Document Coversheet

Study Title: COVID-19: Povidone-Iodine Intranasal Prophylaxis in Front-line Healthcare Personnel and Inpatients (PIIPPI)

Institution/Site:	University of Kentucky
Document (Approval/Update) Date:	4/12/22
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KEY INFORMATION FOR POVIDONE-IODINE INTRANASAL AND OROPHARYNGEAL GARGLE FOR PROPHYLAXIS IN FRONT-LINE PHYSICIANS/HEALTHCARE WORKERS AND INPATIENTS TO PREVENT THE SPREAD OF SARS-COV-2 (COVID19)

We are asking you to choose whether or not to volunteer for a research study about using a nasal spray and gargle containing an iodine containing solution while working in the hospital. We are asking you because of the high potential for catching COVID19 while in the hospital. This page is to give you key information to help you decide whether to participate. We have included detailed information after this page. Ask the research team questions. If you have questions later, the contact information for the research investigator in charge of the study is below.

WHAT IS THE STUDY ABOUT AND HOW LONG WILL IT LAST?

The purpose of this research is to gather information on the safety and effectiveness of povidone-iodine (PVI) nasal sprays and gargle to reduce the risk of contracting and spreading COVID19. Your participation in this research will last 3 weeks. This preparation is approved by the Food and Drug Administration (FDA) but not for this usage. There will be a treatment group that will use PVI and a control group that will provide care as usual without using the preparation if they have a contraindication to doing so or would like to opt out but still participate. You will be contacted up to 6 months afterward to assess any further thoughts and experiences.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE TO VOLUNTEER FOR THIS STUDY?

Subjects have a theoretical benefit of a reduced risk of contracting and spreading COVID19. It is hypothesized that PVI may inhibit viral attachment to cellular receptors and inhibit viral release and spread from infected cells. For a complete description of benefits, refer to the Detailed Consent.

WHAT ARE KEY REASONS YOU MIGHT CHOOSE NOT TO VOLUNTEER FOR THIS STUDY?

You might not want to participate in this trial because it involves having to use a spray in your nose and having to gargle three times a day. Iodine can sometimes cause nasal irritation. For a complete description of risks, refer to the Detailed Consent and/or Appendix. An alternative to using this spray is using nothing and continuing to exercise good hygiene practices.

DO YOU HAVE TO TAKE PART IN THE STUDY?

If you decide to take part in the study, it should be because you really want to volunteer. You will not lose any services, benefits or rights you would normally have if you choose not to volunteer.

WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS OR CONCERNS?

If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study contact Alexandra E. Kejner, MD FACS or Zachary Porterfield MD PhD of the University of Kentucky, Department of Otolaryngology at 859-257-5097 or by email at Alexandra.kejner@uky.edu or zach.porterfield@uky.edu.

If you have any concerns or questions about your rights as a volunteer in this research, contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) between the business hours of 8am and 5pm EST, Monday-Friday at 859-257-9428 or toll free at 1-866-400-9428.

DETAILED CONSENT:

ARE THERE REASONS WHY YOU WOULD NOT QUALIFY FOR THIS STUDY?

If you are pregnant, breast-feeding, have thyroid cancer or take thyroid medications, you will not be eligible to use the nasal and gargle preparations but will still be eligible to participate in the COVID19 testing and questionnaires as what is called the “control group”.

WHERE WILL THE STUDY TAKE PLACE AND WHAT IS THE TOTAL AMOUNT OF TIME INVOLVED?

The research procedures will be conducted at the University of Kentucky Chandler Hospital. You will meet with the research staff to obtain the initial COVID 19 test and to receive materials and instructions. At the end of the study (3 weeks), you will return to meet with the research staff for a follow up COVID 19 test. If you develop symptoms at any time during the study period prior to the end of 3 weeks, you should receive a COVID 19 test as is standard of care and please report the results to us. A positive test ends your involvement in the study.

WHAT WILL YOU BE ASKED TO DO?

You will first be asked to complete a pre-screening questionnaire. Then, if you have never had a positive COVID19 test, you will undergo a COVID19 test. You will be given the results of your COVID test as soon as they are available. You will then be given the nasal spray and gargle preparation

You will be asked to do the nasal spray and gargle 3 times a day, for up to 7 days on, with 3 day breaks, depending on your work schedule, for a total of 3 weeks.

IF during the trial, you begin to develop symptoms, you will be tested for COVID19. If during the study period you do NOT develop symptoms, you will be re-tested at the end of 3 weeks from beginning use.

For participants who are not able to use the iodine nasal sprays or gargle, use standard hand hygiene. If you begin to develop symptoms, your COVID19 test will be repeated. If during the study period you do NOT develop symptoms, you will be re-tested at the end of 3 weeks.

You will be contacted up to 6 months following your participation to assess your thoughts and experience on trial as well as if you ever contracted COVID following participation and if you were vaccinated or not. This information will only be linked to your unique name and will not be shared.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

Potential risks include foul taste from the PVI, discoloration of the throat and nose. There is a minuscule risk of thyroid dysfunction if excess amount of iodine is taken. There is a potential that you could still catch COVID19 while taking this preparation. There is a chance that you may get nasal irritation and dryness and even a small nosebleed while using the nasal spray.

There is always a chance that any medical treatment can harm you. The research treatments/procedures in this study are no different. In addition to risks described in this consent, you may experience a previously unknown risk or side effect.

WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?

We do not know if you will get any benefit from taking part in this study. However, there is a possibility that use of the nasal spray and irrigation may prevent you from contracting the coronavirus that causes COVID19 while you are caring for patients. If you take part in this study, information learned may help others with your condition.

IF YOU DON’T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?

If you do not want to be in the study, there are no other choices except not to take part in the study.

WHAT WILL IT COST YOU TO PARTICIPATE?

You and/or your insurance company, Medicare, or Medicaid will be responsible for the costs of all care and treatment that you would normally receive for any conditions you may have. These are costs that are considered medically necessary and will be part of the care you receive even if you do not take part in this study.

The University of Kentucky may not be allowed to bill your insurance company, Medicare, or Medicaid for the medical procedures done strictly for research.

- The cost of the nasal preparation, gargle, and COVID19 initial test will be covered by a grant, there will be no cost to you
- The cost of the second COVID19 test if medically indicated due to symptoms may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay these costs); ***or***
- The cost of the second COVID19 test if medically indicated due to symptoms may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid. (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid at 1-800-635-2570.)

Your insurer, Medicare, or Medicaid, may agree to pay for the costs. However, a co-payment or deductible may be needed from you. The amount of this co-payment or deductible may be costly.

WHO WILL SEE THE INFORMATION THAT YOU GIVE?

When we write about or share the results from the study, we will write about the combined information. We will keep your name and other identifying information private.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. When you sign up for the study, you will be assigned a serial number and your data will only be associated with that number. Your COVID19 testing will be associated with your name, but will not be publicly disclosed. Your name will only be associated with your testing status so that we can alert you to the results. If you test positive for COVID19, we will refer you to the Infection Prevention and Control (IPAC) group for further treatment.

You should know that in some cases we may have to show your information to our infection control group at the hospital because of the pandemic currently affecting the United States.

For example, the law may require us to share your information with:

- a court or agencies, if you have a reportable disease/condition;
- authorities, if you report information about a child being abused; or if you pose a danger to yourself or someone else.

We will be using REDCap a data collection software. It is important to note that any data collection process undertaken through the use of third-party software comes with potential risks. Included among these risks is a potential breach of confidentiality. The study team will take all available precautions to prevent this from occurring, although we cannot guarantee that your identity will never become known.

We will make every effort to safeguard your data, but as with anything online, we cannot guarantee the security of data obtained by way of the Internet. Third-party applications used in this study may have Terms of Service and Privacy policies outside of the control of the University of Kentucky.

REDCap is a secure, web-based program to capture and store data at the University of Kentucky. We will make every effort to safeguard your data in REDCap. However, given the nature of online surveys, we cannot guarantee the security of data obtained by way of the Internet.

WHAT IF I WITHDRAW FROM THE STUDY EARLY?

You can choose to leave the study at any time. You will not be treated differently if you decide to stop taking part in the study.

If you choose to leave the study early, data collected until that point will remain in the study database and may not be removed.

The investigators conducting the study may need to remove you from the study. You may be removed from the study if:

- you are not able to follow the directions,
- we find that your participation in the study is more risk than benefit to you, or
- the agency paying for the study chooses to stop the study early for a number of scientific reasons.

The study intervention will no longer be provided to you and may not be available for purchase. This may occur for a number of reasons.

ARE YOU PARTICIPATING, OR CAN YOU PARTICIPATE, IN ANOTHER RESEARCH STUDY AT THE SAME TIME AS PARTICIPATING IN THIS ONE?

You may take part in this study if you are currently involved in another research study as long as it does not involve other types of nasal preparations. It is important to let the investigator/your doctor know if you are in another research study. You should discuss this with the investigator/your doctor before you agree to participate in another research study while you are in this study.

WHAT HAPPENS IF YOU GET HURT OR SICK DURING THE STUDY?

If you believe you are hurt or if you get sick because of something that is due to the study, you should call Dr. Alexandra E. Kejner, MD FACS or Dr. Zachary Porterfield, MD PhD immediately at 859-257-5097.

It is important for you to understand that the University of Kentucky does not have funds set aside to pay for the cost of any care or treatment that might be necessary because you get hurt or sick while taking part in this study. Also, the University of Kentucky will not pay for any wages you may lose if you are harmed by this study.

Medical costs related to your care and treatment because of study-related harm

- will be your responsibility;
- may be paid by your insurer if you are insured by a health insurance company (you should ask your insurer if you have any questions regarding your insurer's willingness to pay under these circumstances); ***or***
- may be paid by Medicare or Medicaid if you are covered by Medicare or Medicaid (If you have any questions regarding Medicare/Medicaid coverage you should contact Medicare by calling 1-800-Medicare (1-800-633-4227) or Medicaid 1-800-635-2570.).

A co-payment/deductible may be needed by your insurer or Medicare/Medicaid even if your insurer or Medicare/Medicaid has agreed to pay the costs. The amount of this co-payment/deductible may be costly.

You do not give up your legal rights by signing this form.

Due to the coronavirus public health emergency, the federal government has issued an order that may limit your right to sue if you are injured or harmed while participating in this COVID-19 study. If the order applies, it limits your right to sue and recover losses from the researchers, healthcare providers, any study sponsor, distributor or manufacturer involved with the study. However, the federal government has a program that may provide compensation to you or your family if you experience serious physical injuries or death. To find out more about this "Countermeasures Injury Compensation Program" please go to https://www.hrsa.gov/cicp/about/index.html or call 1-855-266-2427

WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?

You will not receive any rewards or payment for taking part in the study.

WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT YOUR DECISION TO PARTICIPATE?

We will tell you if we learn new information that could change your mind about staying in the study. We may ask you to sign a new consent form if the information is provided to you after you have joined the study.

WILL YOU BE GIVEN INDIVIDUAL RESULTS FROM THE RESEARCH TESTS?

Do you give permission for us to contact you about research results or incidental findings that are determined to be important to you/your family's health? (Incidental findings are unforeseen findings discovered during the course of the research that may affect you or your family's health).

□Yes □No _____Initials

You may also withdraw your consent to be contacted with information about research results or incidental findings by sending a written request to Dr. Alexandra E. Kejner, MD at 740 S. Limestone Rd E300E Kentucky Clinic, Lexington, KY 40502

WILL WE CONTACT YOU WITH INFORMATION ABOUT PARTICIPATING IN FUTURE STUDIES?

We will send a follow up survey up to 6 months following your participation. This will be linked only to your uniquename and will not have any identifiable information. It will not be shared.

WHAT ELSE DO YOU NEED TO KNOW?

If you volunteer to take part in this study, you will be one of about 300 people to do so.

An internal grant is providing financial support and/or material for this study.

The information or specimens that you are providing will no longer belong to you. The research may lead to new clinical or educational knowledge, tests, treatments, or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

A description of this clinical trial will be available on ClinicalTrials.gov as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

WILL YOUR INFORMATION (OR SPECIMEN SAMPLES) BE USED FOR FUTURE RESEARCH?

