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Subject: Coronavirus and Clinical Research – March 12, 2020

With the recent outbreak and spread of the COVID-19 virus, Research Administration has developed this contingency plan to ensure the safety of our research participants and the research team members who work at Dignity Health, Barrow Neurological Institute and Norton Thoracic Institute. Our secondary goal remains to preserve the scientific integrity of all research protocols and sustain clinical research operations.

All Research teams should put in place the following actions:

Limit Group Meetings and Social Gatherings

Until further notice, it is prudent to limit the number of onsite group/team meetings as well as social gatherings to prevent the spread and exposure to COVID-19. It is recommended that all group meetings are converted to remote teleconferences or webinars unless essential for continued business operations.

Telephonic Screening of Research Participants

All study teams should immediately implement procedures to incorporate mandatory telephone screening prior to scheduled study visits at a Dignity Health facility. The Center for Disease Control (CDC) screening algorithm for COVID-19 is utilized by Dignity Health. Such questions relate to recent travel, contacts, and current symptoms; however, the algorithm is rapidly evolving. To ensure the latest version of Dignity Health approved screening questions is applied please reference the Cerner COVID-19 checklist found within the electronic medical record (document within the EMR accordingly) to decide if a research visit should proceed as scheduled.

In the event the telephonic screening participant meets criteria for isolation guidelines, they should be instructed to contact their primary care physician for further evaluation. The research visit should be postponed at least 14 days with a follow-up telephonic screening call to assess symptoms prior to the rescheduled visit. Study personnel should ensure documentation within the EMR for all such correspondence.

The incorporation of this mandatory telephonic screening procedure does NOT require IRB approval.

Onsite Research Visits

The screening algorithm should proceed at every research encounter prior to any scheduled protocol events. If a participant appears symptomatic, they should be isolated and provided with a mask until clinical personnel can determine next steps. If considered appropriate, the symptomatic participant can be transported to the emergency department for further evaluation and treatment.

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Environmental Safety Script

Details of the steps we have taken to make our research environments as safe as possible is summarized as follows.

- Maintain regular housekeeping practices, including routine cleaning and disinfecting of surfaces, equipment and other elements of the work environment using EPA approved disinfectant with claims against emerging viral pathogens.
- Providing tissues to promote respiratory etiquette, including covering coughs and sneezes with deposit in 'no touch' trash cans.
- Promote frequent and thorough hand washing. If soap and running water are not immediately available, alcohol-based hand rubs containing at least 60% alcohol will be provided.
- Employee self-monitoring for signs and symptoms of COVID-19 and international business travel; if present quarantine procedures are in effect for 14 days.
- Employees with any signs of illness are required to stay home; if out of work more than 3 days release from employee health is required before entering the work environment.
- Prompt identification and isolation of potentially infectious individuals.
- Personal Protective Equipment consistently and properly worn when required.
- Personal Protective Equipment properly removed, cleaned and stored or disposed of to avoid contamination of self, others, or the environment.
- Training to employees on COVID-19 infection prevention methods.
- Monitoring the CDC COVID-19 website and state/local health department websites for the latest information and implementation guidelines.
- Providing access to patients and visitors with current and updated COVID-19 facility preparedness plans.
- Screening of patients and visitors for symptoms before entering the facility.
- Limiting visitor access (no more than 2 visitors per patient per day) and non-employed external healthcare representatives (supply vendors, research monitors, etc).
- Limiting/postponing non-essential business travel.
- Cancelling large group in person meetings and converting essential business discussions to telecom meetings.

Reinforcement of these steps is encouraged to minimize research participant fears, encourage continuity of care, and minimize patient(s) lost to follow-up.

