PROTOCOL TITLE:

Open label non-comparative trial of the combination of Hydroxychloroquine and Azithromycin in the treatment of hospitalized patients with moderate or severe COVID-19 infection

PRINCIPAL INVESTIGATOR:

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VERSION NUMBER:

8

DATE: 04/27/2020

REGULATORY FRAMEWORK:

Please indicate all that apply:

☐	DOD (Department of Defense)
☐	DOE (Department of Energy)
☐	DOJ (Department of Justice)
☐	ED (Department of Education)
☐	EPA (Environmental Protection Agency)
☒	FDA (Food and Drug Administration)
☒	HHS (Department of Health and Human Services)
☐	VA
☐	Other:

FUNDING:

Indicate if the protocol is funded. If so, provide sponsor and SPO Click ERA record number (FPXXXXX) – Not funded.

Is this a clinical trial per the NIH definition of a Clinical Trial? ☒ Yes ☐ No

NIH Definition of a Clinical Trial:

A research study in which one or more human subjects are prospectively assigned to one or more interventions. An "intervention" is defined as a manipulation of the subject or

subject's environment for the purpose of modifying one or more health-related biomedical or behavioral processes and/or endpoints. Examples include: drugs/small molecules/compounds; biologics; devices; procedures (e.g., surgical techniques); delivery systems (e.g., telemedicine, face-to-face interviews); strategies to change health-related behavior (e.g., diet, cognitive therapy, exercise, development of new habits); treatment strategies; prevention strategies; and, diagnostic strategies (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

Use the following four questions to determine the difference between a clinical study and a clinical trial:

1) Does the study involve human participants? ☒ Yes ☐ No
2) Are the participants prospectively assigned to an intervention? ☒ Yes ☐ No
3) Is the study designed to evaluate the effect of the intervention on the participants? ☒ Yes ☐ No
4) Is the effect being evaluated a health-related biomedical or behavioral outcome? ☒ Yes ☐ No

Note that if the answers to the 4 questions are yes, your study meets the NIH definition of a clinical trial, even if…

- You are studying healthy participants
- Your study does not have a comparison group (e.g., placebo or control)
- Your study is only designed to assess the pharmacokinetics, safety, and/or maximum tolerated dose of an investigational drug
- Your study is utilizing a behavioral intervention

If yes to all 4 questions, please confirm that the research team is familiar with and agrees to comply with the investigator requirement to register the study on the ClinicalTrials.gov database. Additionally, the approved consent document(s) must be uploaded to the ClinicalTrials.gov database ☒ Yes ☐ No

For any assistance with registration of your trial or the requirements, please contact HSC-CTSCResearchConcierge@salud.unm.edu

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1. Objectives

1.1. To measure the duration of viral shedding in respiratory secretions of patients with moderate or severe COVID-19 infection treated with the combination of Hydroxychloroquine and azithromycin.

1.2. Evaluate the case fatality rate, the clinical response and length of stay in hospitalized patients with moderate and severe COVID-19 infection.

1.3. To report the safety of the drug combination in hospitalized patients with moderate and severe COVID-19 infection.

2. Background

2.1. There is in vitro evidence of activity of Chloroquine against SARSCoV 2. There are several studies that have shown that the use of Azithromycin may improve outcomes in viral respiratory tract infection. There is preliminary clinical data that suggest that the combination of HCQ and Azithromycin can decrease viral shedding in respiratory secretions and improve clinical outcome of patients with COVID-19 respiratory infection. Both drugs are relatively safe, and have been used for many years for other indications.

3. Study Design

3.1. Open label non-comparative prospective trial.

4. Inclusion and Exclusion Criteria

4.1. Adults aged ≥18 years of age to 74 years of age with lower respiratory infection with SARSCo2 documented by a positive RT-PCR in nasopharyngeal sample admitted to the University of New Mexico Hospital, with an oxygen saturation of less than 96%, on room air, or a respiratory rate >20 per minute, or HR >120 per minute of a PaO2/FIO2<150.

4.2. Patient with life expectancy >48 hours.

4.3. Pregnant women may be included if deemed necessary. There is insufficient information regarding the safety of hydroxychloroquine and azithromycin during pregnancy. Consequently, these medications are not recommended when pregnant or planning to become pregnant. However, investigators may prescribe hydroxychloroquine and azithromycin if deemed necessary.

4.4. Azithromycin is excreted in human milk, therefore participants should not breast-feed whilst taking Azithromycin, because it may cause side effects including diarrhoea and infection to a baby. It is recommended to discard the milk during treatment and up until 2 days after discontinuation of treatment. Additionally, hydroxychloroquine should not be taken whilst breast-feeding. However, investigators may prescribe hydroxychloroquine and azithromycin if deemed necessary.