All identifiable information (e.g., your name, medical record number, or date of birth) will be removed from the information or samples collected in this study. This means that no link or code to your identity will be kept. After all identifiers have been removed, the information or samples may be used for future research or shared with other researchers without your additional informed consent. Once you give your permission to have your de-identified information or samples stored, they will be available indefinitely and cannot be removed due to the inability to identify them.

INFORMED CONSENT SIGNATURES

This consent includes the following:

- **Key Information Page**
- **Detailed Consent**

You will receive a copy of this consent form after it has been signed.

_____	_____
Signature of research subject	**Date**
_____	
Printed name of research subject	
_____	_____
Printed name of [authorized] person obtaining informed consent	Date

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PROJECT INFORMATION

0 unresolved comment(s)

Title of Project: (Use the exact title listed in the grant/contract application, if applicable).
If your research investigates any aspect of COVID-19, please include "COVID19" at the beginning of your Project Title and Short Title

COVID19: Povidone-Iodine Intranasal for Prophylaxis in front-line Physicians and Inpatients during the SARS-CoV-2 Pandemic (PIIPPI)

Short Title Description
Please use a few key words to easily identify your study - this text will be displayed in the Dashboard listing for your study.

COVID19 Mucosal Prophylaxis using Povidone-iodine

Anticipated Ending Date of Research Project: 4/1/2023

Maximum number of human subjects (or records/specimens reviewed) 300

After approval, will the study be open to enrollment of new subjects or new data/specimen collection? (•) Yes ( ) No

SUBJECT DEMOGRAPHICS

0 unresolved comment(s)

Age level of human subjects: (i.e., 6 mths.; 2yrs., etc..) 18 to 99

Indicate the targeted/planned enrollment of the following members of minority groups and their subpopulations. Possible demographic sources: Census Regional Analyst Edition, Kentucky Race/Ethnic Table, Kentucky Population Data.
(Please note: The IRB will expect this information to be reported at Continuation Review time for Pre-2019 FDA-regulated Expedited review and Full review applications):

Enter Numbers Only!

Ethnic Origin	#Male	#Female
American Indian/Alaskan Native:		
Asian:	7	
Black/African American:	1	3
Hispanic/Latino:	1	5
Native Hawaiian/Pacific Islander:		
White/Caucasian:	62	59
Other or Unknown:	9	9

If unknown, please explain why: Race & ethnicity data for 18 individuals overall (17 since last CR) were unknown due to the subject not wanting to share the information or the data was unavailable for data collection. Race and ethnic data were collected either verbally or from medical charts if the patient was at UK.

Indicate the categories of subjects and controls to be included in the study. Depending on the subject category applicable to your research you may be required to complete additional forms. [Note, if the study does not involve direct intervention or direct interaction with subjects, (e.g., record-review research, outcomes registries), do not check mark populations which the research does not specifically target. For instance, a large record review of a diverse population may incidentally include a prisoner or an international citizen, but, if the focus or intent of the study has nothing to do with that status, you do not need to check those category(ies).]

Check All That Apply (at least one item must be selected)

ADDITIONAL INFORMATION:

- ☐ Children (individuals under age 18)
- ☐ Wards of the State (Children)
- ☐ Emancipated Minors
- ☐ Students
- ☐ College of Medicine Students
- ☑ UK Medical Center Residents or House Officers
- ☐ Impaired Consent Capacity Adults
- ☐ Pregnant Women/Neonates/Fetal Material
- ☐ Prisoners
- ☐ Non-English Speaking
- ☐ International Citizens
- ☑ Normal Volunteers
- ☐ Military Personnel and/or DoD Civilian Employees
- ☑ Patients
- ☐ Appalachian Population

Please visit the IRB Survival Handbook under the named topic:

- Children/Emancipated Minors
- Students as Subjects
- Prisoners
- Impaired Consent Capacity Adults: Link to required Form

And/Or:

- UKMC Residents or House Officers [see requirement of GME]
- Non-English Speaking [see instructions for recruitment and E-IRB Research Description section on same topic]
- International Citizens (DoD SOP may apply)
- Military Personnel and/or DoD Civilian Employees (DoD SOP may apply)

The next questions involve assessment of the study relative to potential recruitment of subjects with impaired consent capacity (or likelihood).

☐ Check this box if your study does not involve direct intervention or direct interaction with subjects (e.g., record-review research, secondary data analysis). (you will not need to answer the impaired consent capacity questions)

Does this study focus on adult subjects with any of the clinical conditions listed below that present a high *likelihood* of impaired consent capacity or *fluctuations* in consent capacity? (see examples below)

○ Yes ◉ No

If Yes, go to the following link and complete and attach the indicated form unless you are filing for an exemption certification: https://ris.uky.edu/ori/oriforms/formt/Scale.asp

Examples of such conditions include:

- Traumatic brain injury or acquired brain injury
- Severe depressive disorders or Bipolar disorders
- Schizophrenia or other mental disorders that involve serious cognitive disturbances
- Stroke
- Developmental disabilities
- Degenerative dementias
- CNS cancers and other cancers with possible CNS involvement
- Late stage Parkinson's Disease
- Late stage persistent substance dependence
- Ischemic heart disease
- HIV/AIDS
- COPD
- Renal insufficiency
- Diabetes
- Autoimmune or inflammatory disorders
- Chronic non-malignant pain disorders
- Drug effects
- Other acute medical crises

Attachments

INFORMED CONSENT/ASSENT PROCESS/WAIVER

0 unresolved comment(s)

For your informed consent attachment(s), please download the most up-to-date version listed in "All Templates" under the APPLICATION LINKS menu on the left, and revise to be in accord with your research project.

Additional Resources:

- Sample Repository/Registry/Bank Consent (Word)
- Instructions for Proposed Informed Consent Document
- Instructions for Proposed Assent Form

Consent/Assent Tips:

- **If you have multiple consent documents, be sure to upload each individually (not all in a combined file).**
- **Changes to consent documents (e.g., informed consent form, assent form, cover letter, etc...) should be reflected in a 'tracked changes' version and uploaded separately with the Document Type "Highlighted Changes".**
- **It is very important that only the documents you wish to have approved by the IRB are attached; DELETE OUTDATED FILES -- previously *approved* versions will still be available in Protocol History.**
- **Attachments that are assigned a Document Type to which an IRB approval stamp applies will be considered the version(s) to be used for enrolling subjects once IRB approval has been issued.**
  Document Types that do NOT get an IRB approval stamp are:
  - **"Highlighted Changes",**
  - **"Phone Script", and**
  - **"Sponsor's Sample Consent Form".**

How to Get the Informed Consent Section Check Mark

1. **You must check the box for at least one of the consent items and/or check mark one of the waivers, then if applicable attach the corresponding document(s) as a PDF (if open to enrollment).**
2. **If you no longer need a consent document approved (e.g., closed to enrollment), or, the consent document submitted does not need a stamp for enrolling subjects (e.g., umbrella study, or sub-study), only check mark the "Stamped Consent Doc(s) Not Needed".**
3. **After making your selection(s) be sure to scroll to the bottom of this section and SAVE your work!**

Check All That Apply

- ☐ Informed Consent Form (and/or Parental Permission Form)
- ☐ Assent Form
- ☐ Cover Letter (for survey/questionnaire research)
- ☐ Phone Script
- ☑ Informed Consent/HIPAA Combined Form
- ☐ Debriefing and/or Permission to Use Data Form
- ☐ Sponsor's sample consent form for Dept. of Health and Human Services (DHHS)-approved protocol
- ☐ Stamped Consent Doc(s) Not Needed

Attachments

Attach Type	File Name
CoverLetter	coverletter_8.9.2021_update.pdf
CoverLetter	coverletter_8.9.2021_clean.pdf
Informed ConsentHIPAA Combined Form	69189_Informed ConsentHIPAA Combined Form_372824_followupsurvey.pdf
Informed ConsentHIPAA Combined Form	clean 69189_Informed ConsentHIPAA Combined Form_495721 (1).pdf

☐ Request for Waiver of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for the informed consent process, or alteration of some or all of the elements of informed consent (i.e. medical record review, deception research, or collection of biological

specimens), complete Section 1 and Section 2 below.

Note: The IRB does not approve waiver or alteration of the consent process for greater than minimal risk research, except for planned emergency/acute care research as provided under FDA regulations. Contact ORI for regulations that apply to single emergency use waiver or acute care research waiver (859-257-9428).

SECTION 1.

Check the appropriate item:

☐ I am requesting waiver of the requirement for the informed consent process.

☐ I am requesting alteration of the informed consent process.

If you checked the box for this item, describe which elements of consent will be altered, and/or omitted, and justify the alteration.

SECTION 2.

The IRB may consider your request provided that **all** of the following conditions apply to your research and are appropriately justified. Explain in the space provided for each condition how it applies to your research.

a) The research involves no more than minimal risk to the subject.

b) The rights and welfare of subjects will not be adversely affected.

c) The research could not practicably be carried out without the requested waiver or alteration.

d) Whenever possible, the subjects or legally authorized representatives will be provided with additional pertinent information after they have participated in the study.

e) If the research involves using or accessing identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format.

- Private information/specimens are “identifiable” if the investigator may ascertain the identity of the subject or if identifiers are associated with the information (e.g., medical records). This could be any of the 18 HIPAA identifiers including dates of service.
- If not using identifiable private information or identifiable biospecimens, insert N/A below.

☑ Request for Waiver of Documentation of Informed Consent Process

If you are requesting IRB approval for waiver of the requirement for documentation of informed consent (i.e. telephone survey or mailed survey, internet research, or certain international research), **your research activities must fit into one of three regulatory options**:

1. The only record linking the participant and the research would be the consent document, and the principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves participants who use illegal drugs).
2. The research presents no more than minimal risk to the participant and involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script).
3. The participant (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm, and the research presents no more than minimal risk to the subject and there is an appropriate alternative mechanism for documenting that informed consent was obtained.

Select the option below that best fits your study, and explain in the space provided how your study meets the criteria for the selected regulatory option.

Note: The IRB cannot waive the requirement for documentation or alter the consent form for FDA-regulated research unless it meets Option #2 below. FDA does not accept Option #1.

Note: Even if a waiver of the requirement for documentation is approved by the IRB, participants must still be provided oral or written (e.g., cover letter) information including all required and appropriate elements of consent so they have the knowledge and opportunity to consider whether or not to participate. To help ensure required elements are included in your consent document, please use the **Cover Letter Template** as a guide: *English*- [WORD], Spanish- [WORD] The cover letter template was developed specifically for survey/questionnaire research; however, it may be useful as a guide for developing a consent document for other types of research as well.

○ **Option 1**

a) The only record linking the participant and the research would be the consent document:

b) The principal risk would be potential harm resulting from a breach of confidentiality (i.e., a study that involves subjects who use illegal drugs).

Under this option, each participant (or legally authorized representative) must be asked whether (s)he wants to sign a consent document; if the participant agrees to sign a consent document, only an IRB approved version should be used.

◉ **Option 2**

a) The research presents no more than minimal risk to the participant:

The information will be associated with their unique name and not with any identifiable information. The new strategy (follow-up survey) will only apply to the provider arm.

b) Involves no procedures for which written consent is normally required outside of the research context (i.e. a cover letter on a survey, or a phone script):

The follow-up survey will add no more than minimal risk to the subject as it is a subjective review of how the participant is doing and any further thoughts they had of the protocol and whether or not they decided to undergo vaccination. The new strategy (follow-up survey) will only apply to the provider arm.

○ **Option 3**

a) The subject (or legally authorized representative) is a member of a distinct cultural group or community in which signing forms is not the norm.

b) The research presents no more than minimal risk to the subject.

c) There is an appropriate alternative mechanism for documenting that informed consent was obtained.

