VA Special Assurance (VSA) for Providing Expanded Access to COVID-19 Investigational Products by VA Facilities that Do Not Hold a Federalwide Assurance (FWA)

This VA Special Assurance (VSA) is authorized by VHA Handbook 1058.03 §5.a(11) under which the VHA Office of Research Oversight (ORO) may negotiate “special Assurances,” with concurrence by the VHA Office of Research and Development (ORD), in lieu of a Federalwide Assurance (FWA) for the protection of human subjects.

1. Institution Filing VSA

Legal Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (“Institution”)

City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

State/Province: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

2. Institutional Components

This VSA covers all components over which the Institution has legal authority including those that may operate under a different name.

***NOTE:*** *The Signatory Official signing this VSA must be legally authorized to represent the Institution providing this Assurance and all components covered by the Assurance.*

3. Applicability

(a) This VSA applies whenever this Institution provides an investigational drug or biologic or approved drugs that have limited availability due to a risk evaluation and mitigation strategy (REMS) to a patient with a confirmed or presumptive diagnosis of Coronavirus Disease 2019 (COVID-19) for treatment under the following types of expanded access program:

* Individual Patient Expanded Access

1) Individual patient expanded access Investigational New Drug (IND)

1a) Individual patient expanded access IND for emergency use

1b) Individual patient expanded access IND for non-emergency use

 2) Individual patient expanded access protocol

 2a) Individual patient expanded access protocol for emergency use

 2b) Individual patient expanded access protocol for non-emergency use

* Intermediate-Size Patient Populations
1. Intermediate-size patient population expanded access IND
2. Intermediate-size patient population expanded access protocol
* Treatment IND or Treatment Protocol (expanded access for widespread use)
1. Treatment IND
2. Treatment protocol

(b) This VSA does **not** apply to or authorize the institution’s engagement in a clinical research trial.

4. Assurance of Compliance with the Terms of the VSA

a. This Institution assures that whenever it provides investigational drugs or biologics or approved drugs that have limited availability due to a REMS to a patient for COVID-19 under an expanded access program, it will comply with FDA regulations at 21 CFR 312 Subpart I, Investigational New Drug Application: Expanded Access to Investigational Drugs for Treatment Use.

b. This Institution assures that whenever it provides investigational drugs or biologics or approved drugs that have limited availability due to a REMS to a patient for COVID-19 under an expanded access program, it will comply with 38 CFR 16, VHA Directive 1200.05, VHA Directive 1200.01, VHA Handbook 1058.03, and all other relevant VA and VHA policies, as applicable.

c. Written Procedures: The Institution must adopt and implement the written procedures developed by ORD for providing expanded access to COVID-19 investigational products.

d. The Institution will rely upon the VHA Central Office IRB for review and prior approval of any non-emergency expanded access, and review of any emergency expanded access under this VSA. An IRB reliance agreement for this review has been established by ORD.

1. The Institution will rely upon the Research & Development Committee designated by ORD for review and prior approval of non-emergency expanded access under this VSA.

f. The institution assures that no applications for expanded access will be made outside the processes listed in this paragraph.

5. Time Period of the Assurance

This VA Special Assurance for Providing Expanded Access to COVID-19 Investigational Products is effective for three years from the signature date of this Assurance, unless restricted or suspended by ORO.

6. Signatory Official (i.e., Official Legally Authorized to Represent the Institution)

*I have read and agree to the Terms of the VA Special Assurance.*

*I have read and understand my responsibilities under the IRB reliance agreement.*

*I recognize that providing physicians who are administering investigational drugs or biologics under an expanded access program for COVID-19 and other relevant personnel with appropriate initial and continuing education and training about expanded access requirements will help ensure that the requirements of this Assurance are satisfied.*

Acting officially in an authorized capacity on behalf of this Institution and with an understanding of the Institution’s responsibilities under this VSA, I assure compliance with the provisions as specified above.

All information provided with this VSA is up-to-date and accurate.

Signature:

Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

First Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Middle Initial: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Last Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Degrees or Suffix: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institutional Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Institution: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Telephone: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

E-Mail: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

City: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

State/Province: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_