Phased Resumption of Clinical Research Including Non-COVID Studies

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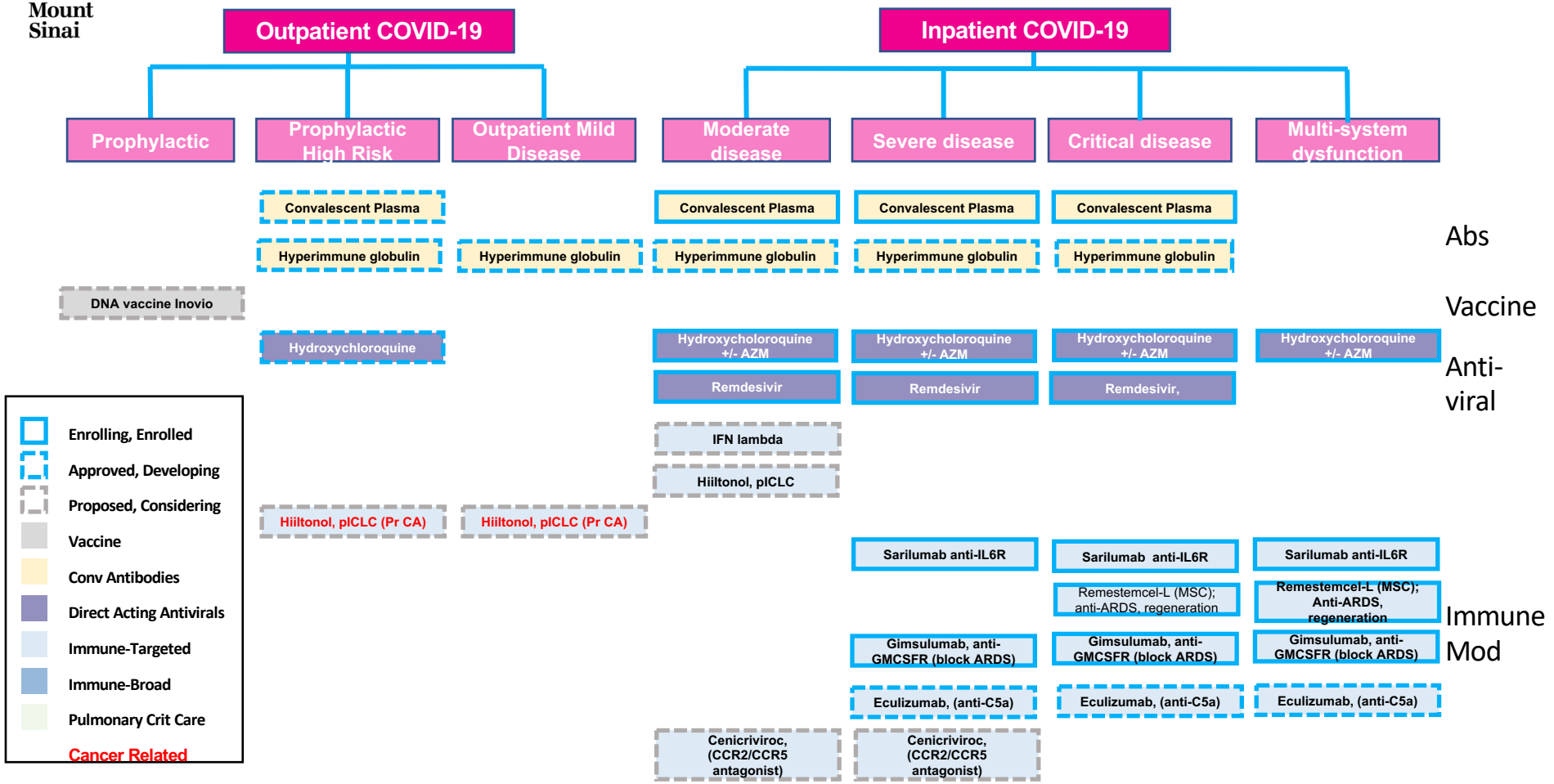
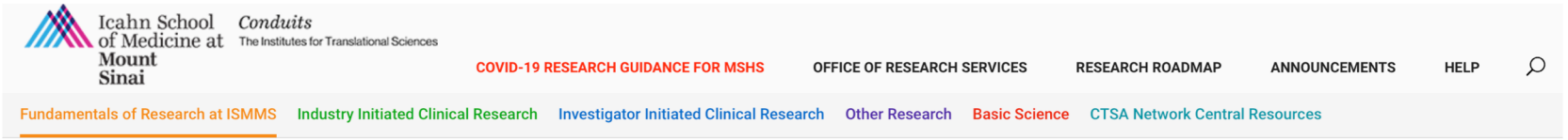
MOUNT SINAI COVID-19 CLINICAL TRIALS DEVELOPMENT PLATFORM