RESEARCH DESCRIPTION

0 unresolved comment(s)

****!!!PLEASE READ!!!** Known Issue: The below text boxes do not allow symbols, web addresses, or special characters (characters on a standard keyboard should be ok). If something is entered that the text boxes don't allow, user will lose unsaved information.**

Workaround(s):

- **Save your work often to avoid losing data.**
- **Use one of the attachment buttons in this section, or under the Additional Information section to include the information with your application. During the document upload process, you will be able to provide a brief description of the attachment.**

Background: Provide an introduction and background information. Describe past experimental and/or clinical findings leading to the formulation of your study. For research involving investigational drugs, describe the previously conducted animal and human studies. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. For research that involves FDA approved drugs or devices, describe the FDA approved uses of this drug/device in relation to your protocol. Attach a copy of the approved labeling as a product package insert or from the Physician's Desk Reference in the applicable E-IRB "Study Drug" or "Study Device" section.

The COVID-19 pandemic, caused by SARS-CoV-2, has been implicated in over 360,000 (now over 7 million) cases in the United States alone and has now been implicated in the deaths of 1000 health care workers and over 200,000 citizens. The most current statistics indicate that up to 80% of infected patients may be asymptomatic or with negligible symptomatology. This, added to the national shortage of personal protective equipment and the need to reuse personal protective equipment, lends to the significantly increased risk to health care providers.

The highest concentration of viral particles resides within the nasopharynx and the virus is thought to spread via respiratory droplets with the potential for transmission via inhalation of droplets, contact to the nose and mouth with infected materials, and a potential for airborne transmission. Given that frontline workers are involved in high risk procedures including intubation, bronchoscopy, as well as proning patients (which can lead to droplet production) and in some cases are reusing PPE, finding ways to reduce viral load or viral exposure are paramount. Interestingly, hospital transmissions have decreased substantially as we have begun to better understand the virus and have practiced increased vigilance in hand hygiene, masking, goggle use, and testing.

However, as lockdowns have begun to abate and there is increasing laxity in social distancing, community spread is becoming more heavily featured with high risk areas including restaurants, schools, and other enclosed areas. As fall and winter begin in the northern hemisphere, the risk of increased community spread paired with national anti-masking sentiment and school reopenings could result in catastrophic outcomes.

Povidone-iodine (PVI) is a broad-spectrum antiseptic with activity against bacteria, fungi, and viruses. It has been previously used in both intranasal preparations against MRSA as well as oral preparations in in-vitro studies of SARS-CoV, MERS-CoV, H1N1, rotavirus, and recently SARS-CoV-2, the coronavirus that causes COVID19.

PVI is widely used as an antiseptic and is well-tolerated and has been shown to have little to no effect on mucociliary clearance, olfaction, or thyroid function as long as the preparation is not used in excess of 24 months.

Our preliminary data has demonstrated the safety of PVI-P in our study group with no adverse outcomes and no transmission of COVID19. With this data and the increased rates of community spread, opening the trial to the community will allow us to assess PVI-P efficacy in the non-healthcare setting.

For interested participants who have had a known COVID-19 exposure but who were not able to sign onto the prophylaxis arms, a post-exposure prophylaxis arm will now be offered as well.

Post-exposure prophylaxis arm: For interested parties who were not able to sign up for the prophylaxis trial and have had a recent COVID-19 exposure per Centers for Disease Control guidelines, a baseline COVID19 test will be performed and for those who are eligible, povidone iodine nasal spray and gargle will be administered for one week during isolation with a follow-up test at the end of that week.

Objectives: List your research objectives. You may reference grant application/sponsor's relevant protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below.

Arm 1 – Healthcare Workers: To utilize povidone iodine nasal spray and gargle as chemical prophylaxis for front line health care workers with efficacy of treatment assessed via pre-intervention COVID19 testing and repeat COVID testing at the end of 3 weeks OR at the time of development of symptoms consistent with COVID19 (fever, cough, anosmia, nasal congestion, conjunctivitis, gastrointestinal symptoms, cardiopulmonary symptoms). A follow-up questionnaire at least 3 months after participation will be used to assess whether participants ever contracted COVID-19 following their involvement in the study.

Arm 2 – Hospitalized Patients: To utilize povidone iodine nasal sprays and gargle as chemical prophylaxis for preoperative patients and patients who will or have been hospitalized for approximately 1 week with efficacy of treatment assessed via pre-intervention COVID19 testing and repeat COVID testing at the end of 2 weeks OR at the time of development of symptoms consistent with COVID19 (fever, cough, anosmia, nasal congestion, conjunctivitis, gastrointestinal symptoms, cardiopulmonary symptoms).

Arm 3 -- Community: To utilize povidone iodine nasal sprays and gargle as chemical prophylaxis for members of the community who are interested in participating in the study and who have not had a prior COVID19 diagnosis

Arm 4 -- Post-exposure prophylaxis arm: As the numbers of community exposures and hospitalizations have increased, more people are being exposed to COVID. For interested parties who were not able to sign up for the prophylaxis trial and have had a recent COVID-19 exposure per Centers for Disease Control guidelines, a baseline COVID19 test will be performed and for those who are eligible, thrice daily povidone iodine nasal spray and gargle will be offered for one week during isolation with a follow-up test at the end of that week. Participants whose initial test is positive for COVID19 will be automatically excluded and referred to their local Department of Public Health. Those with thyroid dysfunction, an allergy to shellfish or contrast dye, or who are pregnant or breast-feeding will automatically be placed into the control group (no iodine preparation).

Study Design: Describe the study design (e.g., single/double blind, parallel, crossover, etc.). Indicate whether or not the subjects will receive placebo medication at some point in the research procedures. Also, indicate whether or not the subjects will be randomized in this study. You may reference sponsor's protocol pages and attach as an appendix in the E-IRB "Additional Information" section, however, a summary paragraph must be provided in the text box below. (Including the study design table from a sponsor's protocol is helpful to IRB members.)

Community-Based Participatory Research: If you are conducting community-based participatory research (CBPR), describe strategies for involvement of community members in the design and implementation of the study, and dissemination of results from the study.

Research Repositories: If the purpose of this submission is to establish a Research Repository (bank, registry) indicate whether the material you plan to collect would or would not be available from a commercial supplier, clinical lab, or established IRB approved research repository. Provide scientific justification for establishment of an additional repository collecting duplicate material. Describe the repository design and operating procedures. For relevant information to include, see the UK Research Biospecimen Bank Guidance [PDF] or the UK Research Registry Guidance [PDF]

Arm 1 - Healthcare Workers:
Front line health care workers (FLHCW) who will be directly interacting with SARS-CoV-2 positive patients will be considered eligible for the study. All interested participants will undergo informed consent per ORI guidelines. All front-line HCWs are eligible unless they have PREVIOUSLY had a positive test for the novel coronavirus. HCWs who are pregnant, nursing, have thyroid cancer/disorder, or a shellfish allergy can still participate but will be automatically put into the control group (standard PPE alone without povidone-iodine). Participants will be given a COVID19 swab test as well as a pre screeningg questionnaire assessing study eligibility. If they test negative, they are eligible for inclusion. All participants will be offered the intervention.

Standard nasal swab testing for COVID19 prior to beginning of front-line work to assess for COVID19 status:

FLHCW with negative COVID19 testing prior to enrollment and no symptoms concerning for COVID19 (fever, cough, anosmia, shortness of breath, conjunctivitis) can participate in trial. Those with a positive test will be referred to IPAC for further guidance but will be excluded from the study.

Intervention: The participants will be asked to complete a pre-participation survey via REDCAP. They will then be given premade gargles and nasal sprays and will utilized email reminds for daily questionnaire follow up. Povidone-Iodine nasal spray and gargle (10% diluted 1:30) will be used prior to the start of shift, mid shift, and at the end of shift. First, the nasal spray will be sprayed in the nose (2 sprays each naris). For adequate coverage, the participant should be able to taste the iodine or see it in the back of the throat. This should be left in place for 30 seconds. Then, the participant will gargle the solution for 30 seconds and not have anything to eat or drink by mouth for 30 minutes.

Control: For participants who either 1) choose NOT to use the iodine preparation OR 2) are allergic, are pregnant, or have thyroid disorders and thus ineligible to receive the nasal preparation, appropriate PPE without povidone-iodine will be utilized. This will not be randomized and participants can self select to participate in this group but not use the povidone-iodine preparation.

Those in this group will still undergo the pre screening questionnaire, pre study COVID 19 test, daily symptom checks, and post study questionnaire and COVID 19 test.

For both intervention and control groups, after 3 weeks OR at the first sign of potential infection, participants will be re-swabbed for COVID19 and will fill out a post study questionnaire.

At least 3 months after participation in the trial, a follow-up survey will be sent to the participants via their unique questionnaire link to assess whether they contracted COVID-19 following the study as well as to gather any subjective insights they had regarding their participation during the pandemic.

Arm 2 - Hospitalized Patients:
Given the high rate of asymptomatic carriers, a second arm will also be planned for patients who have a planned 7+ day hospitalization or who are set to undergo a significant surgical procedure. These patients will be offered participation in the study as

well and will be given the same pre screening questionnaire and undergo preoperative testing if they consent. Patients who test positive for COVID19 will be automatically excluded and referred to IPAC. Patients undergoing surgery for presumed thyroid cancer or who have an allergy to shellfish or contrast dye will automatically be placed into the control group (no iodine preparation). For patients in the study group, PVI gargle and nasal sprays will be applied preoperatively or shortly after admission and enrollment in the study for the non-operative group. The patients will then be retested in 2 weeks or as directed by the presentation of symptoms concerning for infection with SARS-CoV-2. If the patients are no longer admitted at the 2 week time point, they will return to a research clinic for testing. If they are discharged prior to the end of the 2 week period, they will be given the nasal and oral preparation to continue as directed after discharge until follow up in the research clinic. Daily questionnaires via REDCap will be given to follow up on use and either filled out by the patient if able or by study personnel.

Control: For participants who either 1) choose NOT to use the iodine preparation OR 2) are allergic, are pregnant, or have thyroid disorders and thus ineligible to receive the nasal preparation, standard precautions without povidone-iodine will be utilized. This will not be randomized and participants can self select to participate in this group but not use the povidone-iodine preparation.

Those in this group will still undergo the pre screening questionnaire, pre study COVID 19 test, daily symptom checks, and post study questionnaire and COVID 19 test.

For both intervention and control groups, after 2 weeks OR at the first sign of potential infection, participants will be re-swabbed for COVID19 and will fill out a post study questionnaire.

Arm 3 - Community:
Given the high rate of asymptomatic carriers, a third arm will also be planned for community members interested in participating. They must have never tested positive for COVID19.

Those who wish to participate in the study will be given the pre screening questionnaire and undergo preoperative testing if they consent. Participants who test positive for COVID19 will be automatically excluded and referred to their local Department of Public Health. Those with thyroid dysfunction, an allergy to shellfish or contrast dye, or who are pregnant or breast-feeding will automatically be placed into the control group (no iodine preparation). For patients in the study group, PVI gargle and nasal sprays will be mailed directly to them. The participants will then be retested in 3 weeks or as directed by the presentation of symptoms concerning for infection with SARS-CoV-2. Daily questionnaires via REDCap will be given to follow up on use and either filled out by the patient if able or by study personnel if assistance is requested.

Control: For participants who either 1) choose NOT to use the iodine preparation OR 2) are allergic, are pregnant, or have thyroid disorders and thus ineligible to receive the nasal preparation, standard precautions without povidone-iodine will be utilized. This will not be randomized and participants can self select to participate in this group but not use the povidone-iodine preparation.

Those in this group will still undergo the pre screening questionnaire, pre study COVID 19 test, daily symptom checks, and post study questionnaire and COVID 19 test.

For both intervention and control groups, after 3 weeks OR at the first sign of potential infection, participants will be re-swabbed for COVID19 and will fill out a post study questionnaire.

Post-exposure prophylaxis arm: Anyone in the community or in the hospital who have had a known COVID-19 exposure are invited to participate. For interested parties who were not able to sign up for the prophylaxis trial and have had a recent COVID-19 exposure per Centers for Disease Control guidelines, a baseline COVID19 test will be performed and for those who are eligible, thrice daily povidone iodine nasal spray and gargle will be offered for one week during isolation with a follow-up test at the end of that week. Participants whose initial test is positive for COVID19 will be automatically excluded and referred to their local Department of Public Health. Those with thyroid dysfunction, an allergy to shellfish or contrast dye, or who are pregnant or breast-feeding will automatically be placed into the control group (no iodine preparation).