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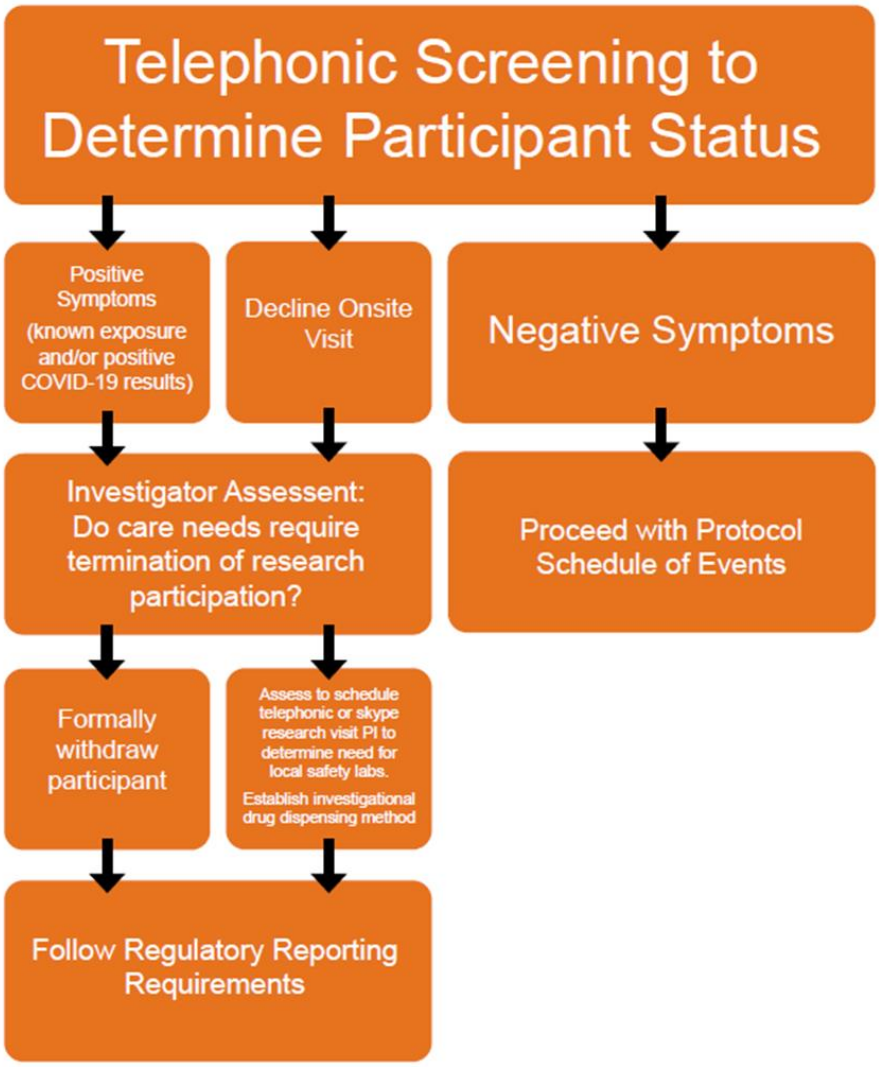
Research Participant Exposure and/or Fears

It is anticipated some research participant(s) may have been exposed to COVID-19, be known actively positive, or decline to keep their study visit appointment due to exposure fears. In these instances the following algorithm applies and should be documented in the medical record.



Safety Labs

If research participants are unable to attend a visit for lab draws involving specimens shipments to a core lab, the investigator must determine if continued access to the investigational drug requires lab results before dispensing. If required, please coordinate directly with your Research Program Manager to explore solutions for external phlebotomy services.

In this instance, the investigator may initiate a written order to a local commercial laboratory indicating the required lab order(s). The results will be provided directly to the investigator to review lab results

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for safety assessments. The goal remains to ensure safety and provide continuity of clinical research activities while minimizing participants lost to follow up.

Investigational Drug Dispensing

If research participants are on investigational drugs and unable to attend an onsite visit, determine if a participant representative is able to pick up the agent (follow COVID-19 screening procedures for participant representative prior to coming onsite). In the event a representative is unavailable, work with local Investigational Drug Services (IDS) and/or pharmacy team to explore a home delivery dispensing plan. Both instances require consultation with IDS to coordinate chain of custody (from dispense to delivery) of the investigational agent. Note, some agents may require temperature control and monitoring which will be determined and managed by IDS/pharmacy.

If investigational agents cannot be dispensed to participant(s), consult with investigator to make plans to transition research participant(s) back to their most appropriate clinically available medications.

Clinical Research Contingency Plan Summary

CLINICAL RESEARCH COVID CONTINGENCY PLAN GUIDELINES		
Pre-Screening	Perform telephonic pre-screening of COVID-19 symptoms per guidelines prior to in-person visit	Follow algorithm and proceed accordingly while ensuring documentation in EMR
Investigator Assessment	Assess if the disruption of a research protocol might impact the safety of your research participants	Treat and document accordingly
Safety Labs	Consider utilization of a commercial lab closer to the participant's location and/or one that may perform the blood draw in the participant's home	Confirm acceptability with sponsor; document accordingly
Investigational Drugs	Use a contracted medical courier to transport investigational drugs to participant home	Coordinate effort with the IDS team, ensure chain of custody and document accordingly
Telephonic Visit	Assess the possibility of conducting the visit via telephone or videoconference	Ensure documentation clearly details the conversation
Remote In-Person Visit	In instances when it is mandatory for continuity of care, all parties screen negative for symptoms, AND **two trained** research personnel agree to facilitate, the study visit may proceed according to protocol	Ensure documentation includes details regarding location, arrival and departure times, persons in attendance, etc.

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IRB Considerations

Please review the policies and stay up-to-date with COVID-19 related announcements from the appropriate IRB of record (e.g. WIRB/Copernicus, Advarra, SMART, etc.).

