To: Dartmouth-Hitchcock & Dartmouth Research Community  
From: Dean Madden, PhD, Vice Provost for Research, Dartmouth College  
       Lionel Lewis, MD, Medical Director, Clinical Trials Office (CTO), Dartmouth-Hitchcock  
       Leigh Burgess, MHA, MEd, MA, Vice President Research Operations (VPRO), Dartmouth-Hitchcock  
Date: March 20, 2020  
Re: SARS-CoV-2/COVID-19 Update

In the face of the current national pandemic and the many potential unknowns associated with this unprecedented moment, working with our research community, senior leadership at Dartmouth-Hitchcock and Dartmouth College, as well as collaborators across other academic institutions we are sending you the following guidance for your human-subjects research.

The Dartmouth-Hitchcock and Dartmouth research administrations wish to assure the Dartmouth research community that the safety of research participants and study teams is paramount during the SARS-CoV-2/COVID-19 pandemic. Because information and processes involving the outbreak are quickly evolving, please monitor the Dartmouth-Hitchcock site, the Office of Research Operations (ORO) and Dartmouth SARS-CoV-2/COVID-19 websites and expect further notifications from Dartmouth-Hitchcock and Dartmouth administrations. Specific information is located in the Dartmouth-Hitchcock Policy on Conduct of Human Research Activities during SARS-CoV-2/COVID-19 Operations and also on the Dartmouth CPHS website. Additional information and guidance from the Federal Drug Administration (FDA) can also be found online.

The below guidance to the research community is grounded in the following overarching principles during this pandemic emergency:

1. We must minimize EVERY opportunity for COVID-19 transmission which necessarily means reducing face-to-face contact for our research participants and our research team members;

2. We wish to continue research activities that may be conducted using communication technologies that allows for needed interaction in a distance/remote manner; and further, want to enable changes in existing studies that allow for such alterations in study plan;

3. We wish to enable research activities directly aimed at the COVID-19 illness.

4. We will make ongoing decisions regarding our operational capacity based upon our medical center and institutions’ bandwidth to assure quality and safety within our research activities.

Mandatory Clinical Research Study Participant/Patient Screening for SARS-CoV-2/COVID-19 Exposure

Effective immediately, all study teams should be screening research participants who will have a face-to-face contact. This screening should be an ongoing process with each subsequent encounter, subject to further notice from Dartmouth-Hitchcock. The D-HH or CPHS IRB’s do not need to be notified of, or approve, the incorporation of mandatory screening into any clinical research protocol. Triage and management of research study participants who are patients and screen positive is outlined for Dartmouth-Hitchcock patients at the Dartmouth-Hitchcock site.
Face-to Face Patient Research Visits

All face-to-face research visits for patients already enrolled in therapeutic studies that are scheduled to receive ongoing required standard of care may continue, but in-person research visits for patients/participants in non-therapeutic studies must be postponed, or changed to remote format. If the currently approved protocol specifies in-person visits, a modification may be required for remote format. D-HH IRB and CPHS will fast-track review of such modifications. We will continue to reassess the need for this restriction or potential extension of the May 18 date. Furthermore, any research personnel who are not required for the delivery of direct patient care should not participate in any face-to-face visits.

On-Site Sponsor Monitoring Visits

Effective, March 23, 2020 all planned in-person face-to-face research Sponsor monitoring visits should be postponed until after May 18, 2020 or changed to remote monitoring where feasible as determined by the study PI. If the currently approved protocol specifies in-person monitoring visits, a modification may be required. D-HH IRB and CPHS will fast-track review of such modifications. We will continue to reassess the need for this restriction or potential extension of the May 18 date.

Non-Therapeutic Enrollment Holds

Effective March 23, 2020, institutional voluntary holds are placed on ALL enrollments that require in-person face-to-face interactions with research study participants for non-therapeutic studies. New patient enrollment in therapeutic clinical trials requiring face-to-face contact can occur in the setting of a scheduled standard of care visit. Clinical trials directly related to SARS-CoV-2 or COVID-19 are exempted from this policy. There are no restrictions on data analysis or non-face-to-face interactions (telephone, web-enabled conference, etc.) or survey work as long as these activities are in an approved protocol.

Preparation for Potential Study Holds/Revision of Study Activities

As knowledge about SARS-CoV-2/COVID-19 continues to develop, Principal Investigators should prepare contingency plans for active research projects. In preparation for more restrictive measure, PI’s should consider alternative plans for conducting research activities if staff are reduced or if research participant accessibility is constrained. This applies not only to direct interactions with research participants but also data and safety monitoring. For example, please consider the appropriateness of substituting phone calls or videoconferencing or other electronic/virtual forms of conducting study visits (e.g. FaceTime etc.). The D-HH IRB and Dartmouth CPHS are available for consultation on these issues. Contact information for the IRB is listed below.

Plans should consider:

- Necessary modifications to the approved research protocol, e.g., should there be a hold on all study activity or further restrictions on in-person face-to-face interactions. Contact the D-HH or CPHS IRB if you have questions;
• Distribution of Investigational products (for drugs, consult with Megan Brown, Director, D-H Investigational Pharmacy);
• Ongoing review of research data, such as lab results or other testing;
• Coordinating with collaborators and/or collaborating institutions, and
• Ongoing oversight on research activities.

