March 27, 2020

COVID-19 Pandemic
Clinical Research FAQs

What type of research is permitted during the COVID-19 pandemic?

- Under certain circumstances:
  - Minimal Risk
  - Greater than Minimal Risk (potential for Direct Therapeutic Benefit to Research Subject

What activities are not considered Research as defined by the Department of Health and Human Services?

- Public health surveillance activities conducted by a *public health authority*, limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance.
  - Including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority.
  - Including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products.
  - Including those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

Under what circumstances can minimal risk studies continue?

- If:
  - Follow up visits do not require research subjects to be present at UMB or UMMC for follow up, except for urgent conditions;
  - Research subjects are enrolled or continued to be followed solely through telemedicine or other remote mechanisms; and
  - Research subjects may be enrolled directly if the condition being studied is part of routine care and enrollment/follow up is performed ONLY by clinical staff providing clinical care and thus designated as clinically essential for pandemic conditions.

Under what circumstances can greater than minimal risk (potential for direct therapeutic benefit to research subject) studies continue?

- If:
  - Research subjects already enrolled may continue in the trial if removal from the trial would negatively impact the safety or welfare of the research subject;
  - Continuing new enrollment in clinical trials is permitted ONLY if there is potential for CRITICAL therapeutic benefit for specific disease processes.

An example is cancer chemotherapy type trials. Investigators who believe their studies meet such criteria require approval of Chairperson, Academic Dean of Research, Program director or his/her designee to affirm appropriateness of EACH trial. New trials for critical therapeutic trials may be initiated under the same approval process

- Continuing new enrollment in and initiation of new clinical trials is not permitted for NON-CRITICAL therapeutic benefit.

Will therapeutic trials for COVID-19 receive priority in ethical review?

- Yes

Under what circumstances can greater than minimal risk (no potential for direct therapeutic benefit to research subject) studies continue?

- None, this category of research is not permitted.

Under what circumstances can Community Research (nursing homes, senior centers, and other community facilitates) continue:

- All UMB research projects in these locations are paused, unless:
  - Subject safety is endangered by NOT performing a necessary intervention, monitoring a treatment, etc. in an ongoing trial: OR
  - The research intervention is performed by the permanent staff of the facility under the guidance of UMB research staff but which does not require the UMB staff to enter the facility.

How should I be supporting our research subjects?

- Communicate with research subjects often to discuss concerns; and
- Frequently follow up with research subjects to determine the feasibility of continuing individual protocols.

What about the study sponsors?

- PIs should be communicating with their study sponsors regarding any interruptions or changes to approved research

What if my study involves/requires distribution of investigational products?

- Contact the Investigation Drug Service at mlee1@umm.edu

How should I document/report changes to approved research?

- For UMB IRB approved research:
  - Modifications to previously approved research should be submitted to the UMB IRB only if changes in proposed research activities will result in increased risk to research subjects.
  - Any changes taken to eliminate immediate apparent hazards to research subjects or staff should be documented locally and reported in aggregate at continuing review.
- For External IRB approved research:

- Contact your IRB of record to determine their requirements for documenting changes during the pandemic.

What about Reportable New Information?

- RNI that meets current reporting guidelines should be submitted appropriately.
  - For UMB IRB approved research, see the HRPO website for further guidance: "HRP-105, Reportable New Information" https://www.umaryland.edu/hrp/for-researchers/study-conduct

What if my research team includes students and/or trainees?

- Students and trainees are not permitted to participate in any research that exposes them to COVID-19 risk and must follow UMB's Step 2 Policy and Clinical Activities Guidance.

What if someone on my research team is exhibiting signs of COVID-19?

- No one with signs, symptoms of COVID or a recent high-risk exposure should be involved in clinical research.

What if a research participant is exhibiting signs of COVID-19?

- No one with signs, symptoms of COVID or a recent high-risk exposure should be involved in clinical research

My research is international, does this apply?

- Yes, but:
  - Directives from local ethics committees or Ministries of Health may supersede this guidance.
  - Follow local in-country directives but keep the UMB IRB informed.

My research is approved by an external IRB, does this apply?

- Yes, and:
  - Check with your IRB for any additional guidance they may have

Where can I find the NIH guidance for clinical trials and human subjects studies?

- Guidance for NIH-funded Clinical Trials and Human Subjects Studies Affected by COVID-19 (NOT-OD-20-087) can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-087.html
- Flexibilities Available to Applicants and Recipients of Federal Financial Assistance Affected by COVID-19 (NOT-OD-20-086 can be found at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-086.html

Where can I find the FDA guidance for clinical trials and human subjects studies?