4.5. Adults unable to consent will be included with the consent of their Legally Authorized Representative (LAR). Assent will be pursued from cognitively impaired participants if they are able to provide assent. Note that this does not preclude the enrollment of cognitively impaired participants that cannot provide assent, but would allow those that can the opportunity to do so.

4.6. The following will be excluded:

- Prisoners
- No Intensive Care Unit (ICU) transfers from outside entities regardless of age
- No nursing home transfers regardless of ageAnyone older than 74 years
- Pre-/co-existing medical conditions, including any of the following:
    - Known allergy to study drugs.
    - Contraindication to treatment with study drugs, including retinopathy, and QTc prolongation defined by QTc>450 in males and >470 in females. Unless, it is the opinion of the treating physician(s) that the benefits to treat with medications outweigh the risks.
    - Known chronic kidney diseaseor receiving dialysis.
    - Glucose-6-phosphate dehydrogenase (G6PD) deficiency. Weight <40 kg.
    - Current use of: hydrocholoroquine or cardiac medicines of: flecainade, Tambocor; amiodarone Cordarone, Pacerone; digoxin or Digox, Digitek, Lanoxin; procainamide or Procan, Procanbid, propafenone, Rythmal.

4.7. English and Spanish speaking participants only will be enrolled.

5. Number of Subjects

5.1. This is a single-site study at the University of New Mexico Hospital.

5.2. Up to 10,000 participants will be enrolled.

5.3. As an observational trial conducted during a national emergency, no power analysis is necessary.

6. Study Timelines

6.1. Description of Study timelines are as follows:

- Participants will participate in the study for the duration of their stay at UNMH and after discharge, as determined by the PI and treating physician.
- Participants will be enrolled on an on-going basis with no defined end date.
- The anticipated completion of the study is 5 years from date of IRB approval/study initiation.

7. Study Endpoints

7.1 Negative PCR test from nasopharyngeal swabs or oropharyngeal swabs in non-ventilator dependent patient or tracheal secretions in ventilator dependent patient on days 3, 6, and 14.
7.2 Resolution of clinical signs and symptoms of COVID19 infection, LOS, and patient outcome.
7.3 Drug related adverse event that motivates therapy discontinuation.

8. Research Setting

8.1. The study will be conducted at the University of New Mexico Hospital and Health Sciences Center.

8.2. Laboratory analysis will be performed at the UNM HSC, Tricore Reference Laboratories and/or the NM Department of Health.

9. Resources Available

9.1. Cristina Beato, MD is the principal investigator for this research study. Dr. Beato is an Associate Professor with the Department of Family and Community Medicine. She also serves as the UNM School of Medicine Chancellor's Office as the Executive Director of Health Policy.

9.2. Meghan Brett, MD is an Associate Professor within the Division of Infectious Diseases, Department of Internal Medicine.

9.3. Nestor Sosa, MD, FACP is the Division Chief of Infectious Diseases, Department of Internal Medicine.

9.4. David Pitcher, MD, FACS is a Senior Associate Dean for Clinical Affairs, UNM School of Medicine, the Chief Medical Officer, UNM Hospitals and a Clinician Ed - Professor: SOM Surgery General.

9.5. Patients will be recruited from those admitted to UNM Hospital and diagnosed with COVID-19, and will be dependent upon the number of patients actually admitted and progression of their disease as determined by the treating physician.

9.6. Depending on the patient´s condition, care will be provided by the Hospital Medicine Teams or Intensive Care unit teams in general wards and ICU specially selected for COVID-19 patients.

9.7. Investigators will utilize the medications under an IND. At this time, it is unclear what company will supply the medications. Most probably, the supplier will have obtained and IND from the FDA. A modification will be submitted to clarify who will supply the study drugs.

9.8. The Executive Director of Research at the UNM Health Sciences Center Office of Research will be working with institutional officials to ensure the use of viral transport media and swabs during the study do not interfere with adequate supplies available for clinical use. A modification will be submitted to clarify who will supply the swabs and the transport media (i.e. TriCore, UNMH).

10. Prior Approvals

10.1. Departmental Scientific Review will be submitted as a modification once study has received approval.

10.2. Drug attachment included

10.3. Material Transfer Agreement(s) will be secured before any material is transferred in or out of UNM. The fully executed MTA will be provided in a future modification.