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Study Population: Describe the characteristics of the subject population, such as anticipated number, age range, gender, ethnic background and health status. Identify the criteria for inclusion and exclusion. Explain the rationale for the use of special classes such as fetuses, pregnant women, children, institutionalized, adults with impaired consent capacity, prisoners, economically or educationally disadvantaged persons or others who are likely to be vulnerable.

If women or minorities are included, please address how the inclusion of women and members of minority groups and their subpopulations will help you meet your scientific objectives. Exclusion of women or minorities requires clear and compelling rationale that shows inclusion is inappropriate with respect to the health of the subjects or that inclusion is inappropriate for the purpose of the study. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be excluded routinely from participation in clinical research.

Provide the following information:

- A description of the subject selection criteria and rationale for selection in terms of the scientific objectives and proposed study design;
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group;

- The proposed dates of enrollment (beginning and end);
- The proposed sample composition of subjects.

You may reference grant application/sponsor's relevant protocol pages and attach as an appendix using the below attachment button, however, a summary paragraph must be provided in the text box below.

For Arm 1 - Healthcare Workers: Any health care provider who will be front-line (ie in the Emergency Department as nurse, technician, physician, radiology technician, pharmacist) or will be coming into direct contact with COVID19 positive or suspected COVID19 positive (intensivists, otolaryngology surgeons, anesthetists, respiratory technologists, etc.) will be invited to participate in the study. Participants who test positive for COVID19 will be excluded and IPAC will be contacted for further assistance with management. Interested parties who cannot use the preparation (as in the case of pregnancy, breast feeding, thyroid cancer or dysfunction, inability to tolerate the preparation), would still be eligible for participation but would be considered the control group. Only adults would be enrolled in the study. Enrollment would begin as soon as possible given the oncoming "peak" of SARS-CoV-2 infections that are anticipated to begin soon.

Residents and fellows will also be invited to participate. Approval has been obtained for the program directors for otolaryngology, obstetrics/gynecology, critical care, trauma, general surgery, anesthesiology, and emergency medicine. They will be invited via general announcements to all healthcare providers delineated in the Advertising section.

The GME office requested a separate consent for trainees with language regarding limiting coercion and negative impact on learning and this was approved. Please see the PDF of emails demonstrating permission from the program directors per ACGME guidelines.

Every effort will be made to prevent anyone who is not on the research team from knowing that the resident gave information, or what that information is including the participant's training program. When signing up for the study, each participant will be assigned a code and data will only be associated with that code. COVID19 testing will be associated with the name, but will not be publicly disclosed. The participant's name will only be associated with testing status so that they can be alerted to the results. If there is positive COVID19 during the study, the participant will be referred to the Infection Prevention and Control (IPAC) group for further treatment. The training programs will not be made aware of the decision about participating or not. Each participant will be treated as any provider participating in this study. The decision to participate is solely based on each participant's choice. Due to minimal involvement, there is not expected effect on education.

For Arm 2 – Hospitalized Patients: Any patient scheduled for surgery or who is admitted and expected to have at least a seven-day hospitalization will be invited to participate in the study. Participants who test positive for COVID19 will be excluded and IPAC will be contacted for further assistance with management. Interested parties who cannot use the preparation (as in the case of pregnancy, breast feeding, thyroid cancer or dysfunction or inability to tolerate the preparation), would still be eligible for participation but would be considered the control group.

For Arm 3 – Community: Anyone in the community who is interested in participating from the community is invited to participate. Participants who have previously tested positive for COVID19 will be excluded. If on their screening swab they are found to be positive, they will be referred to their local Department of Public Health. Interested parties who cannot use the preparation (as in the case of pregnancy, breast feeding, thyroid cancer or dysfunction or inability to tolerate the preparation), would still be eligible for participation but would be immediately put into the control group.

Post-exposure prophylaxis arm: Anyone in the community or in the hospital who have had a known COVID-19 exposure are invited to participate. For interested parties who were not able to sign up for the prophylaxis trial and have had a recent COVID-19 exposure per Centers for Disease Control guidelines, a baseline COVID19 test will be performed and for those who are eligible, thrice daily povidone iodine nasal spray and gargle will be offered for one week during isolation with a follow-up test at the end of that week. Participants whose initial test is positive for COVID19 will be automatically excluded and referred to their local Department of Public Health. Those with thyroid dysfunction, an allergy to shellfish or contrast dye, or who are pregnant or breast-feeding will automatically be placed into the control group (no iodine preparation).

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Subject Recruitment Methods & Privacy: Using active voice, describe plans for the identification and recruitment of subjects, including how the population will be identified, and how initial contact will be made with potential subjects by those having legitimate access to the subjects' identity and the subjects' information.

Describe the setting in which an individual will be interacting with an investigator or how and where members of the research team will meet potential participants. If applicable, describe proposed outreach programs for recruiting women, minorities, or disparate populations as participants in clinical research. Describe steps taken to minimize undue influence in recruiting potential participants.

Please note: Based upon both legal and ethical concerns, the UK IRB does not approve finder's fees or "cold call" procedures made by research staff unknown to the potential participant. The ORI/IRB does not control permission to any UK listserv, mass mailing list, etc. Investigators must secure prior approval for access and use from owners/managers.

For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page and the PI Guide to Identification and Recruitment of Human Subjects for Research [PDF].

Any personnel who will be involved in direct patient care or who perform airway surgical interventions (otolaryngology, anesthesia, pulmonology) would be invited to take part in the study. This will be advertised via email. The prescreening questionnaire will be

provided via email. The research team will meet the participants in their place or work or in a research clinic to perform the initial COVID 19 testing and provide instructions and povidone-iodine materials, depending on convenience to the participant. Please see attached advertisements for healthcare worker participants. For residents, permission has been requested from the program directors per ACGME requirements and documentation of that is included in the pdf attachments.

For patients set to undergo surgery, the study will be offered upon arrival to the pre-anesthesia care unit or during presurgical visits. The will be advertised to surgical departments via email. The research team will meet these inpatient participants in the pre-anesthesia care unit or during the presurgical visit to enroll, provide consent, and provide instructions.

For patients admitted to the hospital, the study will be offered upon admission. Providers in the ED and medicine departments will be informed of recruitment for this study via email. The research team may review the charts of those being admitted to the hospital for eligibility criteria including admission diagnosis, COVID test results, length of stay, and type and dates of procedures performed. Once enrolled, these patients will be informed that their medical records will be reviewed as part of the study to collect data on their names, medical record numbers, age, gender, ethnicity, comorbidities, admission diagnosis, COVID test results, length of stay, type and dates of procedures performed. The research team will meet these inpatient participants in the hospital once they are admitted to enroll, provide consent, and provide instructions.

For community members, information will be disseminated via word of mouth and the website (https://piippi.med.uky.edu). These participants will then be contacted by a member of our study team who will email them more information about the study as well as the consent form for them to review. In that same email, the study team member will ask to schedule a phone call or Zoom meeting to discuss the study and do the informed consent process. Once the meeting occurs, the participant will sign and date the consent (with a wet signature) and return the form back to the study team. Once the study team receives the consent, the participant is officially enrolled.

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Advertising: Specify if any advertising will be performed. If yes, please see "IRB Application Instructions - Advertisements" for instructions on attaching copies of the information to be used in flyers or advertisements. Advertisements must be reviewed and approved by the IRB prior to use. For additional details, see topic "Recruitment of Subjects/Advertising" on ORI's IRB Survival Handbook web page for the *PI Guide to Identification and Recruitment of Human Subjects for Research* [D7.0000] document [PDF]. If you will be recruiting subjects via advertising at non-UK owned or operated sites, you should include a copy of written permission from that site to place the advertisement in their facilities.

Note: Print and media advertisements that will be presented to the public also require review by UK Public Relations (PR) to ensure compliance with UK graphic standards, and equal opportunity language. See Advertising Instructions for PR contacts.

Please see attachment for study invitation and website.

Print advertisements: The study will recruit subjects through flyers, brochures, posters, Research Spotlights, ads placed on campus and in the surrounding community and region (Study Team will place/remove ads), including but not limited to the UK Medical Center, UK Clinics, Good Samaritan Hospital, Student Center, UHS, the 5 UK Center for Clinical and Translational Research wall mounts, Cardinal Hill, monitor screens, and area facilities and businesses.

Internet and Social Media: This study will be advertised on recruitment internet webpages in digital or video form (e.g., UKclinicalresearch.com, ResearchMatch.org, CenterWatch.com, CISCRP, UK, CCTS and may utilize Google Adwords). The study will be promoted via social media, including Facebook boost ads, UK_CCTS Facebook, UK_CCTS Twitter, UK_CCTS Instagram, UK and UKHC social media, and departmental/lab pages. If advertised on UKClinicalresearch.com, the online study flyer will include an option for interested individuals to enter and submit their contact information, they will be asked whether study team can contact them (Yes or No) via study-related text messages, and CCTS will also ask, 'How did you learn about the study? Internet and social media recruitment will follow the terms of use for each site utilized. The study will also be promoted through UK HC monitor screens.

Research Participant Registries: Potential participants may be identified from registry databases, including but not limited to ResearchMatch.org*, Wellness Health and You, Sanders Brown Center on Aging, Infectious Disease, Dentistry, and the Markey Cancer Center.

*ResearchMatch.org will be utilized as a recruitment tool for this protocol. ResearchMatch.org is a national electronic, web-based recruitment tool that was created through the Clinical & Translational Science Awards Consortium in 2009 and is maintained at Vanderbilt University as an IRB-approved data repository (see IRB #090207)." Once UK IRB approval is obtained the researcher or proxy will upload a flyer with no contact information will by email via ResearchMatch to selected de-identified participants in the ResearchMatch registry. If the de-identified participant selects "Yes, I'm interested!" the researcher or proxy will receive information about participant and they may contact them with more information about their research study. If the participant selects "No, thanks", researcher or proxy will not receive any information from de-identified participant.

REDCap prescreening form: The study will employ a pre-screening eligibility survey to determine if a volunteer meets basic inclusion/exclusion criteria We will build and administer the eligibility survey on UK's REDCap which provides HIPAA compliant storage on UK servers and encrypted transmission of survey responses. The portable devices do not download the data, it is directly stored into the secure web-based connection (https) behind the firewall. All files are password protected once entered into the system. All project data is stored and hosted locally. A link to the eligibility survey will be provided in recruitment materials. The link will also be included in study information sent to ResearchMatch participants who have indicated interest in the study. Before redirecting the volunteer outside of ResearchMatch and to the REDCap survey, the volunteer is once again asked to confirm their interest in

completing the pre-screening survey.

Outreach activities: The CCTS attends outreach activities to promote research participation in general (e.g., Roots & Heritage Festival, Latino Festival, Eastern Kentucky University, Transylvania Health fairs, etc.) and will brings all relevant study flyers that are enrolling participants.

Other recruitment databases: Registries that are owned and operated by non-UK research groups (e.g. partnering groups and Health-related Associations).

E-Newsletters and ListServs: This study may also go out on email distribution, listservs, or e- newsletters, e.g., the CCTS list serv, Markey Cancer Affiliates list servs, ResearchMatch.org, Wednesday's Word, Kentucky Office of Rural Health (KORH), Appalachian Translational Research Network (ATRN), etc.

Physician referral letters to community physicians for patient recruitment.

UK Public Relations (College/Dept. PR personnel) and UK HealthCare venues: Articles and interviews about the researchers and research study may be promoted via UKNow, Kentucky living, and other media outlets. Research and study-related articles published on UKNow may contain standard language directing interested individuals on where to read more about research and current studies: You can make a difference through participating in research and discovery. To find more information, including a list of current studies at UK and access to studies nationwide, please visit UKclinicalresearch.com or call 859.257.7856 or join the ResearchMatch.org or wellnesshealthandyou.org registries to be matched today.

UKPR, UK HealthCare marketing or the CCTS PRS may create videos to promote research, researchers and their studies to local, regional and national media venues and on internal hospital monitors.

