-CoV-2.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COVID-19 Research

Research is an important part of Beth Israel Deaconess Medical Center (BIDMC). Researchers at BIDMC are conducting different studies to learn about COVID-19. If you are interested in participating in research, please visit: bidmc.org/covidtrials or scan the QR code with your phone to learn more.

La investigación es una parte importante de Beth Israel Deaconess Medical Center (BIDMC). Los investigadores de BIDMC están llevando a cabo diferentes estudios para aprender sobre COVID-19. Si está interesado en participar en una investigación, visite: bidmc.org/covidtrials o escanee el código QR con su teléfono para obtener más información.

科研是贝斯美以色列迪肯尼斯医疗中心 BIDMC其中一项很重要的项目。现在BIDMC的科研人员正在对冠状病毒COVID-19进行不同层面研究。如果你有兴趣参与这项研究，请上网站 bidmc.org/covidtrials 或用手机扫描以下二维码以查询详情。

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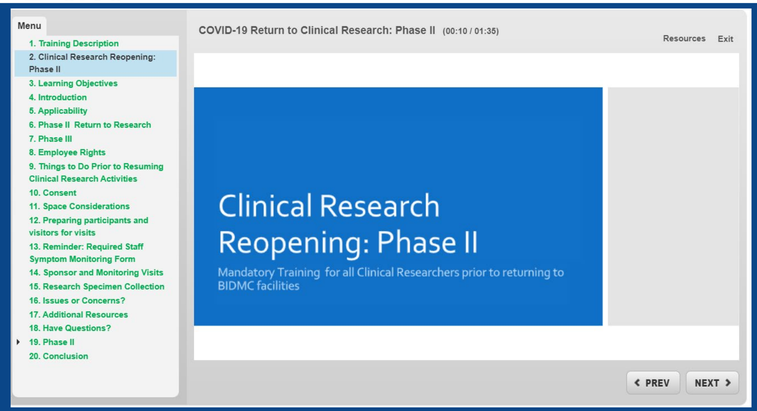
БЕТ ИЗРАЕЛ ЛЭЙКИ ХЕЛТ
МЕДИЦИНСКИЙ ЦЕНТР БЕТ ИЗРАЭЛ ДИКОНЕС
ИССЛЕДОВАТЕЛЬСКАЯ РАБОТА ЯВЛЯЕТСЯ ВАЖНОЙ ЧАСТЬЮ ДЕЯТЕЛЬНОСТИ МЕДИЦИНСКОГО ЦЕНТРА БЕТ ИЗРАЭЛЬ. СПЕЦИАЛИСТЫ БЕТ ИЗРАЭЛЯ ПРОВОДЯТ НЕСКОЛЬКО НАУЧНЫХ ИССЛЕДОВАНИЙ, ЧТОБЫ ПОЛУЧИТЬ КАК МОЖНО БОЛЬШЕ ИНФОРМАЦИИ О ВИРУСЕ КОВИД-19. ЕСЛИ ВЫ ХОТИТЕ УЧАСТВОВАТЬ В НАШИХ ИССЛЕДОВАНИЯХ, ПОЖАЛУЙСТА ПОЙДИТЕ НА САЙТ bidmc.org/covidtrials ИЛИ СОСКАНИРУЙТЕ КОД ПОД ЭТИМ ТЕКСТОМ ПРИ ПОМОЩИ ВАШЕГО ТЕЛЕФОНА.

A recruitment postcard was created and handed out at BIDMC COVID testing sites to eliminate the requests for flyers and recruitment handouts for specific studies. The QR code on the postcard displays all the current COVID research being conducted at BIDMC and contact information for the study team.



All research staff were assigned a return to research training in myPATH. All key information was shared in an email announcement, Town Hall meeting, myPATH training and on the research portal page.

Lessons Learned

- Any guidelines developed by clinical research needed to align with guidelines from hospital incident command.
- Communication was key to ensure that the information was shared with all the individuals that conduct clinical research throughout the medical center.
- The committees that were established were essential for ensuring that the impact of clinical research activities was not going to impede clinical operations while allowing for important research to be conducted.

Next Steps

- Develop an Emergency Preparedness plan for clinical research using the foundation developed from these activities.
- AAHRPP, accreditation agency for human research protections, has indicated that emergency preparedness will be a new standard for institutions to meet. We will use our plans used here to develop our policy and response.

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Steering Committee Members

Steering Committee Members:

- Gyongyi Szabo, MD
- Mark Zeidel, MD
- Richard Schwartzstein, MD
- Howard Gold, MD
- Daniel Talmor, MD
- David Avigan, MD
- Peter Weller, MD
- Kathryn Stephenson, MD
- Michael Yaffe, MD
- Ai-ris Collier, MD
- Nathan Shapiro, MD
- Shahzad Shaefi, MD
- Michelle Beck
- Angela Lavoie

Return to Research Workgroup Members

Re-Opening Workgroup Committee Members:
Andi Hernandez
Michelle Beck
Janet Mullington, PhD
David Avigan, MD
Daniel Press, MD
James Rodrigue, PhD
Peter Weller, MD
Angela Lavoie

For more information, contact:
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