11. Multi-Site Research: Not applicable

The PI will be responsible for conducting the following:

- Trial Monitoring
- Investigational Product Accountability
- Safety and other interim reporting to investigators and FDA
- Unanticipated Problem reporting to investigators, IRBs, and FDA

12. Study Procedures

12.1. Eligibility of the potential study participants will be identified by their treating providers (Hospital Medicine and Intensive Care Unit). The treating providers will notify representatives of the research team. Members of the research team will verify the eligibility of the potential subjects and will obtain informed consent from them or their LAR.

12.2. Once the participant or their LAR gives their written informed consent, the research team will notify the treating provider so they can place the medical order for the investigational products. If LAR consented via phone or conference phone call, a copy of the consent form will be mailed, faxed or sent by secure email to LAR.

12.3. The Investigational regimen consisted of Hydroxychloroquine (HCQ) 200mg po tid for 10 days and Azythromycin 500mg IV or po for 5 days. After extensive review of the latest literature, investigators are revising the HCQ dose. The new doseage is as follows: HCQ 400 mg BID on day 1 and then 200 mg BID day 2 through 7 and Azithromycin 500 mg IV or po for 5 days. If the condition of the patient does not allow for oral therapy, HCQ can be given via a feeding or NG tube. Azithromycin can be given intravenously.

12.4. Sample collection:

Nasopharyngeal and oropharyngeal swabs will be collected from the participants on day 3, 6 and 14. In intubated patients in which an oropharyngeal sample cannot be obtained, alternatively a tracheal secretion sample can be obtained.

12.5. Information from clinical parameters will be obtained from the electronic medical record. A separate electronic dataset (using RedCap) will be constructed to capture the most important clinical information on the patients at the time of presentation including the following: demographic information (gender, age,

DOB, place of residence, ethnicity and race), presenting and daily symptoms and signs (including fever, cough, SOB, sputum production, anosmia, hyposmia, fatigue, sore throat, nasal congestion, diarrhea, headache, vital signs, pulmonary auscultatory findings), initial and subsequent results of laboratory tests (Arterial blood gases WBC, lymphocyte count, Hbg, platelet count, , PaO2, O2 saturation, AST, ALT, LDH, Alkaline phosphatase, creatinine, urea nitrogen, lactate level, , Fibrinogen or IL-6 levels if available) results of radiographic studies and microbiological results, need for oxygen or mechanical ventilation.

12.6. Each person participating in this Study will be assigned a randomly generated study ID that will be linked to identifiers (MRN, DOB) in a linking table to be kept separate from the research data. Data and specimens will be labelled with the study ID only. Only HRRC-approved members of the study team who have the appropriate training will have access to the data and identifiers. All data that we collect in this study will be entered into REDCap, a secure data-base, on a password-protected computer using a secure network. Any hard copy records/data will be kept in a locked file cabinet in the locked office of a designated member of the Study team. The specimens will be kept and stored in the Clinical and Translational Science Center at the UNM HSC and can only be accessed by the members of the study team. Investigators will transport the specimens to TriCore Reference Laboratories for lab analysis through standard transport hospital procedures. After testing, any left-over samples will be delivered in part to CDC for validation testing, and in part to the CTSC for genomic sequencing. Once data collection is complete, data will be de-identified by destruction of the linking table.

12.7. EKG or direct QtC calculation based on telemetry strip will be obtained at baseline as well as daily to exclude individuals with prolonged QT while on both agents. Investigators are limiting exposure and PPE use for a technician doing these tests. As such, this should not need to be done daily. Investigators calculate the QtC on the telemetry and are working on getting an EKG machine to be put in the ICU so the nurse could do it as needed. Investigators are having a hard time getting echos or any other procedure done in the ICU unless the investigators do it as no one wants to come in and we are running through our PPE supply.

12.8. Continue to follow-up with participants at home via phone call if participants discharged <14 days.

12.9. Continue to follow-up with participants if they are in the hospital > 14 days.

12.10. There are 5 patients who received the combination product before the approval of the protocol. These patients will be contacted via phone, consented via phone, after which, their data will be extracted as outlined in the protocol.

12.11. Important variables are as follows:

- Result of the RT PCR test done on days 3, 6 and 14 as well as the determination i.e. positive or negative.

- Overall clinical evaluation of the patients as determined by the treating provider.
- Frequency of Complications related to COVID19 (ARDS, AKI, Metabolic Acidosis, Shock, Secondary infections, Multi-organ failure and death)
- Final disposition of the patient.
- Frequency of adverse events (including GI symptoms, QTc prolongation, visual disturbances, retinopathy)

13. Provisions to Monitor the Data to Ensure the Safety of Subjects

13.1. A DSMB will be convened to include clinicians specializing in infectious diseases and biostatisticians. The roster will be provided in a Modification for HRRC approval once the DSMB has been created.