UK HealthCare may place study recruitment flyers on their internal and external racks (e.g., UK pharmacies, clinics, UK Libraries and Lexington Libraries) or on digital monitors.

Participants may be recruited using newsletters, such as In the Loop, Health Matters, Making a difference, and external news letters.

The study may also be advertised through UKPR and UKHC outreach activities. UKHC and CCTS have booths at many events, and researchers and coordinators are invited to attend any events that pertain to their study populations.

Researchers may participate in radio or TV interviews. General information about their research may be presented with a phone number or website url for more study specify information.

Consenting members of the research team and/or consenting participants may be interviewed about the study for print, radio, or video which may be distributed via the aforementioned activities.

Attachments

Attach Type	File Name
Advertising	SUROGOTL-011 research match PR edit STAMPED.pdf
Advertising	COVID-19 Prevention Study flyer STAMPED.pdf
Advertising	PIIPPI Trial web site prototype NG edit 11 19 20 STAMPED.pdf
Advertising	SURGOTOL-011-flyer PR edit STAMPED.pdf
Advertising	Povidone Ad.docx
Advertising	PIIPPI Trial web site prototype MP edit APPROVED.pdf
Advertising	PIIPPI Trial web site prototype MP edit 5-13 APPROVED.pdf
Advertising	PIIPPI trial_ FINAL.docx
Advertising	UK Now PR Approval Email.pdf
Advertising	SUROGOTL-011 research match APPROVED.pdf
Advertising	SURGOTOL-011-flyer APPROVED.pdf
Advertising	SUROGOTL-011 social media APPROVED.pdf
Advertising	SURGOTOL-011_monitor[3] APPROVED.pdf

Informed Consent Process: Using active voice, describe the consent/assent procedures to be followed, the circumstances under which consent will be sought and obtained, the timing of obtaining informed consent, whether there is any waiting period between informing the prospective subject and obtaining consent, who will seek consent., steps taken to minimize the possibility of coercion or undue influence, the method used for documenting consent, and if applicable who is authorized to provide permission or consent on behalf of the subject. Note: all individuals authorized to obtain informed consent should be designated as such in the E-IRB "Study Personnel" section of this application.

Describe provisions for obtaining consent/assent among any relevant special populations such as children (see Children in Research Policy [PDF] for guidance), prisoners (see Summary of Prisoner Regulations [PDF] for guidance), and persons with impaired decisional capacity (see Impaired Consent Capacity Policy [PDF] for guidance). Describe, if applicable, use of specific instruments or techniques to assess and confirm potential subjects' understanding of the nature of the elements of informed consent and/or a description of other written materials that will be provided to participants or legally authorized representatives. If you have a script, please prepare it using the informed consent template as a guide, and submit it on a separate page.

Informed Consent for Research Involving Emancipated Individuals
If you plan to enroll some or all prospective subjects as emancipated, consult with UK legal counsel **when preparing the IRB application and prior to submitting the application to the IRB**. Include legal counsel's recommendations (legal counsel's recommendations may be attached in the E-IRB "Additional Information" section as a separate document, if necessary). For a complete definition of emancipated minors, see the section on *Emancipated Individuals* in the Informed Consent SOP [PDF].

Informed Consent for Research Involving Non-English Speaking Subjects
If you are recruiting non-English speaking subjects, the method by which consent is obtained should be in language in which the subject is proficient. Describe the process for obtaining informed consent from prospective subjects in their respective language (or the legally authorized representative's respective language). In order to ensure that individuals are appropriately informed about the study when English is their second-language, describe a plan for evaluating the level of English comprehension, and the threshold for providing a translation, or explain why an evaluation would not be necessary. For additional information on inclusion of non-English speaking subjects, or subjects from a foreign culture, see IRB Application Instructions for Recruiting Non-English Speaking Participants or Participants from a Foreign Culture.

Research Repositories
If the purpose of this submission is to establish a research repository describe the informed consent process. For guidance regarding consent issues, process approaches, and sample language see the Sample Repository/Registry/Bank Consent Template [PDF]

We will obtain consent with a combination of written materials and direct explanation. We will then ask for any volunteers to contact us regarding the study. Consent will be done either in person or online with a phone or Zoom contact call. These participants will then be contacted by a member of our study team who will email them more information about the study as well as the consent form for them to review. In that same email, the study team member will ask to schedule a phone call or Zoom meeting to discuss the study and do the informed consent process. Once the meeting occurs, the participant will sign and date the consent (with a wet signature) and return the form back to the study team. Once the study team receives the consent, it will be reviewed to ensure that a wet signature was used. Then the participant is officially enrolled into the study.

For inpatient participants, the iodine preparations will be distributed by the unit's pharmacist that will last the duration of the study. For health care workers and community participants, the iodine nasal and oral preparation will be mailed directly to participants' place of residence. There will be no lead in or waiting period for the study. There will be no incentive or payment given for participation in the study and participants can stop participation in the study whenever they choose as long as they alert the study team.

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Research Procedures: Describe the research procedures that will be followed. Identify all procedures that will be carried out with each group of subjects. Differentiate between procedures that involve standard/routine clinical care and those that will be performed specifically for this research project.

Arm 1 - UK Healthcare workers:
Front line health care workers (FLHCW) who will be directly interacting with SARS-CoV-2 positive patients will be considered eligible for the study and will be given study materials via email and embedded video. All interested participant will undergo informed consent per ORI guidelines. All front-line HCWs are eligible unless they have previously had a positive test for SARS-CoV-2. HCWs who are pregnant, nursing, have thyroid cancer/dysfunction, or a shellfish allergy or who cannot tolerate the preparation can still participate but will be automatically put into the control group (standard PPE alone without povidone-iodine). Participants will be given a COVID19 swab test as well as a questionnaire (Q1) assessing study eligibility. If they test negative, they are eligible for inclusion. All participants will be offered the intervention.

Standard nasal swab testing for COVID19 prior to beginning of front-line work to assess for COVID19 status. FLHCW with NEGATIVE COVID19 testing can participate in trial. Those with a positive test will be referred to IPAC for further guidance.

Intervention: The participants will be mailed premade gargles and nasal sprays to their homes as well as a calendar card to mark compliance. Povidone-Iodine nasal spray and gargle (10% diluted 1:30) will be used prior to the start of shift, during "lunchbreak", and at the end of shift. First, the nasal spray will be sprayed in the nose (2 sprays each naris). For adequate coverage, the participant should be able to taste the iodine or see it in the back of the throat. This should be left in place for 30 seconds. Then, the participant will gargle the solution for 30 seconds.

Control: For participants who either 1) choose NOT to use the iodine preparation or 2) are allergic, are pregnant, or have thyroid disorders and thus ineligible to receive the nasal preparation, standard PPE without povidone-iodine will be utilized.
After initial use, the participants will be asked to fill out a second questionnaire (Q2) assessing study tolerability and to turn in their calendar card to assess how many applications they were able to complete.

After 3 weeks of use OR at the first sign of potential infection, participants will be re-swabbed for COVID19.

Arm 2 - Hospitalized Patients:
Given the high rate of asymptomatic carriers, a second arm will also be planned for patients who have a 7+ day hospitalization or who are set to undergo a significant surgical procedure. These patients will be offered participation in the study as well and will be given the same questionnaire (Q1) and undergo preoperative testing if they consent. Patients who test positive for COVID19 will be automatically excluded and referred to IPAC. Patients undergoing surgery for presumed thyroid cancer or who have an allergy to shellfish or contrast dye will automatically be placed into the control group (no iodine preparation). For patients in the study group, PVIP gargle and nasal sprays will be applied preoperatively or shortly after admission and enrollment in the study for the non-operative group. The patients will then be retested in 2 weeks or as directed by the presentation of symptoms concerning for infection with SARS-CoV-2.

COVID 19 testing done for research purposes alone will be sent out to Solaris who will provide testing with costs paid by grant funding. There is no financial relationship between Solaris and the research personnel. Testing done due to new symptom onset will be paid for by the patient's insurance as this will be standard of care for COVID 19 evaluation.

Arm 3 - Community:
Participants in the community who are interested in participating will be given the same questionnaire (Q1) and undergo a pre-study COVID19 swab which they will upload along with their questionnaire to REDCap. Patients who test positive for COVID19 will be automatically excluded and referred to their local Department of Public Health for further guidance. Participants with thyroid dysfunction, pregnancy, who are breastfeeding, or who have an allergy to shellfish or contrast dye will automatically be placed into the control group (no iodine preparation). For patients in the study group, the iodine gargle and nasal sprays will be mailed to their homes to use during the study period. The participants will then be retested in 3 weeks or as directed by the presentation of symptoms concerning for infection with SARS-CoV-2.

Arm 4 - Post-exposure prophylaxis arm:
Anyone in the community or in the hospital who have had a known COVID-19 exposure are invited to participate. For interested parties who were not able to sign up for the prophylaxis trial and have had a recent COVID-19 exposure per Centers for Disease Control guidelines, a baseline COVID19 test will be performed and for those who are eligible, thrice daily povidone iodine nasal spray and gargle will be offered for one week during isolation with a follow-up test at the end of that week. Participants whose initial test is positive for COVID19 will be automatically excluded and referred to their local Department of Public Health. Those with thyroid dysfunction, an allergy to shellfish or contrast dye, or who are pregnant or breast-feeding will automatically be placed into the control group (no iodine preparation).

Attachments

Attach Type	File Name
ResearchProcedures	GWU Approved IRB.pdf
ResearchProcedures	Fitzgibbon Hospital IRB - PIPPI.pdf

Data Collection: List the data or attach a list of the data to be collected about or from each subject (e.g. interview script, survey tool, data collection form for existing data).

If the research includes survey or interview procedures, the questionnaire, interview questions or assessment scales should be included in the application (use attachment button below).

The data collection instrument(s) can be submitted with your application in draft form with the understanding that the final copy will be submitted to the IRB for approval prior to use (submit final version to the IRB for review as a modification request if initial IRB approval was issued while the data collection instrument was in draft form).

Note: The IRB approval process does not include a statistical review. Investigators are strongly encouraged to develop data management and analysis plans in consult with a statistician.

See attached REDCap questionnaires for both provider and inpatient groups. These will include a pre screening questionnaire, daily questionnaires, and a post study questionnaire. For patients who are unable to use REDCap, study personnel will ask the questions and import the data into REDCap. For the healthcare provider arm who used the online questionnaires, a follow-up questionnaire will be sent to their uniquename. Please see attached REDCap questionnaire "FollowUp PIIPPISurvey"

For enrolled patients that are admitted to the hospital, medical records will be reviewed as part of the study to collect data on their names, medical record numbers, age, gender, ethnicity, comorbidities including Charlson Comorbidity Index, admission diagnosis, COVID-19 test results, length of stay, and type and dates of procedures performed. Data will be extracted from the UKHC Enterprise Data Warehouse via the CCTS Honest Broker Analysts.

Race and ethnicity are being captured in the OnCore Database as well as study enrollment information (i.e. on study date, study IDs, treatment arms, etc).

Attachments

Attach Type	File Name
DataCollection	FollowUpPIIPPISurvey_PIIPPIFol.pdf
DataCollection	DailyQuestionnaire_PEPPI.pdf
DataCollection	PreStudyQuestionnaire_PEPPI.pdf
DataCollection	PostStudyQuestionnaire_PEPPIP.pdf
DataCollection	PreStudyQuestionnaire_Community[1].pdf
DataCollection	DailyQuestionnaire1_Community[1].pdf
DataCollection	PostStudyQuestionnaire_Community[1].pdf
DataCollection	58748 PIIPPI PrestudyQuestionnaire Patient.pdf
DataCollection	58748 PIIPPI DailyQuestionnaire Patient.pdf
DataCollection	58748 PIIPPI PoststudyQuestionnaire Patient.pdf
DataCollection	58748 PIIPPI PreStudyQuestionnaire Provider.pdf
DataCollection	58748 PIIPPI DailyQuestionnaire Provider.pdf
DataCollection	58748 PIIPPI PostStudyQuestionnaire Provider.pdf

Resources: Describe what resources/facilities are available to perform the research (i.e., staff, space, equipment). Such resources may include a) staffing and personnel, in terms of availability, number, expertise, and experience; b) psychological, social, or medical services, including counseling or social support services that may be required because of research participation; c) psychological, social, or medical monitoring, ancillary care, equipment needed to protect subjects; d) resources for subject communication, such as language translation services, and e) computer or other technological resources, mobile or otherwise, required or created during the conduct of the research. Please note: Some mobile apps may be considered mobile medical devices under FDA regulations (see FDA Guidance). Proximity or availability of other resources should also be taken into consideration, for example, the proximity of an emergency facility for care of subject injury, or availability of psychological support after participation.