- Coronavirus (COVID-19) Update: FDA Issues Guidance for Conducting Clinical Trials can be found at: https://www.fda.gov/news-events/press-

announcements/coronavirus-covid-19-update-fda-issues-guidance-conducting-clinical-trials

- FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Pandemic can be found here: https://www.fda.gov/media/136238/download

What general considerations for informed consent should be considered?

- The elements of informed consent, including discussion of the risks and benefits, can be done over the phone
- time for questions needs to be provided and can be done over the phone

Is remote consenting allowed?

- Yes, consent may be obtained by telephone if research team members:
  - Document how the consent form was transmitted to the participant (by email, fax, mail, etc.)
  - Document how signature was obtained, for example:
    - ❖ electronic signature
    - ❖ faxed, scanned and emailed, or mailed back to the study team
    - ❖ photograph of signature/signature page send back to study team
  - FDA regulated the research subject must also date the form.

What do I need to document if I can't obtain a participant signature on an informed consent document?

- Documentation of the method used for communication with the participant;
- Means by which agreement was communicated;
- Documentation that no imaging technology was available to capture a signed consent form;
- A witness to the process (for more than minimal risk research); AND
- A witness signature
- For FDA regulated research the witness should also date the form.

Is the request for research subjects to not sign a consent form, a waiver of documentation?

- No.
- Rely upon the FDA guidance below:
  - July 2014 FDA guidance on informed consent states:
    - ❖ Physically Challenged Subjects A person who is physically challenged (for example, physically unable to talk or write or has hearing or visual loss) can enroll in a clinical investigation if competent and able to signal consent when consistent with applicable State law. The records relating to the clinical investigation must include documentation of the informed consent process (21 CFR 50.27) unless excepted under 21 CFR 56.109(c). FDA recommends that the subject's case history include a description of the specific means by which the prospective subject communicated agreement to take part in the clinical investigation

and how questions were answered. FDA recommends that investigators accommodate the specific needs of the study population.

- ✓ For example, the investigator could use an audio tape of the contents of the consent form or a form with enlarged font, depending on the level of impairment of the visually impaired subjects.

How do I obtain consent from COVID-19 patients in a containment unit or quarantined space or a physically unavailable LAR?

- Have the informed consent form provided to the participant in the containment unit or quarantined space; OR
- Provide an electronic version of the consent to the participant via a tablet, computer or other device; OR
- Provide an audio recording of the informed consent; OR
- Reading the entire consent over the phone is an option, but only if no other option is available.

How do I conduct the process of informed consent with research subjects or LARs?

- The consent form should be reviewed and discussed with the patient and questions answered.
- The clinical team may conduct the research consenting process if it is documented that they were educated in what the research involves so that they can knowledgeably consent someone to the research.
- If the patient agrees to participate, the consent form should be signed.
- Once the participant signs the consent form it can be uploaded, if possible, to a system such as REDCap or a picture can be taken of it, sent to the study team and then the form discarded.
- If it is not possible to obtain a digital image of the signed page, the study team should
  - Document that an imaging device was not available and
  - Have a witness to the consent process.
- The entire process must be documented in the study records.
  - Note: A witness to any consent process under these circumstances would be a best practice.

Do I need to re-consent research subjects about changes?

- Re-consent is not necessary unless the changes to the research are such that the original consent is no longer valid.
  - For example, reconsent is not necessary when changing from clinic visits to remote visits.
- Subjects should be notified of changes to the research via a letter or other form of communication.
- This does not need to be reported to the IRB unless the changes increase the risk of harm to research subjects

Are telemedicine activities compliant with HIPAA?

- Yes
  - Telemedicine is an acceptable option where it can adequately replace an in-person physical examination.
  - For the purpose of HIPAA, HHS has issued a notice waiving penalties for non-compliance with HIPAA. OCR will exercise its enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the HIPAA. Rules against covered health care providers in connection with the good faith provision of telehealth during the COVID-19 nationwide public health emergency. This notification is effective immediately.
  - Please see the full announcement: https://www.hhs.gov/hipaa/for-professionals/special-topics/emergency-preparedness/notification-enforcement-discretion-telehealth/index.html

What about HIPAA Compliance and Covered Entities?

- OCR has published a bulletin advising covered entities of further flexibilities available to them as well as obligations that remain in effect under HIPAA as they respond to crises or emergencies at https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf - PDF.

If I have additional questions or want more information, who should I contact?

- Questions or concerns regarding human subjects research may be addressed to:
  - HRPO Director, Dr. Julie Doherty: hrpo@umaryland.edu, 410-706-5037
  - IRB Chair, Dr. Robert Rosenthal: rrosenthal@som.umaryland.edu, 301-461-3969