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13.2. Review of data after 20 participants have been enrolled.

13.3. Considering the novelty and rapidly changing situation of the COVID-19 pandemic, the investigators will review relevant publications that may help informed decisions related to the efficacy and safety of the investigational products.

13.4. The procedures for analysis and interpretation of the safety data.

The occurrence of any serious adverse event will be notified to the HRRC in accordance to GCP regulations. An analysis of all adverse events will be presented with the analysis of the first 20 patients enrolled and periodically thereafter. We propose to conduct periodic analysis every 20 patients.

13.5. The conditions that would trigger a suspension or termination of the research (i.e., stopping rules), are as follows:

If available published information convincingly reports non-efficacy or significant safety concerns about HCQ+Azithromycin combination

If in the opinion of the investigators an unexpectedly high incidence of serious adverse events is detected during the trial.

If during the preliminary analyses less that 15% of the patients achieve and undetectable viral load on day 6.

13.6. The plan for reporting findings to the sponsor, investigators, and HRRC. A preliminary analysis of the study end points will be performed after 20 patients have been enrolled and end-points reached. The results will be presented to the HRRC and investigators.

14. Withdrawal of Subjects

14.1. Subjects will be withdrawn if the PI determines, in consultation with the treating clinician(s) that continuation in the study is not in the participant's best interest. Subjects may also withdraw (or be withdrawn by their LAR at their

request at any time during their participation in the study by contacting a member of the study team.

14.2. If a patient develops a serious adverse event that may be probably or definitely related to either drug, that may trigger the discontinuation of the offending drug.

14.3. If a participant is withdrawn from the study, chart review will continue to be performed to track the participant's clinical outcomes.

14.4. Data and specimens collected before withdrawal will not be removed from the study.

15. Data Management/Confidentiality

15.1. Participants will be assigned a randomly generated study ID that will be linked to identifiers (MRN, DOB) in a linking table to be kept separate from the research data. Data and specimens will be labelled with the study ID only.

15.2. Only HRRC-approved members of the study team who have the appropriate training will have access to the data and identifiers.

15.3. Data will be entered into REDCap on a password-protected computer using a secure network.

15.4. Any hard copy records/data will be kept in a locked file cabinet in the locked office of a designated member of the study team

15.5. The specimens will be kept and stored in the Clinical and Translational Science Center at the UNM HSC and can only be accessed by the members of the study team. Then specimens will be transported to TriCore Laboratory and can only be accessed by laboratory personnel for the purpose specified in the protocol.

15.6. Once data collection is complete, data will be de-identified by destruction of the linking table. Study records will be kept for 6 years past study closure.

16. Data and Specimen Banking: Not applicable

17. Risks to Subjects

17.1. Risks of hydroxychloroquine include headache, dizziness, loss of appetite, nausea, diarrhea, stomach pain, vomiting and skin rash.

17.2. Risks of azithromycin include mainly gastro-intestinal symptoms, as well as cardiovascular, genitourinary, nervous system, allergic reaction and fatigue.

17.3. Risk of retinopathy.

17.4. Administration of study drugs individually or in combination may have risks to the subjects that are currently unforeseeable. Review of the clinical record as well as monitoring by the DSMB as described above will be conducted to mitigate these risks.

17.5. Risks also include a loss of privacy and/or confidentiality. This will be mitigated by conducting all study activity in private areas of the hospital and labelling all data/specimens with a study ID.

17.6. Suicidal ideation is also potential risk.

17.7. Unforeseen risk to participants, and if applicable, to an unborn fetus.

17.8. Refer to the Protocol Appendix for the detailed list of risks associated with hydroxychloroquine and azithromycin.

18. Potential Benefits to Subjects

18.1. Participants may benefit from reduction in/elimination of the viral load associated with their condition, and a reduction of morbidity and mortality associated with COVID-19 infection and sequelae.

19. Recruitment Methods

19.1. Once the result of the initial COVID19 test is reported as positive, the provider will ask potential participants and/or their LAR for permission to be approached by a member of the research team for recruitment.

19.2. The study staff will screen the patient's electronic medical record for potential eligibility. This will allow the research team to review the potential participant's medical records in detail and assist in determining eligibility. Once consent is obtained, specific research tests or procedures for determining eligibility for the study can then be conducted. Investigators will inform a potential participant or their LAR that eligibility must be checked and verified prior to enrollment on the study. There is still a possibility that potential subjects may not ultimately be eligible and thus cannot participate in the research study.