COVID-19 Protocol Clinical Research Guidance



Fundamentals of Research at ISMMS

- COVID-19 Research Guidance for MSHS
- Orientation
- Am I Eligible to be a PI?
- Approvals Needed for Research
- Find Your Patient Population
- Training
- Transferring To ISMMS
- Leaving ISMMS
- Walk-in Consultations

Resources

- Administration Offices
- Central Resources
- Institutional Policies & Manuals

COVID-19 Protocol Review Process for Clinical Research

What

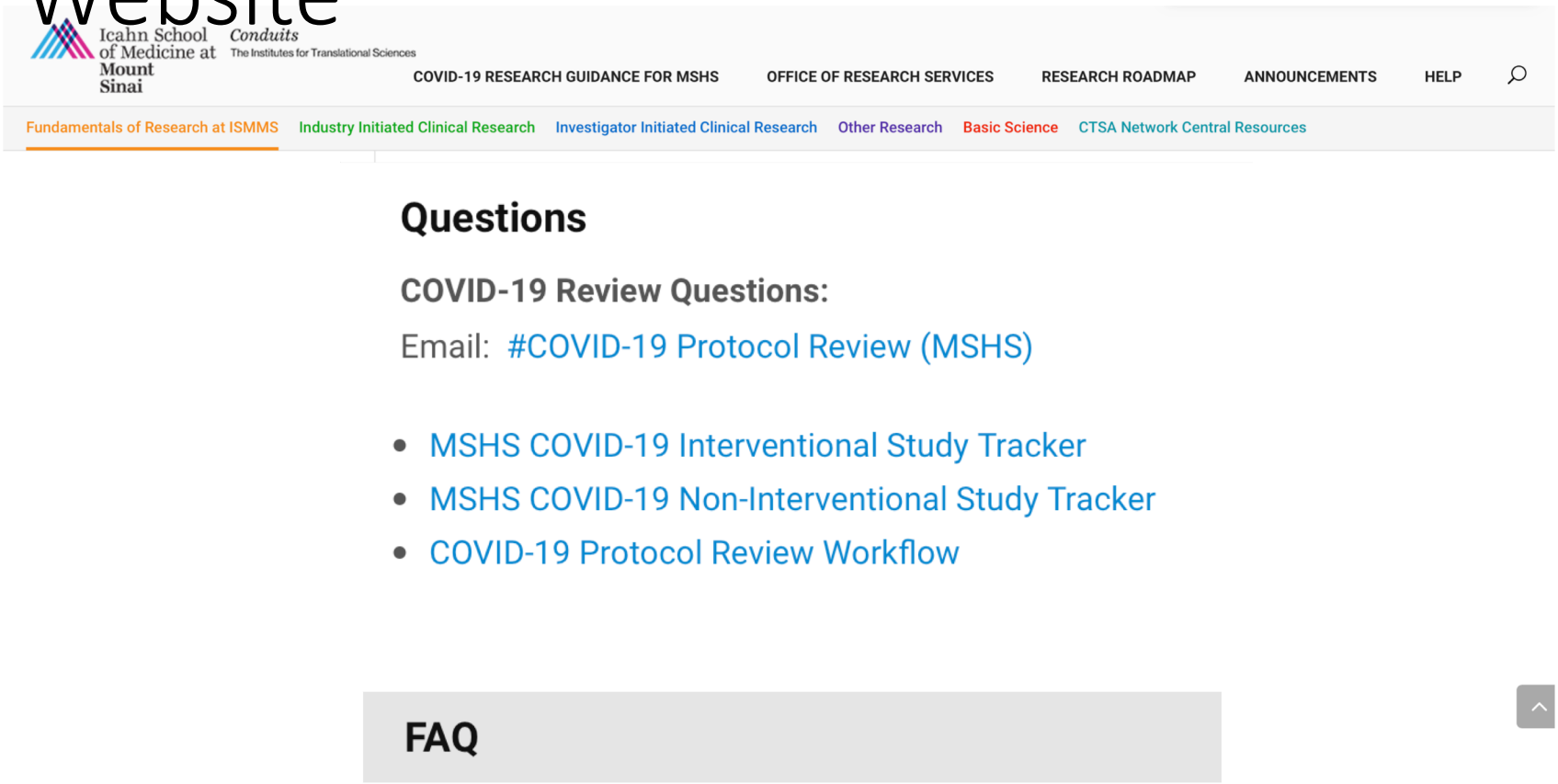
A COVID-19 protocol review committee has been established to enhance the research that is being performed at Mount Sinai and ensure that we can provide resources to accommodate as many meritorious studies as possible by minimizing redundancies and competition for finite resources and promoting team science and collaboration. Review is required for the following clinical research studies:

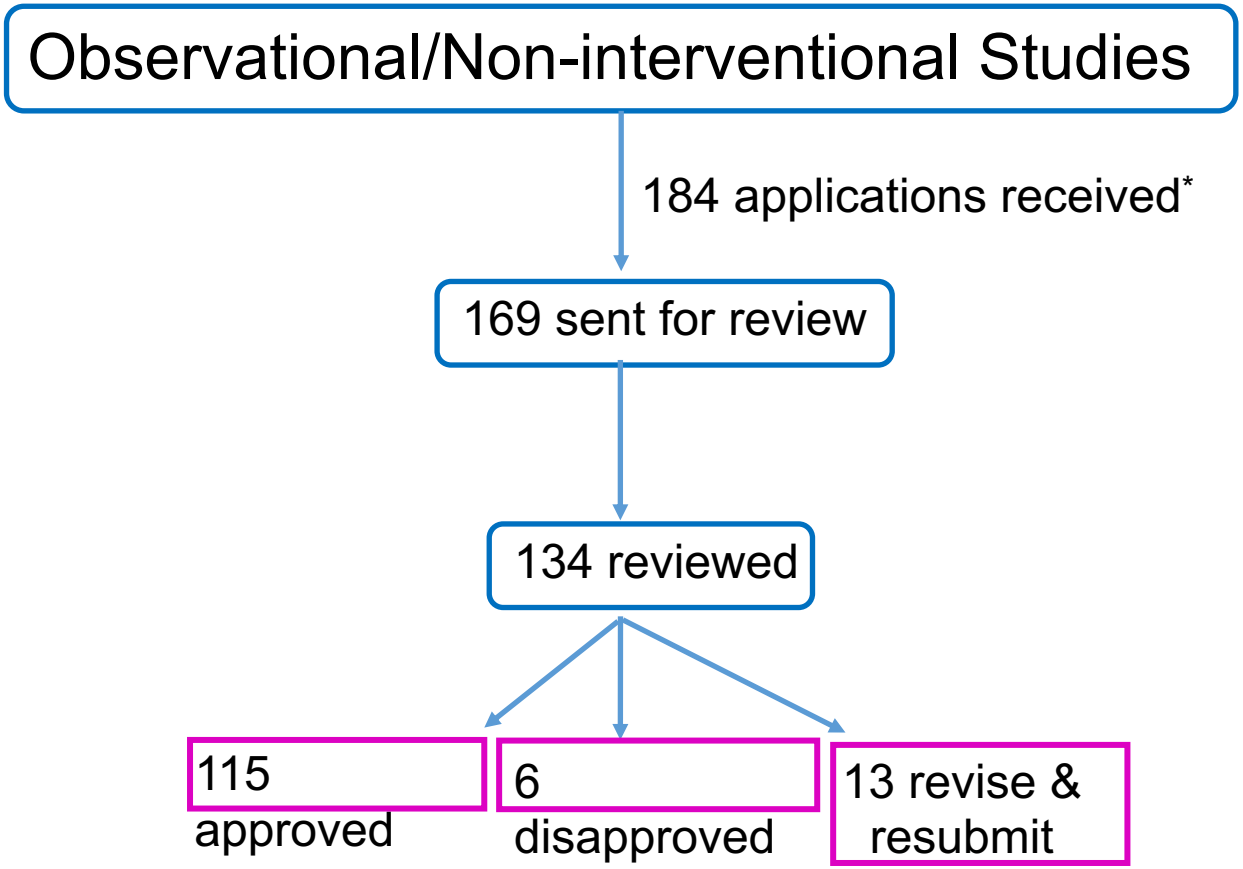
- Interventional/therapeutic trials
- Observational
- Retrospective
- Registry
- Correlative