Research activities conducted at performance sites that are not owned or operated by the University of Kentucky, at sites that are geographically separate from UK, or at sites that do not fall under the UK IRB's authority, are subject to special procedures for coordination of research review. Additional information is required (see IRB Application Instructions - Off-Site Research web page); supportive documentation can be attached in the E-IRB "Additional Information" section. Provide a written description of the role of the non-UK site(s) or non-UK personnel who will be participating in your research. The other site may need to complete its own IRB review, or a cooperative review arrangement may need to be established. Contact the Office of Research Integrity at (859) 257-9428 if you have questions about the participation of non-UK sites/personnel.

If the University of Kentucky is the lead site in a multi-site study, or the UK investigator is the lead investigator, describe the plan for managing the reporting of unanticipated problems, noncompliance and submission of protocol modifications and interim results from the non-UK sites.

The University of Kentucky will be the lead site in a multi-site study including George Washington University and Fitzgibbon Hospital. Both of these outside sites have received their own institutional IRB approvals attached. The coordinators at each site will oversee the recruitment of subjects and use their protocols for managing and reporting of unanticipated problems, etc. Should questions arise regarding reporting, recruitment, unanticipated problems, the PI and co-investigators will be contacted immediately via email or phone. Any concern for adverse events will be communicated to the University of Kentucky team immediately.

All noncompliance/adverse events/unanticipated problems will be sent to each individual site and the principle investigator of that specific site for determinations. The UK study team can receive all noncompliance/AEs/UP information from other sites as the lead site, but the UK study team will not need to submit any information pertaining to noncompliance/AE/UPs from other sites to the UK IRB for review purposes.

Deidentified data will be shared with the UK site for data analysis with our cohort of participants. Participant requirements are the same as for the UK site. The deidentified data will include COVID 19 initial and final tests, survey data consisting of an initial intake questionnaire, daily questionnaire regarding compliance with protocol and symptoms, and a final questionnaire regarding completion of participation. For inpatient data, also included will be age, reported gender, ethnicity, comorbidities, admission diagnosis, length of stay, type and date of procedures performed. The data will be transferred via secure encrypted email. Questionnaire data will be delivered via paper and scanned or via REDCap accessible to both sets of investigators.

Data user agreements with the partnering sites is reviewed by Ali Yankey at UK prior to sharing data.

This data will be received on a rolling basis as patients are recruited and reviewed quarterly.

Potential Risks: Describe any potential risks or likely adverse effects of the drugs, biologics, devices or procedures subjects may encounter while in the study. Please describe any physical, psychological, social, legal or other risks and assess their likelihood and seriousness.

Risks include a false negative COVID test, potential infection even while using the iodine preparations, foul taste, and nasal irritation, dryness, skin discoloration, or nosebleed. There is a minuscule risk of thyroid dysfunction if excessive amounts of the iodine preparations are used (ie not according to protocol).

Safety Precautions: Describe the procedures for protecting against or minimizing any potential risks, *including risks of breach of confidentiality or invasion of privacy*. Where appropriate, discuss provisions for ensuring necessary medical or professional intervention in the event of adverse events, or unanticipated problems involving subjects. Also, where appropriate, describe the provisions for monitoring the data collected to ensure the safety of subjects. If vulnerable populations other than adults with impaired consent capacity are to be recruited, describe additional safeguards for protecting the subjects' rights and welfare.

In order to reduce risks, patients will be screened for allergy to iodine or shellfish as well as for thyroid cancer/dysfunction history. Women of child-bearing age will be offered a pregnancy test. Participants who develop symptoms of COVID19 infection will be tested even if it is prior to to the 3 week interval. Participants will report any changes in smell/taste/bleeding to the PI and will stop use immediately.

Benefit vs. Risk: Describe potential benefits to the subject(s); include potential benefits to society and/or general knowledge to be gained. Describe why the risks to subjects are reasonable in relation to the anticipated benefit(s) to subjects and in relation to the importance of the knowledge that may reasonably be expected to result. If you are using vulnerable subjects (e.g., impaired consent capacity, pregnant women, etc…), justify their inclusion by describing the potential benefits of the research in comparison to the subjects' vulnerability and the risks to them. For information about inclusion of certain vulnerable populations, see the IRB/ORI Standard Operating Procedure for Protection of Vulnerable Subjects [C3.0100] [PDF].

The possible benefit is that povidone-iodine oral and nasal preparations may be an additional measure of protection for front line health care workers as well as vulnerable patients in the hospital who have the potential for nosocomial infection with the SARS-CoV-2 virus. The risks of minor nasal irritation and staining are minuscule compared to the substantial risk of infection with the virus.

Available Alternative Treatment(s): Describe alternative treatments and procedures that might be advantageous to the subjects, should they choose not to participate in the study. This should include a discussion of the current standard of care treatment(s).

If participants choose not to enroll in the study, they may choose to use nasal saline irrigations or throat gargles containing saline. Personal protective equipment should be used whenever possible and when in contact with suspected COVID19 patients.

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Research Materials, Records and Privacy: Identify the sources of research material obtained from living human subjects. Indicate what information (specimens, records, data, genetic information, etc.) will be recorded and whether use will be made of existing specimens, records or data. Explain why this information is needed to conduct the study.

Return of Research Results or Incidental Findings (if applicable):
If research has the potential to identify individual results or discover incidental findings that could affect the health of a subject, describe plans to assess, manage, and if applicable disclose findings with individual subjects or provide justification for not disclosing. For IRB expectations, refer to the UK IRB "Frequently Asked Questions (FAQs) on the Return of Research Results or Incidental Research Findings" [PDF].

Participants who take part in the study will be notified regarding the results of their COVID19 testing as well as pregnancy test should this be an issue. Inpatients will be notified that their medical record will be reviewed to collect data regarding patient names, medical record numbers, age, gender, ethnicity, comorbidities, admission diagnosis, COVID test results, length of stay, type and dates of procedures performed. This data will be deidentified after collection and reported only in aggregate.

Confidentiality: Specify where the data and/or specimens will be stored and how the researcher will ensure the privacy and confidentiality of both. Please address the following items or indicate if the following has been addressed in a HIPAA or Limited Review form:

- physical security measures (e.g., locked facility, limited access);
- data security (e.g., password-protection, data encryption);
- who will have access to the data/specimens and identifiers;
- safeguards to protect identifiable research information (e.g., coding, links, certificate of confidentiality);
- procedures employed when sharing material or data, (e.g., honest broker if applicable, written agreement with recipient not to re-identify, measures to ensure that subject identifiers are not shared with recipients).
- management after the study

Describe whether data/specimens will be maintained indefinitely or destroyed. If maintained, specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them. If the data/specimens will be destroyed, describe how and when the data/specimens will be destroyed. For multi-site studies, the PI consults the study sponsor regarding retention requirements, but must maintain records for a minimum of six years after study closure. Also, specify who will access the identified data/specimens, and why they need access. If applicable, describe what measures will be taken to ensure that subject identifiers are not given to the investigator. If applicable, describe procedures for sharing data/specimens with entities not affiliated with UK (If the research is non-sponsored you need a data use agreement to share data/specimens [Transfer Agreements]).

HIPAA/FERPA Minimal Access Standards: The IRB expects researchers to access the minimal amount of identifiers to

conduct the study and comply with applicable HIPAA and Family Educational Rights and Privacy Act (FERPA) requirements. If data are going to be collected, transmitted, and/or stored electronically, for appropriate procedures please refer to the guidance document "Confidentiality and Data Security Guidelines for Electronic Data" [PDF].

Cloud storage: For storage of data on cloud services other than UK OneDrive, please verify security settings are sufficient and in accordance with respective departmental, UK Corporate Compliance, and/or UK Information Technology requirements.

Creation of digital data application/program: If a research protocol involves the creation and/or use of a computer program or application, mobile or otherwise, please specify whether the program/application is being developed by a commercial software developer or the research team and provide any relevant information regarding the security and encryption standards used, how data is stored and/or transmitted to the research team, what information about the subjects the program/application will collect, etc. For relevant information to include, see Considerations for Protocol Design Concerning Digital Data [PDF]. The IRB may require software programs created or used for research purposes be examined by a consultant with appropriate Internet technology expertise to ensure subject privacy and data are appropriately protected.

NIH-funded genomic research: The National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy sets forth expectations that ensure the broad and responsible sharing of genomic research data consistent with the informed consent of study participants from which the data was obtained. If you are submitting genomic data to an NIH data repository, describe your NIH data sharing plan.

Management after study: Describe how the collected data/specimens will be managed after the end of the study. Specify whether identifiers will be removed from the maintained information/material. If identifiers will not be removed, provide justification for retaining them and specify what steps will be taken to secure the data/specimens (e.g., maintaining a coded list of identifiers separate from the data/specimens).

If the data/specimens will be destroyed, describe how, when, and why this will be done. Note that destruction of primary data may violate NIH and NSF retention and sharing requirements, journal publication guidance, and University Data-Retention policies. Additionally, primary data may be necessary for other purposes (to validate reproducibility, for data sharing, or for evidence in various investigations). PIs should carefully consider whether the destruction of data is justified.

The investigator is responsible for retaining signed consent and assent documents and IRB research records for at least six years after study closure, as outlined in the Study Closure SOP [PDF]. If the research falls under the authority of the FDA or other regulatory agencies, or a study sponsor is involved, additional requirements may apply.

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Data will be stored in a locked office on an encrypted computer at the University of Kentucky in the PI's office at 740 S. Limestone Rd Kentucky Clinic E300E in Dr. Kejner's office. REDCAP will be used for data collection. The data will be destroyed 6 years after study closure in accordance with UK Policy A13-050 and UK Policy A05-055.

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Payment: Describe the incentives (e.g., inducements) being offered to subjects for their time during participation in the research study. If monetary compensation is offered, indicate how much the subjects will be paid and describe the terms and schedule of payment. (It is IRB policy that provision should be made for providing partial payment to subjects who withdraw before the completion of the research. Monetary payments should be prorated or paid in full.)

No incentives will be provided.

Costs to Subjects: Describe any costs for care associated with research (including a breakdown of standard of care procedures versus research procedures), costs of test drugs or devices, and research procedure costs that are the subject's responsibility as a consequence of participating in the research. Describe any offer for reimbursement of costs by the sponsor for research related injury care.

There will be no cost to the participants. The PVI will be provided. If a COVID 19 test is clinically indicated based on symptoms either at the beginning of the study or during the study then that will be charged to insurance as part of standard of care. If patients are discharged from the hospital prior to the 2 week end point, then there is one additional visit to the research clinic for post study COVID 19 testing (with no charge unless testing clinically indicated due to COVID symptom onset).

Each participant will have 2 COVID 19 tests, timing will be planned for pre participation in the study and at the end of the study, unless symptom onset is sooner and testing is clinically indicated. The research team will cover the cost of COVID 19 tests performed solely for the purpose of this study. If there are routine or indicated tests being performed (i.e. routine preoperative testing, testing due to symptom onset) as part of standard of care, these will be charged in the routine fashion as any other patient's or employee's test would be charged. This could be to the participants insurance.as part of their standard of care.

Data and Safety Monitoring: The IRB requires review and approval of data and safety monitoring plans for greater than minimal risk research, or NIH-funded/FDA-regulated clinical investigations.

If you are conducting greater than minimal risk research, or your clinical investigation is NIH-funded/FDA-regulated, describe your Data

and Safety Monitoring Plan (DSMP). Click here for additional guidance on developing a Data and Safety Monitoring Plan.

