Joint Guidance from UMCCTS & UMMS IRB
COVID-19 Guidance for Investigators
Addendum Version 7: November 25, 2020

UMMS has implemented aggressive measures to mitigate the spread of COVID-19. This document provides guidance to investigators regarding the conduct of human subjects research during this period. In an effort to more quickly communicate changes with study teams, this addendum will only address current issues/topics.

Items updated TODAY are flagged by yellow highlighting: New items in Addendum Version 7, November 25, 2020: Updated Section 2.1 to reflect new restrictions to patient and research subjects utilizing CRC space; Appendix B, Appendix C. Minor typographical and grammatical revisions.

Contacts for Questions:

For IRB-related questions:

Allison Blodgett, PhD, CIP, Director of IRB Operations ---------- allison.blodgett@umassmed.edu
Carol Bova, PhD, RN, IRB Committee Chair ---------- carol.bova@umassmed.edu
General Contact ----------irb@umassmed.edu

For OCR-related questions:

General Contact ----------clinicalresearch@umassmed.edu
Danielle Howard, Director Clinical Research Operations----------danielle.howard@umassmed.edu

For CRC-related questions:

General Contact ----------clinicaltrialsunit@umassmed.edu
Bethany Trainor, RN, Clinical Research Nurse Manager ---------- bethany.trainor@umassmed.edu

NOTICE:

Restrictions pertaining to human subjects-related research were lifted, effective June 23, 2020, with the exceptions noted in this document.

Study teams are reminded to watch for updates as they become available. Updates will continue to be posted to https://www.umassmed.edu/ccts/covid-19/

In-person interactions with participants in human subjects research studies currently remain open. However, COVID-19 cases are on the rise, and UMass Memorial has begun implementing changes to ensure patient and provider safety and to facilitate access to care.

While it is our hope that restrictions on human subjects-related research visits will not be necessary, we strongly encourage all investigators to plan for this possibility.

We thank all UMMS clinical research investigators and staff for working with us to ensure that we can continue to provide critical research resources, while ensuring that we do not burden our clinical partners during the provision of routine clinical care.

TIP:

For faster reference, try pressing “CTRL+F”, and entering a keyword relevant to the topic for which you

are searching. Otherwise, try holding "CTRL" and left clicking on the desired heading on the table of contents.

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1.0 Resumption of Research Activities

1.1 Adherence to Massachusetts state guidelines

Study teams are required to follow the Massachusetts state guidelines related to COVID-19. This includes travel restrictions for members of the study team, study participants, and anyone accompanying a study participant.

1.2 Adherence to institutional restrictions

Study teams are required to adhere to any clinical restrictions imposed by UMMHC or other applicable health care facilities being utilized. Departments will differ. Principal Investigators should help study teams navigate the research activity conduct in a manner that is respectful of clinical needs. These restrictions include any travel restrictions and policies put into place by the institutions, in addition to the state requirements.

1.3 Research Visits

Study teams should continue to conduct any visits for enrolled subjects remotely when possible, as allowed by the sponsor. As stated in Job Aid for Reopening Human Subjects Research – V1.0 – June 19, 2020, "Investigators are permitted to use remote procedures for enrolled subjects, such as phone or Zoom interviews, without obtaining prior approval from the IRB. These changes, however, must be submitted promptly as Reportable New Information, and they must be incorporated into the Investigator Study Plan at the next regularly scheduled Modification or Continuing Review."

Study teams are reminded that patients and study participants are expected to comply with all travel restrictions and policies (as described in sections 1.4)

1.4 Travel Restrictions and Policies / Visitor and Vendor Policies

1.4.1 UMMS Travel Policy

Study teams should regularly be reviewing the UMMS travel guidance page for the most up-to-date information regarding UMMS travel policies. This travel policy applies to all UMMS employees and nonclinical students at all sites, including individuals returning to work, new hires, vendors and visitors.