COVID-19 Resources

- Research Guidance for MSHS
- FAQs for Research
- COVID-19 Protocol Review Process for Clinical Research
- Department Specific Guidance
- Town Hall Meetings
- Funding Opportunities
- General (non-research) COVID-19 Information

COVID-19 Protocol Questions Website




Observational/Non-interventional Studies
184 applications received*
169 sent for review
134 reviewed
115 approved
6 disapproved
13 revise & resubmit

* As of 5/12 @ 3PM

Phase 1 – Effective May 18th for at least two weeks:

- The safety of our patients and research staff is the overarching consideration in planning to resume clinical research involving in-person encounters
- Balancing maximal compliance with the protocol with need to minimize exposure of trial participants/staff to coronavirus
- Research always involves shared decision on risk/benefit with added considerations:
  - Understanding of COVID risk as well as traditional risks
  - Given underlying comorbidities, how vulnerable patients are to coronavirus infection and/or severe course if infected
  - Risk of exposure given travel to and from clinical site
- Feasibility issues needing consideration for in-person visits
  - How comfortable will patients be to travel to/from clinical site?
- In-person visits will be resumed in phases, effective May 18, 2020 we will resume essential clinical trials (e.g., ongoing intervention studies requiring study drug where risk/benefit decision supports such)
- When remote encounters aren't possible, study patients must be seen in an ambulatory practice area for screening.
  - 5 East 98th, Hess, CAM

Phase 1 – Effective May 18th for at least two weeks:

Ambulatory area guidance - Guidelines for Return to Practice.

- Note process for pre-visit screening and day of visit registration on page 10
  - Proactively reach out to patients 24 hours prior to their scheduled appointment to screen for COVID symptoms.
  - Provide guidance to arrive 20 minutes prior to scheduled visit given need for pre-visit screening
- The Health System's Visitor Policy applies – only patients for whom a support person has been deemed essential will be allowed one healthy visitor

https://www.mountsinai.org/about/covid19/staff-resources/policies

- Feasibility issues needing consideration for in-person visits
  - Does study require support from clinical services such as radiology, endoscopy, etc?
  - It is the responsibility of the study team to coordinate with the relevant ambulatory practice as needed to ensure these expectations are met

Phase 1 – Effective May 18th for at least two weeks:

- Study teams should continue to schedule encounters remotely whenever possible, particularly while NYC remains under a stay-in-place executive order

- Consider performing safety visits remotely and use of external lab/blood draw services for safety monitoring when possible

Phase 1 – Effective May 18th for at least two weeks:

Clinical Research Unit (CRU)

- Current policies and procedures will be revised to align with the Guidelines for Return to Practice.
- Patients must enter through the 5 East 98th Street entrance to be screened including a temperature check before coming to the CRU
- Walk-in phlebotomy will not be offered. All phlebotomy visits must be scheduled.
- Contact Joanne.Zephir@mssm.edu with any questions.

Phase 2 - Revisit in two weeks considering

- NYS and NYC Executive Orders
- Experience data from ambulatory practices
- Changes in hospital metrics