**Written Statement of IRB Oversight Waiver**

|  |  |
| --- | --- |
| Name of Principal Investigator**:** | FWA No**.** |
| Sponsor**:**  | Protocol No.  [ ]  N/A |
| Protocol (Project) Title and Date:  |
|  |
| Name of IRB or Institution:      |
| Address: |
| Phone: (     )      | Fax:(     )      |

 *The Officials signing below agree that the INSERT NAME OF ORGANIZATION HERE will rely on Advarra, Inc. for review and continuing oversight of its human subjects research submitted to Advarra’s IRB for review.*

*The review performed by Advarra’s IRB will meet the human subject protection requirements of FDA and OHRP. Advarra IRB will follow written procedures for reporting its findings and actions to appropriate officials at INSERT NAME OF ORGANIZATION HERE . INSERT NAME OF ORGANIZATON HERE remains responsible for ensuring compliance with the IRB’s determinations. This document must be kept on file by both parties and provided to FDA and OHRP upon request.*

[ ]  I confirm our institution has an IRB that waives study oversight authority for this research study to Advarra.

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*Printed Name of Authorized Institutional Representative*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*Title of Institutional Representative*

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

*Signature of Authorized Institutional Representative*

*Signature of Signatory Official (Designated IRB):*

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

*Print Full Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Institutional Title: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

If you want to be copied on all correspondence for this PI, you must first register at [www.cirbi.net](http://www.cirbi.net). Once you have registered, you can either ask the Principal Investigator to have you added as a CC contact on their submission or contact the CIRBI Help Desk at 1-866-992-4724 to request you be added as an Institutional Administrator for this PI.