Study teams must continue to comply with restrictions to on-site visits by sponsors or outside study personnel as outlined in section 4.2.1.

Travel policies apply to both sponsored and personal travel.

Staff are reminded to discuss any upcoming travel plans with their supervisors to ensure adherence to institutional and state policies.

A reminder that there are currently three different travel forms at UMMS/UMMHC that are associated with different travel policies.

The form that you complete and the policy you follow depend on the location(s) in which you will work in the 14 days following return from travel to a 'high risk' area.

The UMMS Employee Travel Form should be filled out by employees who will be working in UMMS locations (e.g. medical school, LRB, ASC, Biotech 2, Clinical Research Center) in the 14 days following return. Until the 14-day quarantine period or test out option is complete, entry into UMMS restricted research areas (LRB, ASC, Biotech 2) is not permitted and ID badges will be deactivated.

The UMMHC Travel Form should be completed by school employees who will be working in clinical areas (UMMHC sites, Worcester Recovery Center and other healthcare facilities) in the 14 days following return. This includes dually employed physicians, residents, fellows and other clinical employees. UMass Memorial and other clinical sites follow the Massachusetts COVID-19 Travel Order and permit a return to work with a negative PCR test within 72 hours of arrival or testing on arrival with quarantine until a negative test is obtained.

1.4.2 Massachusetts Travel Order

Governor Baker has also issued COVID-19 Travel Orders which being updated regularly. A copy of Governor Baker's Travel Order can be found Here: https://www.mass.gov/info-details/covid-19-travel-order. Pursuant to that order, "All visitors entering Massachusetts, including returning residents, who do not meet an exemption, are required to:

- Complete the Massachusetts Travel Form prior to arrival, unless you are visiting from a lower-risk state as designated by the Department of Public Health.
- Quarantine for 14 days or produce a negative COVID-19 test result that has been administered up to 72-hours prior to your arrival in Massachusetts.

If your COVID-19 test result has not been received prior to arrival, visitors, and residents must quarantine until they receive a negative test result."

Further information regarding the Massachusetts Travel Order, as well as a list of exemptions, can be found at the link above.

1.4.3 Visitor and Vendor Policy

1.4.3.1 UMMS Visitor and Vendor Policy

UMMS is updating their visitor and vendor policy regularly. A copy of the current policy can be found here - https://www.umassmed.edu/parking/visitor-management/. As a reminder, visits by outside study personnel (monitors, sponsor, etc.) are not currently permitted. Should you need to request a possible exemption from the current research policy, please email Eric Stratton (eric.stratton@umassmed.edu) with the following information:

- OnCore/eIRB#'s
- PI
- Who is access being requesting access for?
- When they will need access (Requests should provide adequate time for review)

- Where will they need to access (UMMS space? UMMHC space? CRC?)
- Why is access being requested – that is, what is the rationale for an on site visit given the remote monitoring tools currently available?
- How will these individuals be traveling to the site?
- Are the individuals currently being tested?

Please note that an exemption is only from the current research policy, and that compliance with all current institutional and state policies is required.

1.4.3.1 UMMHC Visitor Policy

UMMHC is updating their visitor policy regularly. Please refer to the appropriate campus for the most current visitor policy.

- UMass Memorial Medical Center
- UMass Memorial Health Alliance – Clinton Hospital
- UMass Memorial – Marlborough Hospital

1.5 Can study staff retrieve equipment from subjects at the time of the subject's clinical visit?

Yes –So long as study staff continue to act within UMMHC/UMMS guidelines, retrieval of equipment is being permitted during normally scheduled visits, so long as it can be done safely. During this time study staff should ensure that all equipment is decontaminated according to institutional and study guidelines.