19.3. The member of the research team will verify if the potential participant fulfills the inclusion/exclusion criteria and will proceed to enroll the patient.

20. Provisions to Protect the Privacy Interests of Subjects

20.1. All study procedures will be conducted in the participant's room or other private area of the hospital.

21. Economic Burden to Subjects

21.1. The study is responsible for the cost of any research-related procedures. The participant and/or third party payer us responsible for any standard of care procedures. However, if the University of New Mexico cannot bill the participant's insurance company, Medicare, or Medicaid for the medical procedures done strictly for research, a participant may have to pay out-of- pocket for these costs.

21.2. Investigators do not anticipate any additional costs.

22. Compensation: Not applicable

23. Compensation for Research-Related Injury

23.1. The University of New Mexico does not have funds set aside to pay for the cost of any care or treatment that might be necessary or for any wages lost as a result of participating in this study. Medical costs to care and treatment of study related harm will be billed to the participant and/or third party payer.

24. Consent Process

24.1. An approved member of the study team will conduct the consent process with the participant and/or their LAR, and if applicable, their witnesses (witness/translator for Spanish speaking participant and impartial witness of phone consent) in a private area of the hospital or by phone if needed. If the consent is performed over the phone, an impartial witness of the phone consent will be utilized.

24.2. It may not be possible to have an in-person discussion of the study with participants or their LAR, and their witnesses as applicable. Investigators may need to conduct a phone consent via conference phone call because the investigator, participant or their LAR and the witnesses (as applicable) may not be in the same location. Documenting written informed consent in these instances must involve a process as follows: the participant or their LAR and witnesses receives a copy of the informed consent document in advance of a telephone discussion. The investigator obtains consent over the telephone with the participant or their LAR and if applicable the impartial witness of the phone consent and if applicable the witness/translator for a Spanish speaking participant. If the participant or their LAR consented via phone, a copy of the consent will be mailed, faxed or sent via secure email to participant or their LAR.

24.3. The informed consent form may be mailed, emailed or faxed to the participant or their LAR and to their witnesses (as applicable). The consent discussion may then be conducted by phone, conference phone call or in person so that the participant or particpcant's LAR and participant's witnesses (as applicable) can read the consent form during the discussion.

24.4. Investigators will explain the study to the potential participant or their LAR and if applicable to their witnesses by reading the informed consent document to the participant and/or LAR and if applicable their witnesses, providing all pertinent information (purpose, procedures, risks, benefits, alternatives to participation), and allowing the potential participant or their LAR ample opportunity to ask questions. This can be done by phone, conference phone callor in person.

24.5. Investigators will ensure a thorough verbal discussion was conducted by phone, conference phone call or in person of the consent form. Investigators will allow the potential participant or LAR time to read the consent form and allow the participant or their LAR sufficient time to consider whether or not to participate in the research.

24.6. Investigators will ensure the potential participant or their LAR's additional questions have been addressed.

24.7. Participants and/or their LAR will be asked to explain the purpose of the study, procedures involved, and/or conditions for participation to confirm understanding.

24.8. If the participant or LAR agrees to participation, s/he signs the consent form and returns it to the investigator for signature and date. If informed consent took place via the phone or via conference phone call, the signed and dated consent form can be returned to investigators by mail, fax, or by scanning the consent form and returning it through a secure e-mail account by the participant or their LAR and by the witnesses as applicable. It is possible that multiple consent forms will be obtained for a single participant because the investigator obtaining consent, the participant or their LAR, and their witnesses (as applicable) were not in the same location but together via conference phone call. In this instance, each separate consent will be signed and dated by each individual appropriately. All dates on the multiple consent forms will be congruent for the day the consent took place. In these instances, a note-to-file will explain that separate consent forms exist for a single participant because all individuals could not be in the same room and that the consent took place over a conference phone call in an effort to decrease the contact and exposure to the novel coronavirus.

24.9. Once the signed consent form or if applicable forms are received, the investigator who conducted the informed consent will ensure the participant or their LAR receives a copy of the signed consent form or forms as applicable. The fully signed original consent form or forms will be filed with the participant's study records along with the note-to-file that details the consent process.