If this is a *non-sponsored investigator-initiated* protocol considered greater than minimal risk research, or your clinical investigation is FDA-regulated, *and* if you are planning on using a Data and Safety Monitoring Board (DSMB) as part of your DSMP, click here for additional guidance for information to include with your IRB application.

If relying on an independent agent or committee for DSMB services, it is the PI's responsibility to establish the services with the agent or committee. Please be reminded that the PI must submit DSMB reports to the IRB via modification or continuing review.

Monitoring:
Questionnaires will be used primarily for monitoring. Pre screen questionnaires will be reviewed at the time of study inclusion to confirm eligibility. Daily questionnaires will be sent via reminder email from REDCap to both participating providers and patients. If a patient is unable to access email or fill out the questionnaire, study personnel will call the patient or nurse for the necessary information. There will be an order in SCM for administration of the nasal sprays and oral gargle while patients are hospitalized. After discharge, study personnel will call patients who cannot complete the REDCap questionnaires without assistance.
Providers will be instructed to contact the PI if any adverse events or concerns arise. Daily questionnaires from providers will be monitored weekly, if not more often. Inpatients will be monitored by their inpatient physicians and nursing teams. As we will be distributing daily questionnaires, we will be checking compliance with these daily for patients who are able to fill them out without assistance or will be contacting the patients ourselves to fill out these questionnaires. If the patient becomes unable to answer questions during the study for some reason, we will contact the nurse taking care of them. Monitors will look for reporting of adverse events or concerns relating to the study including symptoms of COVID and reporting them to the primary team.

Assuring compliance for reporting:
Adverse events will be reported to the IRB if they occur. Data analysis will be performed weekly to review for these events as well as any aggregate safety data to determine if harm or benefit can be ascertained.

Reporting temporary or permanent suspension:
Any adverse events will be reported to the IRB. Criteria for temporary or permanent suspension of the study include poor tolerance of the preparation by a majority of participants or demonstration that there is a deleterious effect of the prophylaxis toward development of COVID 19. This will be noted by early COVID 19 positive testing prior to completing the planned treatment course at a rate higher than that in the control group or general inpatient or provider population.

Assuring data accuracy and protocol compliance:
As above, questionnaires will be used primarily for monitoring. Pre screen questionnaires will be reviewed at the time of study inclusion to confirm eligibility. Daily questionnaires will be sent via reminder email from REDCap to both participating providers and patients. If a patient is unable to access email or fill out the questionnaire, study personnel will call the patient or nurse for the necessary information. There will be an order in SCM for administration of the nasal sprays and oral gargle while patients are hospitalized. After discharge, study personnel will call patients who cannot complete the REDCap questionnaires without assistance. These daily reminders are in place to ensure protocol adherence and understanding as well as monitoring.

This data will be received on a rolling basis as participants are recruited and reviewed quarterly by the University of Kentucky team.

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Subject Complaints: Describe procedures (other than information provided in consent document) for handling subject complaints or requests for information about the research. The procedures should offer a safe, confidential, and reliable channel for current, prospective, or past research subjects (or their designated representative) permitting them to discuss problems, concerns and questions, or obtain information.

Patient complaints will be addressed directly to the PI via email or phone call. Study participants will be advised that they can contact staff in the University of Kentucky (UK) Office of Research Integrity (ORI) with any issues.

Are you recruiting or expect to enroll **Non-English Speaking Subjects or Subjects from a Foreign Culture**? (does not include short form use for incidentally encountered non-English subjects)

○ Yes ◉ No

Non-English Speaking Subjects or Subjects from a Foreign Culture

Describe how information about the study will be communicated to potential subjects appropriate for their culture, and if necessary, how new information about the research may be relayed to subjects during the study.

Include contact information for someone who can act as a cultural consultant for your study. The person should be familiar with the culture of the subject population and/or be able to verify that translated documents are the equivalent of the English version of documents submitted. The consultant should not have any direct involvement with the study. If you do not know someone who would be willing to act as your cultural consultant, the Office of Research Integrity will try to find someone to fill this role (this may delay the approval process for your protocol). Please include the name, address, telephone number, and email of the person who will act as the cultural consultant for your study. For more details, see the

IRB Application Instructions on Research Involving Non-English Speaking Subjects or Subjects from a Foreign Culture.

For recruitment of Non-English speaking subjects, the consent document needs to be in the subject's native language. Download the informed consent template available in the E-IRB "Informed Consent/Assent Process" section and use it as a guide for developing the consent document. (Note: Your translated consent document can be attached to your application in the "Informed Consent" section; **be sure to save your responses in this section first.**)

If research is to be conducted at an international location, identify local regulations, laws, or ethics review requirements for human subject protection. If the project has been or will be reviewed by a local Ethics Committee, attach a copy of the review to the UK IRB using the attachment button below. You may also consult the current edition of the International Compilation of Human Research Standards

Does your study involve **HIV/AIDS research and/or screening for other reportable diseases (e.g., Hepatitis C, etc…)**?

○ Yes ◉ No

HIV/AIDS Research

If you have questions about what constitutes a reportable disease and/or condition in the state of Kentucky, see ORI's summary sheet: "Reporting Requirements for Diseases and Conditions in Kentucky" [PDF].

HIV/AIDS Research: There are additional IRB requirements for designing and implementing the research and for obtaining informed consent. Describe additional safeguards to minimize risk to subjects in the space provided below.

For additional information, visit the online IRB Survival Handbook to download a copy of the "Medical IRB's requirements for Protection of Human Subjects in Research Involving HIV Testing" [D65.0000] [PDF], and visit the Office for Human Research Protections web site for statements on AIDS research, or contact the Office of Research Integrity at 859-257-9428.

PI-Sponsored FDA-Regulated Research

Is this an investigator-initiated study that:

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1) involves testing a Nonsignificant Risk (NSR) Device, or
2) is being conducted under an investigator-held Investigational New Drug (IND) or Investigational Device Exemption (IDE)?

○ Yes ◉ No

PI-Sponsored FDA-Regulated Research

If the answer above is yes, then the investigator assumes the regulatory responsibilities of both the investigator and sponsor. The Office of Research Integrity provides a summary list of sponsor IND regulatory requirements for drug trials [PDF], IDE regulatory requirements for SR device trials [PDF], and abbreviated regulatory requirements for NSR device trials [PDF]. For detailed descriptions see FDA Responsibilities for Device Study Sponsors or FDA Responsibilities for IND Drug Study Sponsor-Investigators.

- Describe the experience/knowledge/training (if any) of the investigator serving as a sponsor (e.g., previously held an IND/IDE); and
- Indicate if any sponsor obligations have been transferred to a commercial sponsor, contract research organization (CRO), contract monitor, or other entity (provide details or attach FDA 1571).

IRB policy requires mandatory training for all investigators who are also FDA-regulated sponsors (see Sponsor-Investigator FAQs). A sponsor-investigator must complete the applicable Office of Research Integrity web based training, (drug or device) before final IRB approval is granted.

Has the sponsor-investigator completed the mandatory PI-sponsor training prior to this submission?

○ Yes ○ No

If the sponsor-investigator has completed equivalent sponsor-investigator training, submit documentation of the content for the IRB's consideration.

Attachments

HIPAA

0 unresolved comment(s)

Is HIPAA applicable? ◉ Yes ○ No

(Visit ORI's Health Insurance Portability and Accountability Act (HIPAA) web page to determine if your research falls under the HIPAA Privacy Regulation.)

If yes, check below all that apply and attach the applicable document(s):

☐ HIPAA De-identification Certification Form

☑ HIPAA Waiver of Authorization

Attachments

Attach Type	File Name
Waiver	58748 HIPAA WOA form 11 3 20.pdf

STUDY DRUG INFORMATION

0 unresolved comment(s)

The term drug may include:

- FDA approved drugs,
- unapproved use of approved drugs,
- investigational drugs or biologics,
- other compounds or products intended to affect structure or function of the body, and/or
- complementary and alternative medicine products such as dietary supplements, substances generally recognized as safe (GRAS) when used to diagnose, cure mitigate, treat or prevent disease, or clinical studies of e-cigarettes examining a potential therapeutic purpose.

Does this protocol involve a drug including an FDA approved drug; unapproved use of an FDA approved drug; and/or an investigational drug?

◉ Yes ○ No

If yes, complete the questions below. Additional study drug guidance.

LIST EACH DRUG INVOLVED IN STUDY IN THE SPACE BELOW

Drug Name:

3M Skin and Nasal Antiseptic (Povidone-Iodine Solution 5% w/w [0.5% available iodine]

Note: Inpatient studies are required by Hospital Policy to utilize the Investigational Drug Service (IDS). Use of IDS is highly recommended, but optional for outpatient studies. Outpatient studies not using IDS services are subject to periodic inspection by the IDS for compliance with drug accountability good clinical practices.

Indicate where study drug(s) will be housed and managed:

☑ Investigational Drug Service (IDS) UK Hospital

Other Location:

This is an over the counter preparation which will be provided directly to the involved participants at the time of enrollment.

Is the study being conducted under a valid Investigational New Drug (IND) application?

○ Yes ◉ No

If Yes, list IND #(s) and complete the following:

IND Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Checkmark if the study is being conducted under FDA's Expanded Access Program (e.g., Treatment IND) or if this is an Individual Patient Expanded Access IND (FDA Form 3926).

FDA's Expanded Access Program Information for Individual Patient Expanded Access INDs, and attach the following:

- FDA Form 3926;
- FDA expanded access approval or correspondence;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the "Expanded Access

SOP" [PDF].

Please also complete and attach the Study Drug Form (PDF) (required):

Attachments

Attach Type	File Name
StudyDrug	58748_StudyDrug_278408 edit 4 22 20.pdf

STUDY DEVICE INFORMATION

0 unresolved comment(s)

A DEVICE may be a:

- component, part, accessory;
- assay, reagent, or in-vitro diagnostic device;
- software, digital health, or mobile medical app;
- other instrument if intended to affect the structure or function of the body, diagnose, cure, mitigate, treat or prevent disease; or
- a homemade device developed by an investigator or other non-commercial entity and not approved for marketing by FDA.

For additional information, helpful resources, and definitions, see ORI's Use of Any Device Being Tested in Research web page.

Does this protocol involve testing (collecting safety or efficacy data) of a medical device including an FDA approved device, unapproved use of an approved device, humanitarian use device, and/or an investigational device?

○ Yes ◉ No

[Note: If a marketed device(s) is only being used to elicit or measure a physiologic response or clinical outcome, AND, NO data will be collected on or about the device itself, you may answer "no" above, save and exit this section, (Examples: a chemo drug study uses an MRI to measure tumor growth but does NOT assess how effective the MRI is at making the measurement; an exercise study uses a heart monitor to measure athletic performance but no safety or efficacy information will be collected about the device itself, nor will the data collected be used for comparative purposes against any other similar device).]

If you answered yes above, please complete the following questions.

LIST EACH DEVICE BEING TESTED IN STUDY IN THE SPACE BELOW

Device Name:

Is the study being conducted under a valid Investigational Device Exemption (IDE), Humanitarian Device Exemption (HDE) or Compassionate Use?

○ Yes ○ No

If Yes, complete the following:
IDE or HDE #(s)

IDE/HDE Submitted/Held by:

Sponsor: ☐ Held By:

Investigator: ☐ Held By:

Other: ☐ Held By:

☐ Check if this is a Treatment IDE or Compassionate Use under the Food and Drug Administration (FDA) Expanded Access program.

For Individual or Small Group Expanded Access, see FDA's Early Expanded Access Program Information, and attach the following:

- FDA expanded access approval or sponsor's authorization;
- An independent assessment from an uninvolved physician, if available;
- Confirmation of agreement from manufacturer or entity authorized to provide access to the product.

For guidance and reporting requirements at the conclusion of treatment see the "Medical Device Clinical Investigations, Compassionate Use, and Treatment IDE SOP" [PDF]

Does the intended use of any research device being tested (not clinically observed) in this study meet the regulatory definition of Significant Risk (SR) device?

- Yes. Device(s) as used in this study presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject.
- No. All devices, as used in this study do not present a potential for serious risk to the health, safety, or welfare of subjects/participants.