However, if equipment cannot be retrieved in the course of a normal visit, it should be delayed. Study staff may contact subjects to make arrangements to have them mail equipment back or to ask them to hold equipment until further notice. This would be reported to the IRB as a change to eliminate an apparent immediate hazard to subjects. If there is a specific sponsor that is concerned about equipment, please contact Danielle Howard in the Office of Clinical Research (danielle.howard@umassmed.edu).

1.6 Will influenza shots be required for staff this fall?

Yes – As communicated on September 14, 2020, all UMMS employees who plan to enter any of the medical school buildings for even one day from Oct. 1, 2020 through April 1, 2021, and all UMMS students, are required to receive a flu vaccine by Dec. 15, 2020.

Please note:

- UMMS will offer influenza vaccinations free of charge to all employees and students.
- Flu shots will be given by appointment only; no drop-ins are allowed.
- Individuals who receive a flu vaccine through services other than Employee or Student Health Services (e.g. physician's office or pharmacy) must provide proof of immunization to EHS/SHS by Dec. 15, 2020.
- Remote employees who will not be accessing the campus during the window listed above are not required to receive the influenza vaccination, however it is still strongly encouraged.

Further instructions and information can be found with the official communication – here.

1.7 Proper use of PPE

Effective November 10, 2020, UMMHC has approved a new policy for personal protective equipment (PPE) requirements for all caregivers.

What are the main components of the new policy?

- The use of surgical masks is required in all clinical and non-clinical settings, unless you are alone in an enclosed office.
- Only surgical masks provided by UMass Memorial will be allowed for use. Homemade masks cannot be used either alone or in combination with another mask.
- Eye protection is required for clinical care areas and is strongly recommended in all non-clinical care areas.
- Caregivers who wear eyeglasses will be required to use additional eye protection, as eyeglasses do not provide adequate side protection.
- Procedure or condition-specific guidance for PPE should still be followed as appropriate, i.e., C.diff., MRSA, central line placement, etc.

What do I need to know about eye protection?

- Acceptable eye protection for clinical areas:
  - For COVID-19 positive patients or patients under investigation (PUI) – Face shield or goggles
  - For COVID-19 negative patients or surveillance test-pending patients, as well as those deemed at low risk for COVID-19 based on symptoms – Face shield, goggles, two-piece eye protection or safety glasses
- Acceptable eye protection for non-clinical areas include face shield, goggles, two-piece eye protection, or safety glasses
- Providers should obtain the appropriate eye protection from any inpatient floor or any clinic.
- All eye protection is meant to be reused and should NOT be used as a single use item. It should be replaced only if the eye protection becomes damaged or is soiled and unable to be adequately wiped down.

What is the definition of clinical care area?

Clinical care area is defined as an area used for patient care and treatment or is regularly accessed by patients when visiting a UMass Memorial site for any purpose. Clinical care areas also include, but are not limited to, patient rooms, inpatient units, ambulatory clinics and waiting areas, clinical laboratories, elevators, lobbies, food service areas/cafeterias and other areas regularly accessed by patients when visiting any UMass Memorial site.

Please note, proper eye protection will now be required to be used in the CRC.

Studies teams should obtain PPE through their departments and ensure adherence to UMMHC and other institutional requirements. If they have questions about ordering, please contact Eric Stratton (eric.stratton@umassmed.edu).

2.0 Clinical Research Center

2.1 Will the CRC be accessible during this time?

Yes – the CRC is accessible, and the facilities and staff continue to support research protocols. Access is limited to those individuals that are required to meet the staffing needs of research protocols. For questions about the use of the CRC laboratory, see section 2.2. All staff who are accessing the CRC one or more days a week must undergo weekly screening for COVID per UMMS policy and must adhere to proper use of PPE, including proper eye protection.

Use of the CRC space should be reserved in advance using the UMMS Room Scheduler as the primary method to request all space. This will allow research staff to view available space and request specific CRC rooms and resources. All requests should be submitted at least 2 business days in advance, and will be reviewed by the CRC team. Please contact Bethany Trainor (see Contacts) with any CRC related questions.

