PROTOCOL TITLE:

**INSTRUCTIONS[[1]](#footnote-1):**

* *Depending on the nature of your study, some sections may not be applicable to your research. If so mark as “NA”. For example, research involving a retrospective chart review may have many sections with “NA.” For subsections, like 1.x or 8.x, you can delete it if it’s not applicable.*
* *When you write a protocol, keep an electronic copy. You will need to modify this copy when making changes.*
* *As you are writing the protocol, remove all instructions in italics so that they are not contained in the final version of your protocol.*

**PROTOCOL TITLE:**

*Single patient IND of study drug for patient XX*

**PRINCIPAL INVESTIGATOR:**

*Name*

*Department*

*Telephone Number*

*Email Address*

**VERSION NUMBER/DATE:**

*Include the version number and date of this protocol.*

**REVISION HISTORY**

|  |  |  |  |
| --- | --- | --- | --- |
| **Revision #** | **Version Date** | **Summary of Changes** | **Consent Change?** |
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# Study Summary

|  |  |
| --- | --- |
| **Protocol Information** | **Description** |
| **Study Title** |  |
| **Study Design** | This is a single patient IND intended to treat XX. |
| **Primary Objective** | The objective of this protocol is to provide treatment through a single patient IND to XX for condition |
| **Secondary Objective(s)** | N/A |
| **Research Intervention(s)/ Investigational Agent(s)** |  |
| **IND/IDE #** |  |
| **IND/IDE Holder** |  |
| **Study Population** | Patient XX |
| **Sample Size** | 1 |
| **Study Duration for individual participants** |  |
| **Study Specific Abbreviations/ Definitions** |  |

# Objectives

* 1. The objective of this protocol is to provide treatment through a single patient IND to XX for condition.

# Background

* 1. Describe the condition being treated.
  2. Briefly describe the investigational drug being used.
  3. Provide a brief patient history including age, sex, medical condition(s), previous treatments (if they have been treated for this condition before and response) and rationale for single patient IND use (why patient needs this rather than clinical trial or SOC).

# Study Endpoints

* 1. No formal statistical analysis will be completed.

# Study Intervention/Investigational Agent

* 1. Description: Describe the study intervention and/or investigational agent (e.g., drug, device) that is being evaluated.
  2. Storage and stability
  3. Compatibility
  4. Drug/Device Handling: If the research involves drugs or device, describe your plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators. If the control of the drugs or devices used in this protocol will be accomplished by using the Investigational Drug Service (IDS) pharmacy, please reference that in this section.
  5. Preparation
  6. Ordering: How the drug will be ordered
  7. Accountability
  8. Destruction and return

# Procedures Involved

* 1. Provide a description of all research procedures being performed and when they are performed, including procedures being performed to monitor subjects for safety or minimize risks.
  2. Treatment regimen and administration

# Data and Specimen Banking

* 1. N/A

# Sharing of Results with Subjects

* 1. Any relevant test results that indicate patient status or that could change course of treatment will be shared with the patient.

# Study Timelines

* 1. The participant will remain on treatment until the drug becomes commercially available, patient withdraws consent, are not receiving anymore clinical benefit or have side effects that unmanageable. They will then be followed for x days as safety follow up before going off study.

# Inclusion and Exclusion Criteria

* 1. Inclusion criteria:
  2. Exclusion criteria:
* Patient is unwilling to consent
  1. *Indicate specifically whether you will include or exclude each of the following special populations: (You may not include members of these populations as subjects in your research unless you indicate this in your inclusion criteria.)*
     + *Adults unable to consent*
     + *Individuals who are not yet adults (infants, children, teenagers)*
     + *Pregnant women*
     + *Prisoners*

# Vulnerable Populations

* 1. *If the research involves individuals who are vulnerable to coercion or undue influence, describe additional safeguards included to protect their rights and welfare.*
     + *If the research involves pregnant women, review HRP-412 - CHECKLIST - Pregnant Women to ensure that you have provided sufficient information.*
     + *If the research involves neonates of uncertain viability or non-viable neonates, review HRP-413 - CHECKLIST - Non-Viable Neonates or HRP-414 - CHECKLIST - Neonates of Uncertain Viability to ensure that you have provided sufficient information.*
     + *If the research involves prisoners, review HRP-415 - CHECKLIST - Prisoners to ensure that you have provided sufficient information.*
     + *If the research involves persons who have not attained the legal age for consent to treatments or procedures involved in the research (“children”), reviewHRP-416 - CHECKLIST - Children to ensure that you have provided sufficient information.*
     + *If the research involves decisionally impaired adults, review HRP-417 - CHECKLIST - Cognitively Impaired Adults to ensure that you have provided sufficient information.*
     + *Check if the research involves any of the following groups:*

☐ *Wards of the State*

☐ *VCU/VCUHS students or trainees*

☐ *VCU/VCU Health System employees*

☐ *Active military personnel*

☐ *Student populations in K-12 educational settings or other learning environments*

☐ *Members of a federally recognized American Indian or Alaska Native tribe*

# Number of Subjects

* 1. This protocol will enroll 1 participant.