The Dignity Health IRB reminds you of the federal regulatory requirements:

Each IRB shall … **(a) Follow written procedures for ensuring that changes in approved research, during the period for which IRB approval has already been given, may not be initiated without IRB review and approval except where necessary to eliminate apparent immediate hazards to the human subjects.** [21 CFR 56.108(a)(4).]

If a sponsor or investigator needs to make a change in order to eliminate apparent ***immediate*** hazards to research participants, these changes can be made and then reported to the IRB within five (5) business days per policy. Eliminating immediate hazards may include actions to reduce potential exposure to COVID-19 or to continue to provide medically necessary study care (including administration of investigational drug) to participants who have been placed in isolation or quarantine because of suspected or known exposures. The IRB encourages sponsors and investigators to take steps as necessary to eliminate additional risks to participants.

Please keep in mind any changes will ultimately require a formal submission to the governing IRB of record. This may be done through a modification with protocol amendment, memo, letter or other documentation explaining the changes being made. The submission mush provide enough information for the IRB to assess the relative risks resulting from the changes. The submission should proceed through the normal IRB review process.

Dignity Health IRB(s) are actively working with study teams seeking prospective approval for options for research participants who test positive for COVID-19. The IRB staff are available for consultation on contingency plans for active research studies. Please contact the IRB staff with any related questions.

IRB	Contact	Phone	Email
Arizona - East Valley Facilities	Julie Lynk	480-728-3582 (O)	Julie.Lynk@DignityHealth.org
Arizona - St. Joseph's Hospital & Medical Center	Julie Barton	480-570-1546 (M)	Julie.Barton@DignityHealth.org
	Kim Hedden	602-406-3195 (O)	Kim.Hedden@DignityHealth.org
California & Nevada Facilities	Russell Stolp	831-295-0610 (M)	Russell.Stolp@DignityHealth.org
	Mary Rydman	801-910-2792 (M)	Mary.Rydman@DignityHealth.org

(M) Mobile / (O) Office

Sponsor Representative Onsite Visits

Sponsor Representative Visits should be limited at this time. Unless essential for clinical research operations, all onsite monitoring and training activities are to be completed remotely. Essential monitoring activities pertain to research participant(s) safety and/or critical regulatory compliance to keep the trial open if participants are actively enrolled. This determination should be made by the investigator in consult with Research Administration.

If deemed essential, the sponsor is required to provide their respective organizational COVID-19 screening procedures/policies for review and approval prior to scheduling the onsite visit. Upon receipt,

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please review these materials in coordination with Research Administration to ensure procedures meet CommonSpirit Health mandatory CDC requirements. Once confirmed, outside representatives should undergo telephonic screening at least two days prior to the scheduled visit. If the Sponsor representative has any active symptoms during the last two weeks or recently been exposed to anyone with confirmed COVID-19, the visit should be canceled and scheduled for a later date, or assigned to another sponsor representative team member. During all Sponsor visits it is essential that staff, adhere to standard universal precautions, and limit access to any patient care area(s).

Sponsor Representative Remote Visits

All efforts should be made to facilitate remote monitoring visits in lieu of onsite visits well in advance. Guidance documents outlining tools available for remote monitoring procedures, particularly pertaining to the sharing of any study records are available from Research Administration upon request. If Sponsors request certified copies of source documentation for review, please utilize tools like Box.com, which is DHRI's recommended, HIPPA compliant way of sharing study records that may contain PHI. As a friendly reminder you should limit the amount of PHI that is shared with Sponsors via Fax. Please also ensure that all visit logs are updated with remote monitoring activity, including the amount of time clinical research staff dedicated to the remote visit.

If you have any additional questions regarding Sponsor representative visits please reach out to your Program Manager.

Business Travel

Effective immediately suspension of all international and non-essential domestic travel for all CommonSpirit Health employees, including all research personnel, have gone into effect. This includes work-related business and/or academic travel to meetings and conferences.

Persons who must travel for **essential** (defined and approved by Research Leadership) business within the US and/or overseas should make every effort to stay up to date regarding often fast-changing governmental regulations, including Executive Orders and guidance issued by U.S. Citizenship and Immigration Services, the Department of State, and U.S. Customs and Border Protection.

Those that are currently traveling or plan to travel (personal or approved essential business) to or through any CDC Level 2 country or domestic state declared in a current emergency status will be required to self-isolate for a minimum of 14 days upon return.

The institution will continue to follow CommonSpirit Health directives in coordination with federal requirements regarding travel restrictions and guidelines until further notice.

Additional Information

The COVID-19 pandemic is rapidly evolving and a fluid situation. Please reference local facility websites for the most up-to-date information. In the event of questions, please contact your local Research Administration office for guidance.