Study teams are required to prescreen all patients and study participants who will be seen in the CRC and must utilize the CRC phone screening script (Current Version – Version 2 / 07/31/2020). Study teams may request a copy of this script by emailing Bethany Trainor (see Contacts) or Eric Stratton (Eric.Stratton@umassmed.edu). ***All study participants MUST adhere to both state and institutional travel policies.***

As of November 21, VT and HI are the only states designated as "low risk" on the MA travel guidance. Until further notice, only the following may be seen in the CRC:

- Clinic patients, for clinical care, from the New England states (CT, RI, MA, VT, NH, ME) only.
- Research subjects from states from MA and VT unless an exemption has been received from Bethany Trainor.

For Research subjects from states other than VT and MA who are already on clinical trials, study teams are asked to strongly consider shifting collection of safety labs, routine research visits, and sending research medications remotely, if at all possible.

Study teams are reminded to discuss and report these changes with sponsors and the IRB as required. Additionally, the Office of Clinical Research will have no control over billing conducted at outside laboratories. Collection of lab certifications, reference ranges, will also likely be required by study teams, along with possibly adding labs to the 1572 where applicable.

Please contact Bethany Trainor (see Contacts) for an exemption for the visit if that is not possible.

2.2 Will the CRC Laboratory be accessible during this time?

In the event that laboratory access is required for processing, please contact either Bethany Trainor or clinicaltrialsunit@umassmed.edu (See Contacts) to arrange.

All samples that had previously been transported from the CRC to the Biotech 2 laboratory have been returned. This transfer occurred over two days (7/31/2020 & 8/3/2020) to minimize temperature fluctuations in the CRC -80 freezer. A note to file has been distributed to the CRPG mailing list for use as

study documentation. Study teams may contact Bethany Trainor (see Contacts) to request a copy of the note to file, or with any questions regarding the transfer.

Samples from patients and participants who are either confirmed or suspected of being COVID+ cannot be processed in the CRC laboratory; study teams should arrange sample collection and processing by the Biorepository by contacting Karl Simin at Karl.Simin@umassmed.edu at least 2 business days in advance.

3.0 IRB Reporting / Review

3.1 Standard Guidance

With the resumption of research activities on the campus effective June 23, 2020, standard guidance for research activities should be followed unless otherwise stated. Questions, concerns, or requests for clarifications should be sent to the appropriate individual listed in the Contacts section.

3.2 CITI Training

Previously, relative to the date an individual was added as study staff in eIRB, the UMMS IRB had been permitting a 30-day grace period for back-up staff to complete required online CITI training. However, with the lifting of restrictions on June 23, 2020, all study staff are expected to have appropriate training before being added as study staff in eIRB.

3.3 Has UMMS HRPP resumed conducting audits?

Yes - HRPP has resumed conducting audits. The CCTS Quality Improvement Manager will be communicating directly with study teams to schedule and conduct any audits that had been postponed due to COVID-19. If you needs to request an audit of a study, or you have questions about the audit process, please contact Eric Stratton (eric.stratton@umassmed.edu).

In order to adhere with social distancing guidelines and remote work schedules, debriefings following the QA audit may be scheduled via zoom. In-person access to research records is still required during the QA audit.

4.0 Data Management / Services

4.1 Can DocuSign be used for research records, logs, notes-to-file?

At this time, the UMMS version of DocuSign is not considered to be part 11 compliant, and therefore may not be used for research records, logs, or notes-to-file that require compliance with FDA 21 CFR Part 11.

We are currently working on setting up a part 11 compliant DocuSign system, and further guidance will be released when this becomes available. Please note that there will be additional charges to sponsors and study teams for use of the part 11 DocuSign system.