# Recruitment Methods

* 1. No recruitment methods will be utilized for this protocol.

# Withdrawal of Subject

* 1. Patient will be removed from the treatment when any of the following criteria apply:
* Disease progression
* Intercurrent illness that prevents further administration of treatment
* Unacceptable adverse event(s)
* Patient decides to withdraw from the protocol therapy
* General or specific changes in the patient’s condition that render the patient unacceptable for further treatment in the judgement of the treating investigator

Patient will be removed from the protocol when any of the following criteria apply:

* Lost to follow-up
* Withdrawal of consent
* Death
* Progressive disease followed by completion of protocol-specified follow-up

# Risks to Subjects

* 1. *List the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related the subjects’ participation in the research. Include as may be useful for the IRB’s consideration, a description of the probability, magnitude, duration, and reversibility of the risks. Consider physical, psychological, social, legal, and economic risks. Describe any impact the study might have on students’ opportunity to learn required educational content. Describe any interventions that may be perceived as offensive or embarrassing.*
  2. *If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.*
  3. *If applicable, indicate which procedures may have risks to an embryo or fetus should the subject be or become pregnant.*
  4. *If applicable, describe risks to others who are not subjects.*
  5. *Describe how the study design, inclusion/exclusion criteria, and any other relevant factors minimize risks of harm or discomfort.*
  6. Adverse Event Reporting Requirements

All AEs will be reported to the IRB and the FDA in accordance to IRB and FDA regulations.

*Include any language on reporting any AEs to the supplier of the investigational product as applicable including what needs to be reported, time frame and how to report.*

# Potential Benefits to Subjects

* 1. It is not known if the patient will receive direct benefit from this single patient IND. The hope is that the patient will receive complete benefit from this treatment.

# Data Management and Confidentiality

* 1. Data analysis will not occur for this single patient IND.
  2. *Describe the steps that will be taken to secure the data (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data) during storage, use, and transmission.*

*Select all that apply to* ***paper*** *research material:*

☐ *Maintaining control of paper documents at all times, including when at off-campus location*

☐ *Storing paper documents in a secure location accessible only by study team*

☐ *Promptly transcribing, scanning, or abstracting data from paper into electronic platform and destroying the paper copy*

*Select all that apply to* ***electronic*** *research material:*

☐ *Use VCU-approved methods of data storage, transmission, and transfer (see https://dms.vcu.edu)*

☐ *Using individual logins/separate accounts on shared devices*

☐ *Using VCU approved data collection tools and apps (e.g., REDCap, Qualtrics)*

☐ *Consulting with VCU Information Security when using non-VCU approved data collection tools (https://ts.vcu.edu/askit/essential-computing/information-security/)*

*Select all that apply for research* ***biospecimens****:*

☐ *Maintaining control of specimens at all times, including when at off-campus location*

☐ *Storing specimens in a secure location only accessible only by study team*

☐ *Labeling specimens with subject ID or other coded information instead of direct identifiers*

☐ *Final destruction of specimens will be devoid of any identifiable information*

* 1. *Describe any procedures that will be used for quality control of collected data.*

# Provisions to Monitor the Data to Ensure the Safety of Subject

* 1. N/A

# Provisions to Protect the Privacy Interests of Subject

* 1. The steps taken to insure patient privacy will include:
* Conducting study activities in locations that maximize privacy
* Verifying identify before discussing personal information
* Asking the subject if they are comfortable answering in the location
* Asking the subject if they are comfortable with others present (as applicable\_
* Offering alternate ways to respond (e.g., pointing, writing) if they do not want to respond verbally
  1. Identifiers that will be collected at any time as part of this study:
* Names
* Dates
* Ages over 89 (age under 89 is not an identifier)
* Phone Numbers
* Medical Record Numbers

# Compensation for Research-Related Injury

* 1. There is no compensation available for research-related injuries.

# Economic Burden to Subjects

* 1. The patient will have no additional costs to them as a result of this single patient IND. All procedures and tests are being done under standard of care. The drug is being provided free of charge by the company.