24.10. Alternately, on a case-by-by case basis, and per the FDA regulation 21 CFR 50.23 Exception from general requirements, the following will be done:

(a) The obtaining of informed consent shall be deemed feasible unless, before use of the test article (except as provided in paragraph (b) of this section), both the investigator and a physician who is not otherwise participating in the clinical investigation certify in writing all of the following:
(1) The human subject is confronted by a life-threatening situation necessitating the use of the test article.
(2) Informed consent cannot be obtained from the subject because of an inability to communicate with, or obtain legally effective consent from, the subject.
(3) Time is not sufficient to obtain consent from the subject's legal representative.
(4) There is available no alternative method of approved or generally recognized therapy that provides an equal or greater likelihood of saving the life of the subject.

(b) If immediate use of the test article is, in the investigator's opinion, required to preserve the life of the subject, and time is not sufficient to obtain the independent determination required in paragraph (a) of this section in advance of using the test article, the determinations of the clinical investigator shall be made and, within 5 working days after the use of the article, be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation.
(c) The documentation required in paragraph (a) or (b) of this section shall be submitted to the HRRC as a Reportable New Information (RNI) within 5 working days after the use of the test article.
The documentation to be used within the RNI is titled "Informed Consent Exception from General Requirements". The form can be completed via eSignatures by utilizing the fillable form or hand written signatures by utilizing the non-fillable form.

24.11. Ongoing consent from participants and and/or their LAR will be ascertained as research procedures are being conducted.

Subjects not fluent in English

24.11.1. Given the public health emergency surrounding this research, non-English speaking patients may be included in the study, and this will only include Spanish speaking individuals.

24.11.2. The consent process will be conducted by a member of the study team fluent in the Spanish language and/or with the assistance of a qualified interpreter.

24.11.3. The qualified interpreter can serve as the witness of the informed consent process. If the interpreter is a study team member, they will not serve as the impartial witness to the informed consent process when there is a phone consent or conference call informed consent. The interpreter can sign the informed consent form in the section that states they have witnessed the informed consent process. Additionally, the interpreter, by signing, confirms the informed consent was verbally reviewed with the participant or the LAR in addition to the HRRC approved short consent form and the informed consent form functioned as the summary of the discussion.

***Cognitively Impaired Adults/Adults Unable to Consent/Use of a Legally* Authorized Representative**

24.11.4. Some participants are expected to be cognitively impaired, either due to a pre-existing condition, or because of conditions related to their infection with COVID-19. Cognitively impaired participants will be enrolled in the study with the consent of their LAR.

24.11.5. The study team, in consultation with the clinical care provider, will determine if a participant has capacity to consent. Specifically, the investigators will utilize the Capacity to Consent Quiz with the consent form. After the consent form has been discussed with the participant, the investigator will administer the Capacity to Consent Quiz. Based on the results, the investigators will determine if the participant has the ability to consent.

24.11.6. Capacity to consent will be evaluated by the study team, in consultation with the clinical care provider, as part of the ongoing consent process as described above. If the participant regains capacity to consent, a member of the study team will conduct the consent process as described above.

24.11.7. We will obtain evidence of agency under a durable power of attorney or surrogate health decision maker status under the NM Uniform Health Care Decisions Act, NMSA 1978, 24-7A-1 et seq.

Subjects who are not yet adults (infants, children, teenagers)

N/A

Waiver or Alteration of Consent Process (consent will not be obtained, required element of consent will not be included, or one or more required elements of consent will be altered)

Waivers of consent and HIPAA authorization are requested for screening/ recruitment purposes. For the waiver of HIPAA authorization, the Data Warehouse will generate a daily list of patients with documented positive COVID-19 with their locations in the hospital. The attending will be contacted via tigerconnect to consent and start the treatment.

25. Documentation of Consent

25.1. For English-speaking participants (or LARs), consent will be documented using an HRRC-approved consent document.

25.2. For Spanish speaking participants (or LARs), a Short Form of Consent in their preferred language will be used to document consent.

26. Study Test Results/Incidental Findings

26.1. Results of the nasopharyngeal RT-PCR will be share with study participants and their inpatient medical attending. Test result will be posted in the electronic medical record. The information on clinical parameters will be available in the electronic medical record as is customary .All laboratories are performed in a CLIA certified Laboratory.

27. Sharing Study Progress or Results with Subjects

See section 26.1

28. Inclusion of Vulnerable Populations

N/A

29. Community-Based Participatory Research

N/A

30. Research Involving American Indian/Native Populations

N/A

31. Transnational Research

N/A

32. Drugs or Devices

32.1. The investigational drugs will be store and handle by the inpatient pharmacy of the Institution in accordance to their standard operating procedures and investigational product requirements.

33. Principal Investigator's Assurance

By submitting this study in the Click IRB system, the principal investigator of this study confirms that:

☒ The information supplied in this form and attachments are complete and correct.