4.2 Monitoring

4.2.1 When will site initation / study monitoring / close-out be allowed to resume in-person visits?

While some access to the campus by outside essential personnel has been eased at this time, *restrictions for visits by sponsor/CRO personnel will remain restricted until further notice*. At this time, all

monitoring activities should continue to take place remotely. The Office of Clinical Research will communicate to study teams once these types of visits are being permitted to take place in-person.

Questions or concerns regarding site initiation / monitoring / close-out may be sent to Eric Stratton, Quality Improvement Manager, CCTS (Eric.Stratton@umassmed.edu).

4.2.2 What tools are available to assist in remote monitoring?

The following resources are available to teams utilizing remote monitoring:

- Epic
  - Epic Research Job Aids listed on the OCR webpage
  - EpicCare Link Job Aid – Research Coordinator Workflow – Updated Aug 13, 2020 (intranet access required)

  EpicCare Requests should be submitted with a reasonable amount of notice prior to the remote monitoring visit. Remote monitoring of Epic records should only be conducted through EpicCare Link, and not through Zoom or WebEx.

  Please note that only documents directly related to treatment should be uploaded into Epic, as this is the patient's legal medical record. Items such as patient diaries, questionnaires, and logs, for example, should not be uploaded into Epic.

- Zoom
  - The Medical School uses the HIPAA compliant version of Zoom exclusively. Zoom may be used to share screens for remote monitoring and review of documents not available in Epic. If using Zoom, study teams should ensure that both a passcode and waiting room are used to ensure that unauthorized persons are not able to join the meeting. Zoom is available for free to all UMass Medical School or Commonwealth Medicine employees with a @umassmed.edu email. Accounts can be requested here (UMMS Intranet).
- WebEx
  - For UMMHC personnel, HIPAA compliant WebEx is available for use for review of documents not available in Epic. Please note that there is a cost to the department per account. Study teams may request an account here (UMMHC Intranet).

NOTE: For study teams that are working to review regulatory or subject binders via HIPAA compliant Zoom or WebEx, an external webcam can be set up to be aimed downward at the binder as a document reader to help facilitate faster, remote review of documents.

- MoveIT
  - MoveIT is a secure file transfer software provided through UMMS IT that may be utilized if approved in a study's monitoring plan. PHI should not be shared unless it has been specifically approved by the IRB in the study ISP and consent. Additional information about MoveIT can be found here: https://www.umassmed.edu/it/security/secure-data-transfer-guidance/

4.2.3 What should I do if monitors require access/information from IDS?

In person access to IDS remains restricted. At this time remote monitoring visits with IDS must be scheduled in advance – ideally two or more weeks in advance. All requests should include the following:

- Date IDS documents will be needed
- Where/to whom documents are to be sent
- List of all documents from IDS which the CRA is requesting
- IDS cannot always honor requests for temperature logs from the present month; please let the CRAs know that the sponsor, PI and study team would be made aware of any excursions
- Effective October 30, 2020, the IDS policy around returns will be strictly enforced. IDS will be destroying all returned drugs on site at the University and Memorial campuses.
- IDS is not able to accommodate screen sharing or video visits; please make the CRAs aware of this limitation.

Direct all inquiries for monitor visits, subject visits, etc. to: mailto:ids@umassmemorial.org

4.3 Where has the FastTRAcs option gone?

TRAcs should continue to be used for all studies. Due to decreased urgency for implementing COVID-19 studies at UMMS, the COVID-19 FastTRAcs option in TRAcs has been disabled. TRAcs will continue to ask you to identify COVID-19 related study requests in order to prioritize requests, but requests for services for COVID-19 studies will be entered using the usual menu options.

If you have a COVID-19 study that requires an urgent response and you don't have the required documents to complete the request, please enter as much information as you can into TRAcs and contact the UMCCTS Clinical Research Navigator, Ann Han (ann.han@umassmed.edu).