# Consent Process

* 1. The principal investigator or a sub-investigator will obtain informed consent. The consent will occur in a private room face to face. The patient will be given the opportunity to ask any questions and it will be confirmed they under the potential benefits, risks and what is required of them in order to receive this drug.

***Non-English Speaking Subjects***

* + - *Indicate what language(s) other than English are understood by prospective subjects or representatives.*
    - *If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate the language that will be used by those obtaining consent.*

***Waiver or Alteration of Consent Process (consent will not be obtained, required information will not be disclosed, or the research involves deception)***

* + - *Review HRP-410 - CHECKLIST - Waiver or Alteration of Consent Process to ensure you have provided sufficient information for the IRB to make these determinations. Describe whether you are requesting to waive some elements of consent (describe which ones), or all elements of consent. Provide justification.*
    - *If the research involves a waiver of the consent process for planned emergency research, please review HRP-419 - CHECKLIST - Waiver of Consent Process for Emergency Research to ensure you have provided sufficient information for the IRB to make these determinations.*
    - *If the research involves deception, describe whether subjects prospectively authorize the deception and plans for de-briefing subjects.*

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

* + - *Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted. (E.g., individuals under the age of 18 years.)*
      * *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “children.”*
      * *For research conducted outside of the state, provide information that describes which persons have not attained the legal age for consent to treatments or procedures involved the research, under the applicable law of the jurisdiction in which research will be conducted. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “children” in HRP-013 - SOP - LARs, Children, and Guardians .*
    - *Describe whether parental permission will be obtained from:*
      * *Both parents unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.*
      * *One parent even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child.*
    - *Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals’ authority to consent to each child’s general medical care.*
    - *Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. If not obtaining assent, include justification.*
    - *When assent of children is obtained describe whether and how it will be documented.*

***Cognitively Impaired Adults***

* + - *Describe the process to determine whether an individual is capable of consent or assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require cognitively impaired adults to sign assent documents.*

***Adults Unable to Consent***

* + - *List the individuals from whom permission will be obtained in order of priority. (E.g., durable power of attorney for health care, court appointed guardian for health care decisions, spouse, and adult child.)*
      * *For research conducted in the state, review HRP-013 - SOP - LARs, Children, and Guardians to be aware of which individuals in the state meet the definition of “legally authorized representative.”*
      * *For research conducted outside of the state, provide information that describes which individuals are authorized under applicable law to consent on behalf of a prospective subject to their participation in the procedure(s) involved in this research. One method of obtaining this information is to have a legal counsel or authority review your protocol along the definition of “legally authorized representative” in HRP-013 - SOP - LARs, Children, and Guardians.*
    - *Describe the process for assent of the subjects. Indicate whether:*
      * *Assent will be required of all, some, or none of the subjects. If some, indicated, which subjects will be required to assent and which will not.*
      * *If assent will not be obtained from some or all subjects, an explanation of why not.*
      * *Describe whether assent of the subjects will be documented and the process to document assent. The IRB allows the person obtaining assent to document assent on the consent document and does not routinely require assent documents and does not routinely require subjects to sign assent documents.*

***Humanitarian Use Device (HUD)***

* + - *For HUD uses provide a description of how the patient will be informed of the potential risks and benefits of the HUD and any procedures associated with its use.*

# Process to Document Consent in Writing

* 1. *Describe whether you will be following HRP-091 - SOP - Written Documentation of Consent. If not, describe whether and how consent of the subject will be documented in writing.*

# Setting

* 1. *Describe the sites or locations where your research team will conduct the research.*
     + *Identify where your research team will identify and recruit potential subjects.*
     + *Identify where research procedures will be performed.*
     + *Describe the composition and involvement of any community advisory board.*
     + *For research conducted outside of the organization and its affiliates describe:*
       - *Site-specific regulations or customs affecting the research for research outside the organization.*
       - *Local scientific and ethical review structure outside the organization.*

# Resources Available

* 1. *Describe the resources available to conduct the research: For example, as appropriate:*
     + *Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period. For example, how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?*
     + *Describe the time that you will devote to conducting and completing the research.*
     + *Describe your facilities.*
     + *Describe the availability of medical or psychological resources that subjects might need as a result of an anticipated consequence of the human research.*
     + *Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.*

1. This template satisfies AAHRPP elements 1.7.B, I.8.B, I-9, II.2. A, II.2.I, II.3.A, II.3.B, II.3.C-II.3.C.1, II.3.D-F, II.4.A, III.1.C-F, II.2.D [↑](#footnote-ref-1)