☒ The PI has read the Investigator's Manual and will conduct this research in accordance with these requirements.

☒ Data will be collected, maintained and archived or destroyed per HSC Data Security Best Practices, including:

1. **Best Practice for data collection** is for it to be directly entered onto a data collection form that is in a secured access folder on an HS drive behind a firewall, or in a secure UNM Data Security approved system such as RedCap.
2. **Data collection of de-identified data**, if done in a clinical setting or other setting that does not allow direct entry into a secured system, may be done temporarily using a personal or university owned electronic storage device or hard copy document. **The important security safeguard is that no identifiers be include if the data is entered or stored using an untrusted device or storage.**
3. **Permanent (during data analysis, after study closure**) storage must reside on HSC central IT managed storage. Processing of data (aggregation, etc.) are to be carried out in such a way as to avoid creating/retaining files on untrusted storage devices/computers. Trusted devices are HSC managed and provide one or more of following safeguards: access logs, encryption keys, backups, business continuity and disaster recovery capabilities.

4. **Alternate storage media** must be approve by HSC IT Security as meeting or exceeding HSC central IT provided security safeguards.

34. CHECKLIST SECTION

This section contains checklists to provide information on a variety of topics that require special determinations by the IRB. Please complete all checklists relevant to your research.

35. Partial Waiver of Consent for Screening/Recruitment

Complete this checklist if you are requesting a partial waiver of consent so that you can review private information to identify potential subjects and/or determine eligibility prior to approaching potential subjects for consent or parental permission.

A. Describe the data source that you need to review (e.g., medical records):

Medical record

B. Describe the purpose for the review (e.g., screening):

Screening and recruitment

C. Describe who will conducting the reviews (e.g., investigators, research staff):

Principal Investigator or other member of the study team

D. Do all persons who will be conducting the reviews already have permitted access to the data source?

☒ Yes

☐ No. Explain:

i. Verify that each of the following are true or provide an alternate justification for the underlined regulatory criteria:

1. <u>The activity involves no more than minimal risk to the subjects</u> because the records review itself is non-invasive and the results of the records review will not be used for any purposes other than those described above.

☐ True

☐ Other justification:

2. <u>The waiver or alteration will not adversely affect the rights and welfare of the subjects</u> because eligible subjects will be approached for consent to participate in the research and are free to decline. Further, the information accessed during the records review will not be disclosed to anyone without a legitimate purpose (e.g., verification of eligibility).

☐ True

☐ Other justification:

3. The research could not practicably be carried out without the waiver or alteration because there is no other reasonably efficient and effective way to identify who to approach for possible participation in the research.

   ☐ True

   ☐ Other justification:

4. Whenever appropriate, potentially eligible subjects will be presented with information about the research and asked to consider participation. *(Regulatory criteria: Whenever appropriate, the subjects will be provided with additional pertinent information after participation.)*

   ☐ True

   ☐ Other justification:

36. Partial Waiver of HIPAA Authorization for Screening/Recruitment

Complete the following additional questions/attestations if the records you will review to identify potential subjects and/or determine eligibility include Protected Health Information (PHI).

A. Will you be recording any PHI when conducting the records review to identify potential subjects and/or determine eligibility?

   ☐ Yes. Describe:

   ☒ No

B. If you answered "Yes" to question 6 above, please describe when you will destroy identifiers (must be the earliest opportunity consistent with the conduct of the research) or provide justification for why they must be retained:

C. The PHI accessed or recorded for identification/screening purposes will not be reused or disclosed to (shared with) any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the PHI would be permitted under the Privacy Rule.

   ☒ True

   ☐ False

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37. Vulnerable Populations (Checklist)

A. Adults with Cognitive Impairments

Complete this checklist if the subject population will include adults with cognitive impairments.

This checklist does not need to be completed if the research doesn't involve interactions or interventions with subjects and will be conducted under a waiver of consent.

1. Describe why the objectives of the study cannot be met without inclusion of adults with cognitive impairments.

   COVID-19 infection may affect persons with pre-existing cognitive impairment for whom no SOC treatment exists. COVID-19 infection can cause conditions resulting in cognitive impairment.

2. Describe how capacity to consent will be evaluated.

   By the research team in consultation with clinical care provider

3. If subjects may regain capacity to consent, or if subjects may have fluctuating capacity to consent, describe your plans to evaluate capacity to consent throughout the research and to obtain consent to continue participation if capacity is regained.

   Capacity to consent will be assessed as part of the ongoing consent process

4. Describe your plans, if any, to provide information about the research to subjects and the steps you will take to assess understanding.