4.4 Interpreter Services for Research Activities

Study teams should be aware that the visitor restrictions at UMass extend to interpreter services (both clinical and research). This may affect a study team's ability to conduct the short form informed consent process. Over the phone and video interpreter services for research are available, however the LanguageLine interpreter services for research studies is unable to provide a witness signature on the short form, which is required for FDA-regulated research (45 CFR §46.117(b)(2) & 21 CFR §50.27(b)(2)) as well as research conducted under the purview of UMMS (HRP-802).

There is a local interpreter service provider who has a HIPAA compliant zoom platform and is willing to provide remote video services and coordinate for a witness signature via fax or picture, however, study teams will need to provide as much lead time as possible before the informed consent meeting. Study teams will also need to be able to fax or e-mail a copy of the informed consent and short form for the interpreter.

Please be aware that some languages will be easier to provide on short turnaround than others. Study teams should plan accordingly.

In addition, it would also be possible to use a subject's family member observing remotely via video, but study team's will need to figure out the logistics of collecting their signature on the short form.

4.5 How will laboratory accreditations/certifications be impacted?

At this time it is not anticipated that there will be any impact on the Clinical Laboratory Improvement Amendments (CLIA) accreditation, currently not set to expire until 2021.

The College of American Pathologists (CAP) certification had previously been postponed due to COVID-19. It has since been conducted, and the current laboratory certifications can be found here on the UMMHC Clinical and Anatomic Pathology page here (UMMHC Hub).

More information on this change can be found here:
https://www.cap.org/laboratory-improvement/news-and-updates/cap-inspections-covid-19-update

Appendix A: Relevant Links

Massachusetts COVID-19 Travel Order https://www.mass.gov/info-details/covid-19-travel-order
UMMS - Corona Virus Updates https://umassmed.edu/coronavirus
UMMHC – Turning the Tide on COVID-19 https://www.umassmemorialhealthcare.org/turning-the-tide-covid-19
UMMS IRB https://www.umassmed.edu/ccts/irb/
UMMS CCTS - Coronavirus (COVID-19) Related Guidance to Researchers https://www.umassmed.edu/ccts/covid-19/
UMMS OSP - COVID-19 Resources for Researchers https://www.umassmed.edu/research/sponsored-programs/covid-19-resources-for-researchers/
Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html
FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-guidance-conduct-clinical-trials-medical-products-during-covid-19-pandemic
Epic Research Job Aids (https://www.umassmed.edu/ocr/epic-research-job-aids/)
COVID-19 Collaboration Platform (https://covidcp.org/)
March 18, 2020 – Extension of Professional Licensure Order https://www.mass.gov/doc/march-18-2020-extension-of-professional-licensure-order/download
CAP Inspections COVID-19 Update https://www.cap.org/laboratory-improvement/news-and-updates/cap-inspections-covid-19-update
UMMS Return to Work Resources https://www.umassmed.edu/coronavirus/return-to-work-resources/
New mandatory flu immunization policy at UMMS https://www.umassmed.edu/news/news-archives/2020/09/new-mandatory-flu-immunization-policy-at-umms/
EpicCare Link – Research Coordinator Workflow https://teams.umassmemorial.org/sites/jobaids/JobAids/Shared%20Documents/Epic%20Carelink%20for%20Study%20Monitor.pdf
UMMHC - New policy for personal protective equipment (PPE) requirements for all caregivers https://www.umassmemorialhub.org/documents/personal-protective-equipment-requirements-covid-19

Appendix B: Prior UMCCTS Memos

Note: Items below are hyperlinked with the exception of items marked with an asterisk (*).