**New Study Submissions Continuing to be Processed**

The Dartmouth-Hitchcock research operations teams (CTO, D-HH IRB, SPA and Grants Teams) will continue to process newly submitted studies and trials involving human participants but **NO NEW STUDIES** (Non-SARS-CoV-2/COVID-19 related) will open to enrollment until May 18, 2020, subject to the appeals process outlined below. We will continue to work on all studies and trials that are newly submitted and already processing in the pipeline, negotiate budgets, hold virtual resource meetings, etc. and will bring all studies/trials to the point to open, but will place them on voluntary hold to open on May 18, 2020. This date will be assessed in an ongoing manner.

**Sponsor/Funding Notifications**

*Please contact DHgrants@hitchcock.org (D-HH investigators) or sponsored.projects@dartmouth.edu (Dartmouth investigators) before reaching out to any external sponsors.* If you plan to temporarily suspend or revise any part of your study (enrollment, interventions, data/safety monitoring) due to SARS-CoV-2/COVID-19:

• For all externally-funded studies, it may be necessary to inform the funding source or the study lead PI;
• For any studies for which a Dartmouth-Hitchcock PI holds the IND/IDE, please contact the D-HH IRB
• For Dartmouth-Hitchcock funded studies, please inform your D-H Divisional Research Administrator for your Department and DHgrants@hitchcock.org

**IRB Approval**

D-H investigators and Dartmouth investigators conducting clinical research: please see the Policy on Conduct of Human Research Activities during SARS-CoV-2/COVID-19 Operations. D-HH IRB meetings are currently being held virtually and all CPHS and D-HH IRB operations are continuing.

**SARS-CoV-2/COVID-19 Research Studies**

Should Dartmouth-Hitchcock or Dartmouth College investigators wish to submit clinical research studies specifically focused on SARS-CoV-2/COVID-19, please email the following IRB personnel: Candi Loeb, Director D-HH IRB or Ann O’Hara, CPHS IRB Director, and Leigh Burgess to alert them of the submission. All SARS-CoV-2/COVID-19 studies will be placed as a priority and at the top of the IRB’s review queue.
Excerpt from the Current FDA Guidance

The FDA recognizes that the SARS-CoV-2/COVID-19 pandemic may impact the conduct of clinical trials of medical products, including drugs, devices and biological products. Challenges may arise, for example, from quarantines, site closures, travel limitations, interruptions to the supply chain for the investigational product, or other considerations if site personnel or trial subjects become infected with SARS-CoV-2, the virus that causes COVID-19. These challenges may lead to difficulties in conducting the clinical trials. The FDA is aware that protocol modifications may be required, and that there may be unavoidable protocol deviations due to SARS-CoV-2/COVID-19. Although the impact of SARS-CoV-2/COVID-19 on trials will vary depending on many factors, including the nature of disease under study, the trial design and in what region(s) the study is being conducted, the FDA outlines considerations to assist sponsors in assuring the safety of trial participants, maintaining compliance with good clinical practice and minimizing risks to trial integrity. Considerations recommended include, among others, sponsors evaluating alternative methods for assessments, like phone contacts or virtual visits and offering additional safety monitoring for those trial participants who may no longer have access to investigational product or the investigational site.

IRB Operations

Please be assured that D-HH IRB and Dartmouth CPHS operations will continue uninterrupted during the pandemic. Office personnel and committee Chairs will continue to be available even if working remotely. Contingency plans are already in place to conduct convened IRB meetings remotely.

Appeal Process to Continue Patient Contact in Non-Therapeutic Studies OR to Activate a New Non-SARS-CoV-2/COVID-19 related Study/ Trial

If you feel your:

(a) Non-therapeutic (if not related to SARS-CoV-2/COVID-19) should continue to permit face-to-face contact;

OR

(b) New trial (not related to SARS-CoV-2/COVID-19) should be activated,

THEN

One or more of the following criteria must apply, and the questions below should be submitted to begin the appeal process, which will be reviewed on a rolling basis.

Questions for Appeal:

- **Case (a):** Please state the reasoning why your non-therapeutic trial requiring face-to-face interaction needs to remain open and why this study does not entail additional risk of face-to-face interactions that would not otherwise occur in the face of normal clinical care.
- **Case (b):** Please state why activation of your new study/trial during the SARS-CoV-2/COVID-19 pandemic is justified.
• **Feasibility:** What research participants/patient population (Not SARS-CoV-2/COVID-19) will benefit and need this study/trial urgently?
• **Priority:** Does the study compete with an already open study?
• **Enrollment:** What is the projected enrollment in the first 3 months? 6 months?
• **Staffing:** How will the research team be organized/infrastructural supported to achieve enrollment in the study?
• **Risk:** How will you prevent face-to-face contact and minimize risk during the SARS-CoV-2/COVID-19 pandemic? How will you perform screening of potential research patients?

Appeals should be submitted to Lionel Lewis, Leigh Burgess, and Dean Madden and cc: Duane Compton. The appeal review will be performed by the VPR, VPRO, Medical Director CTO, Sue Reeves, and one designated Dartmouth-Hitchcock Clinical Chair. Please note COVID RESEARCH MEMO APPEAL in your email subject line and understand that the extraordinary situation may require delays in the review of appeals.

**Contact Information**

Lionel D. Lewis       Ldl@dartmouth.edu  
Leigh Burgess        Leigh.A.Burgess@hitchcock.org  
Candi Loeb           Candice.M.Loeb@hitchcock.org  
Dean Madden           Dean.R.Madden@dartmouth.edu  
Anne O’Hara         Ann.O’Hara@dartmouth.edu