Please also complete and attach the Study Device Form (PDF) (required):

Attachments

RESEARCH SITES

0 unresolved comment(s)

In order for this section to be considered complete, you must click "SAVE" after ensuring all responses are accurate.

A) Check all the applicable sites listed below at which the research will be conducted. If none apply, you do not need to check any boxes.

UK Sites

- ☐ UK Classroom(s)/Lab(s)
- ☑ UK Clinics in Lexington
- ☐ UK Clinics outside of Lexington
- ☐ UK Healthcare Good Samaritan Hospital
- ☑ UK Hospital

Schools/Education Institutions

- ☐ Fayette Co. School Systems *
- ☐ Other State/Regional School Systems
- ☐ Institutions of Higher Education (other than UK)

***Fayette Co. School systems, as well as other non-UK sites, have additional requirements that must be addressed. See ORI's IRB Application Instructions - Off-site Research web page for details.**

Other Medical Facilities

- ☐ Bluegrass Regional Mental Health Retardation Board
- ☐ Cardinal Hill Hospital
- ☐ Eastern State Hospital
- ☐ Norton Healthcare
- ☐ Nursing Homes
- ☐ Shriner's Children's Hospital
- ☐ Veterans Affairs Medical Center
- ☐ Other Hospitals and Med. Centers

- ☐ Correctional Facilities
- ☐ Home Health Agencies
- ☐ International Sites

List all other non-UK owned/operated locations where the research will be conducted:*

*A letter of support and local context is required from non-UK sites. See *Letters of Support and Local Context* on the IRB Application Instructions - Off-Site Research web page for more information.

Attachments

B) Is this a multi-site study for which you are the lead investigator or UK is the lead site? ◉ Yes ○ No

If **YES**, you must describe the plan for the management of reporting unanticipated problems, noncompliance, and submission of protocol modifications and interim results from the non-UK sites in the E-IRB "Research Description" section under *Resources*.

If the non-UK sites or non-UK personnel are *engaged* in the research, there are additional federal and university requirements which need to be completed for their participation, such as the establishment of a cooperative IRB review agreement with the non-UK site. Questions about the participation of non-UK sites/personnel should be discussed with the ORI staff at (859) 257-9428.

RESEARCH ATTRIBUTES

0 unresolved comment(s)

Indicate the items below that apply to your research. Depending on the items applicable to your research, you may be required to complete additional forms or meet additional requirements. Contact the ORI (859-257-9428) if you have questions about additional requirements.

☐ Not applicable

Check All That Apply

- ☐ Academic Degree/Required Research
- ☐ Aging Research
- ☐ Alcohol Abuse Research
- ☐ Cancer Research
- ☐ Certificate of Confidentiality
- ☐ CCTS-Center for Clinical & Translational Science
- ☐ Clinical Research
- ☑ Clinical Trial
- ☐ Clinical Trial Multicenter(excluding NIH Cooperative Groups)
- ☐ Clinical Trial NIH cooperative groups (i.e., SWOG, RTOG)
- ☐ Clinical Trial Placebo Controlled Trial
- ☐ Clinical Trial UK Only
- ☐ Collection of Biological Specimens
- ☐ Collection of Biological Specimens for Banking
- ☐ Community-Based Participatory Research
- ☐ Data & Safety Monitoring Board
- ☑ Data & Safety Monitoring Plan
- ☐ Deception
- ☐ Drug/Substance Abuse Research
- ☐ Educational/Student Records (e.g., GPA, test scores)
- ☐ Emergency Use (Single Patient)
- ☐ Genetic Research
- ☐ Gene Transfer
- ☐ GWAS (Genome-Wide Association Study) or NIH-funded study generating large scale genomic data
- ☐ International Research
- ☐ Internet Research
- ☐ Planned Emergency Research Involving Waiver of Informed Consent
- ☐ Pluripotent Stem Cell Research
- ☐ Recombinant DNA
- ☑ Survey Research
- ☐ Transplants
- ☐ Use of radioactive material, ionizing radiation, or x-rays [Radiation Safety Committee review required]
- ☐ Vaccine Trials

Click applicable listing(s) for additional requirements and/or information:

- Cancer Research (MCC PRMC)
- Certificate of Confidentiality (look up "Confidentiality/Privacy...")
- CCTS (Center for Clinical and Translational Science)
- Clinical Research (look up "What is the definition of....)
- Clinical Trial (look up "What is the definition of....)

  Determine if research meets NIH definition of clinical trial;
  *Reminder: Ensure compliance with applicable requirements including:
  - Clinicaltrials.gov registration;
  - Good Clinical Practice (GCP) training; and
  - Consent Posting Requirement [PDF] for federal funded trials.

- Collection of Biological Specimens for Banking (look up "Specimen/Tissue Collection...")
- Collection of Biological Specimens (look up "Specimen/Tissue Collection...")
- Community-Based Participatory Research (look up "Community-Engaged...")
- Data & Safety Monitoring Board (DSMB)

  *For Medical IRB: Service Request Form for CCTS DSMB

- Data & Safety Monitoring Plan
- Deception*

  *For deception research, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver of Informed Consent Process"

- Emergency Use (Single Patient) [attach Emergency Use Checklist] (PDF)
- Genetic Research (look up "Specimen/Tissue Collection...")
- Gene Transfer
- HIV/AIDS Research (look up "Reportable Diseases/Conditions")
- Screening for Reportable Diseases [E2.0000] (PDF)
- International Research (look up "International & Non-English Speaking")
- NIH Genomic Data Sharing (GDS) Policy (PDF)
- Planned Emergency Research Involving Waiver of Informed Consent*

  *For Planned Emergency Research Involving Waiver of Informed Consent, also go to the E-IRB Application Informed Consent section, checkmark and complete "Request for Waiver

of Informed Consent Process"

- Use of radioactive material, ionizing radiation or x-rays for research

FUNDING/SUPPORT

0 unresolved comment(s)

If the research is being submitted to, supported by, or conducted in cooperation with an external or internal agency or funding program, indicate below all the categories that apply.

☐ Not applicable

Check All That Apply

☐ Grant application pending
☐ (HHS) Dept. of Health & Human Services
☐ (NIH) National Institutes of Health
☐ (CDC) Centers for Disease Control & Prevention
☐ (HRSA) Health Resources and Services Administration
☐ (SAMHSA) Substance Abuse and Mental Health Services Administration
☐ (DoJ) Department of Justice or Bureau of Prisons
☐ (DoE) Department of Energy
☐ (EPA) Environmental Protection Agency
☐ Federal Agencies Other Than Those Listed Here
☐ Industry (Other than Pharmaceutical Companies)
☑ Internal Grant Program w/ proposal
☐ Internal Grant Program w/o proposal
☐ National Science Foundation
☐ Other Institutions of Higher Education
☐ Pharmaceutical Company
☐ Private Foundation/Association
☐ U.S. Department of Education
☐ State

Other:

Click applicable listing(s) for additional requirements and/or information:

- (HHS) Dept. of Health & Human Services
- (NIH) National Institutes of Health
- (CDC) Centers for Disease Control & Prevention
- (HRSA) Health Resources & Services Administration
- (SAMHSA) Substance Abuse & Mental Health Services Administration
- Industry (Other than Pharmaceutical Companies) [IRB Fee Info]
- National Science Foundation
- (DoEd) U.S. Department of Education [PDF]
- DoJ) Department of Justice or Bureau of Prisons ([PDF]
- (DoE) Department of Energy Summary [PDF] and Department of Energy Identifiable Information Compliance Checklist [PDF]
- (EPA) Environmental Protection Agency [PDF]

Specify the funding source and/or cooperating organization(s) (e.g., National Cancer Institute, Ford Foundation, Eli Lilly & Company, South Western Oncology Group, Bureau of Prisons, etc.):

UK CURE COVID 19 Pilot Program

Add Related Grants

If applicable, please search for and select the OSPA Account number or Electronic Internal Approval Form (eIAF) # (notif #) associated with this IRB application using the "Add Related Grants" button.
If required by your funding agency, upload your grant using the "Grant/Contract Attachments" button.

Add Related Grants

Grant/Contract Attachments

The research involves use of Department of Defense (DoD) funding, military personnel, DoD facilities, or other DoD resources. (See DoD SOP [PDF] and DoD Summary [PDF] for details)

○ Yes ◉ No

Using the "attachments" button (below), attach applicable materials addressing the specific processes described in the DoD SOP.

DOD SOP Attachments

Additional Certification: (If your project is federally funded, your funding agency may request an Assurance/ Certification/Declaration of Exemption form.) Check the following if needed:

☐ Protection of Human Subjects Assurance/Certification/Declaration of Exemption (Formerly Optional Form – 310)

OTHER REVIEW COMMITTEES

0 unresolved comment(s)

If you check any of the below committees, additional materials may be required with your application submission.

Does your research fall under the purview of any of the other review committees listed below? [*If yes, check all that apply and attach applicable materials using the attachment button at the bottom of your screen.*]

◉ Yes ○ No

☐ Institutional Biosafety Committee
☐ Radiation Safety Committee
☐ Radioactive Drug Research Committee
☐ Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)
☑ Graduate Medical Education Committee (GME)
☐ Office of Medical Education (OME)

Additional Information

- Institutional Biosafety Committee (IBC)--Attach required IBC materials
- Radiation Safety Committee (RSC)-- For applicability, see instructions
- Radioactive Drug Research Committee (RDRC)--information
- Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC)**--Attach MCC PRMC materials, if any, per instructions
- See requirement of Office of Medical Education (OME)
- See requirement of Graduate Medical Education Committee (GME)

Attachments

** **If you are proposing a study involving cancer research, be sure to have "Cancer Research" marked in the E-IRB "Research Attributes" section.** If your study involves cancer research, ORI will provide a copy of your research protocol to the Markey Cancer Center (MCC) Protocol Review and Monitoring Committee (PRMC). The MCC PRMC is responsible for determining whether the study meets the National Cancer Institute (NCI) definition of a clinical trial and for issuing documentation to you (the investigator) which confirms either that PRMC approval has been obtained or that PRC review is not required. Your IRB application will be processed and reviewed independently from the PRMC review.

ADDITIONAL INFORMATION/MATERIALS

0 unresolved comment(s)

Do you want specific information inserted into your approval letter? ○ Yes ◉ No

Approval Letter Details (e.g., serial #):

Submission Description: If you wish to have specific details included in your approval letter (e.g., serial #, internal tracking identifier, etc…), type in the box below exactly what you wish to see on the approval letter. What you type will automatically appear at the top of all approval letters, identical to how you typed it, until it is changed by you (Hint: don't include instructions or questions to ORI staff as those will appear in your approval letter). **If these details need to be changed as a result of revisions, continuation review, or modifications to the application, you are responsible for updating the content of the field below accordingly.**

Protocol/Product Attachments - For each item checked, please attach the corresponding material.

- ☐ Detailed protocol
- ☐ Dept. of Health & Human Services (DHHS) approved protocol (such as NIH sponsored Cooperative Group Clinical Trial)
- ☐ Drug Documentation (e.g., Investigator Brochure; approved labeling; publication; FDA correspondence, etc.)
- ☐ Device Documentation (e.g., Manufacturer information; patient information packet; approved labeling; FDA correspondence, etc.)
- ☐ Other Documents

Protocol/Product Attachments

Attach Type	File Name
AddInfoProtocol	Copies of last 2 consents 1.21.22[98].pdf

NOTE: [Instructions for Dept. of Health & Human Services (DHHS)-approved protocol]

If you have password protected documents, that feature should be disabled prior to uploading to ensure access for IRB review.

Additional Materials:

If you have other materials you would like to include in your application for the IRB's consideration, please attach using the Attachments button below.

[To view what materials are currently attached to your application, go to "Application Links" in the menu bar on the left and click "All Attachments".]

Attachments

Attach Type	File Name
AdditionInfoConsiderations	Kejner RL 58748.pdf
AdditionInfoConsiderations	Povidone Iodine FDA Label.pdf
AdditionInfoConsiderations	Form K approval letter Kejner 58748.pdf
AdditionInfoConsiderations	IM approval GME.pdf
AdditionInfoConsiderations	RE_ Continuation Review for EIRB 58748[31].pdf