03/12/2020	Changes in Clinical Research Operations due to COVID19
03/12/2020	UMass Memorial Health Care 2019 Novel Coronavirus (COVID-19) Ambulatory Clinic/Practice Procedure AMBULATORY CLINICS v. 03 02 2020*
03/12/2020	COVID19-IRB Updates
03/13/2020	COVID 19 Clinical Research Memo March 13
03/16/2020	Joint UMCCTS IRB COVID19 Guidance 16mar2020 (Version 1)
03/17/2020	Joint UMCCTS IRB COVID19 Guidance 17mar2020 (Version 2)
03/18/2020	Joint UMCCTS IRB COVID19 Guidance 18mar2020 (Version 3)
03/20/2020	Joint UMCCTS IRB COVID19 Guidance 20mar2020 (Version 4)
03/24/2020	Joint UMCCTS IRB COVID19 Guidance 24mar2020 (Version 5)
03/31/2020	HRP-803 Investigator Guidance - Documentation of Informed Consent- Temporary Exceptions for COVID19 Therapeutic Trials
04/02/2020	Joint UMCCTS IRB COVID19 Guidance 02apr2020 (Version 6)
04/03/2020	CRC Protected Unit Opening Today
04/03/2020	Changes in Clinical Research and Operations due to COVID 19 [Update 1]
04/13/2020	Joint UMCCTS IRB COVID19 Guidance 13apr2020 (Version 7)
04/28/2020	Joint UMCCTS IRB COVID19 Guidance 28apr2020 (Version 8)
04/29/2020	Changes in Clinical Research and Operations due to COVID 19 [Update 2]
05/14/2020	Clinical Research Ramp Up Memo
06/01/2020	Joint UMCCTS IRB COVID19 Guidance 01jun2020 (Version 9)
06/15/2020	Clinical Research Phase II June 2020
06/19/2020	Job Aid for Reopening Human Subjects Research – V1.0 – June 19, 2020
07/20/2020	Joint UMCCTS IRB COVID19 Guidance 20jul2020 (Addendum Version 1)
08/06/2020	Joint UMCCTS IRB COVID19 Guidance 06aug2020 (Addendum Version 2)
08/13/2020	Joint UMCCTS IRB COVID19 Guidance 13aug2020 (Addendum Version 3)
10/05/2020	Joint UMCCTS IRB COVID19 Guidance 05oct2020 (Addendum Version 4)
11/12/2020	Joint UMCCTS IRB COVID19 Guidance 12nov2020 (Addendum Version 5)
11/18/2020	Joint UMCCTS IRB COVID19 Guidance 18nov2020 (Addendum Version 6)

Appendix C: Document History

Version 1	July 20, 2020	Initial
Version 2	August 06, 2020	Added highlighting; section 1.4 and subsections addressing travel restrictions and policies; Added section 4.2.2 addressing tools are available to assist in remote monitoring; Added section 4.4 addressing interpreter services for research activities; Added appendices A, B, and C; Updated section 2.1, 2.2, 4.5, appendices A (updated links), B (directly linked to documents), and C.
Version 3	August 12, 2020	Updated section 1.4 and subsections addressing travel restrictions and policies; Updated section 4.2.2 addressing tools are available to assist in remote monitoring; Updated appendices A, B, and C
Version 4	October 5, 2020	Added section 1.6 re influenza policy; section 4.2.3 re monitoring of IDS; Updated section 1.4.1 re UMMS Travel Policy; section 3.3 re QA audits, section 4.2.2 re remote monitoring tools; Appendix A, Appendix B, Appendix C.
Version 5	November 12, 2020	Added Section 1.4.3 Visitor and Vendor Policy; Section 1.7 Proper use of PPE per new UMMHC requirements; Updated section 2.1 to reflect need for screening of staff working in CRC one or more days a week; Appendix A, Appendix B, Appendix C. Minor typographical and grammatical revisions.
Version 6	November 18, 2020	Updated Notice to reflect recommendation for planning for possible restrictions; section 1.7 and section 2.1 for clarification re new PPE requirements; Appendix A, Appendix B, Appendix C. Minor typographical and grammatical revisions.
Version 7	November 25, 2020	Updated Section 2.1 to reflect new restrictions to patient and research subjects utilizing CRC space. Appendix B, Appendix C. Minor typographical and grammatical revisions.