   The investigators will utilize the Capacity to Consent Quiz with the consent form. After the consent form has been discussed with the participant, the investigator will administer the Capacity to Consent Quiz. Based on the results, the investigators will determine if the participant has the ability to consent.

5. Describe your plans to obtain assent, including whether assent will be obtained from none, some, or all subjects.

   Assent will be obtained from those participants able to give assent.

6. Describe why risks to subjects are reasonable in relation to anticipated benefits to the subjects.

   There is no SOC treatment for COVID-19 infection

7. If this study involves a health or behavioral intervention, describe why the relation of the anticipated benefit to the risk of the research is at least as favorable to the subjects as that presented by alternative procedures.

   There is no SOC treatment for COVID-19 infection

8. Describe your plans for monitoring the well-being of subjects including any plans to withdraw subjects from the research if they appear to be unduly distressed.

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38. Data Transfer/Sharing (Checklist)

Complete this checklist if the research involves transferring/sharing of data with an external entity (institution, company, etc.).

A. Will data be transferred/shared with an external entity (institution, company, etc.)?

☐ Yes

☒ No. **The remainder of this section does not apply.**

B. Indicate if the data is incoming and/or outgoing:

C. Provide the name of the entity that data will be transferred/shared with:

D. Provide the contact name, email and phone number with whom data is being transferred/shared with:

E. Who is responsible for transmission of the data?

F. Who is responsible for receiving the data?

G. Describe how the data will be transferred/shared. Please note data cannot be transferred/shared without assistance from UNM HSC IT. **Requesting HSC Central IT Transfer is detailed on the Sponsored Projects website:**

H. For data being transferred/shared with outside locations or entities, describe the following:

- Where is data storage and how will it be maintained in a secure manner (i.e. encryption, password protection, use of Qualtrics or REDCap, etc)?
- What is method in which data will be collected and stored (i.e. electronic, hard copy, etc)?
- How long will the data be stored?
- Who will have access to data?

I. Please list all specific data elements, variables, etc. to be sent out and/or received. Indicate if the data contains identifiers and health information. Please note that identifiers that MUST be removed to make health information de-identified are as follows: Names, All geographic subdivision smaller than a State, All elements of year (except year), Telephone, Fax numbers, E-mail addresses, Social Security, Medical record number, Health plan beneficiary, Account numbers, Certificate/license numbers, Vehicle identifiers and serial numbers, Device identifiers and serial numbers, Web URLs, IP address numbers, Biometric identifiers, full face photographic images, and Any other unique identifying number, characteristic or code.)

J. If the research requires the access, use, or disclosure of any of the 18 individually identifiable protected health information (PHI) identifiers that can be used to identify, contact, or locate a person (e.g., name, medical record number, etc.), are the subjects

going to consent to or authorize the disclosure of their individually identifiable health information?

a. ***Or*** is HIPAA authorization altered or waived?

K. What is the classification of the data (de-identified, limited data set, protected health information, other).

L. Does the request to transfer/share data include clinical data that belongs to the UNM Health Systems?

M. Does the data to be transferred/shared include information about patients seen at external health system or at a third party medical provider?

N. Is the external entity a "covered entity"?

O. Is the data that is going to be transferred/shared owned or partially owned by another party or have any type of restrictions including regulatory restrictions (i.e. HIPAA, FERPA, etc.)?

P. Is the data publically available? If yes, please provide details:

Q. Does the data include information about substance abuse treatment, sexually transmitted diseases, genetic testing results, HIV/AIDS testing results, and/or mental health?

39. Specimen Transfer/Sharing (Checklist)

Complete this checklist if the research involves transferring/sharing of specimens with an external entity (institution, company, etc.).

A. Will specimens be transferred/shared with an external entity (institution, company, etc.)?

☒ Yes

☐ No. **The remainder of this section does not apply.**

B. Indicate if the specimens are incoming and/or outgoing: *TriCore, CDC*

C. Provide the name of the entity that specimens will be being transferred/shared with:

D. Provide the contact name, email and phone number with whom specimens are being transferred/shared with:

E. Who is responsible for sending out the specimens? Please note specimens cannot be sent out without a fully executed material transfer agreement.

F. Who is responsible for receipt of the specimens? Please note specimens cannot be received without a fully executed material transfer agreement.

G. For specimens being transferred/shared with outside locations or entities, describe the following:

- *Where is specimen storage and how will it be maintained in a secure manner?*
- *What is method in which specimens will be collected and stored?*
- *How long will the specimens be stored?*
- *Who will have access to the specimens?*