# CONFIDENTIALITY AND NON-USE AGREEMENT

This agreement ("Agreement"), by and between _____("Recipient")
_____
and **HealthCore ("CRO"),** a contract research organization, is effective this _____ day of _____20____ **("Effective Date")** for the purpose of ensuring confidentiality in connection with discussions related to the following study as sponsored by **Eli Lilly and Company** or its local affiliate **("Lilly"):** Protocol I4V-MC-JAJD: A Randomized, Controlled Pragmatic Phase 3b/4 Study in Patients with Rheumatoid Arthritis (RA-Branch) **("Purpose").** CRO and Recipient may be referred to individually as a "Party" and collectively as the "Parties." In consideration of CRO, Lilly or Lilly-designated representatives disclosing Confidential Information (as defined below) to Recipient and other valuable consideration, Recipient shall comply with the following:

- to keep 1) all information provided to Recipient by CRO, Lilly or Lilly-designated representatives in connection with this Agreement, and 2) all notes, analysis, or information generated by Recipient related to information provided to Recipient by CRO, Lilly or Lilly-designated representatives which could not have been generated by Recipient without information provided to Recipient by CRO, Lilly or Lilly-designated representatives (collectively defined as "Confidential Information") in confidence and not use Confidential Information for any purpose not contemplated by this Agreement for five (5) years from the date of disclosure;

- to the extent disclosure of Confidential Information is requested by any third party, Recipient shall promptly notify CRO and Lilly and shall not disclose any Confidential Information without Lilly's prior written consent. If such disclosure is sought under a claim of legal right, or to the extent disclosure of such Confidential Information is required by law, regulation, or judicial or other governmental order, Recipient shall i) promptly notify CRO and Lilly of such claim; ii) permit Lilly, at Lilly's expense, to defend against any such claim; and iii) reasonably cooperate with Lilly in such defense, provided, however, that no event shall Recipient be obligated to defy any law (including applicable Open Records Acts), regulation, or judicial or governmental order; and

- to return, upon written request and at the expense of Lilly, all Confidential Information of a returnable nature, provided, however, that Recipient may retain one (1) copy of such material solely for archival purposes in order to ensure compliance with the terms of this Agreement. Any such copy shall be stored and maintained in a secure and confidential manner and in accordance with all applicable privacy laws and regulations.

If applicable, and to the extent CRO provides Recipient with the personal health information ("PHI") of individuals, Recipient shall maintain, store, and, if required to carry out the purpose of the disclosure, transfer all such PHI in a secure manner and confidential manner and in accordance with all applicable privacy laws and regulations. Transfer of PHI includes internal transfer to employees or contractors of Recipient.

The foregoing obligations of confidentiality and non-use will not apply to Confidential Information that: i) is or later becomes part of the public domain other than through Recipient's act or omission; ii) was known by Recipient prior to disclosure by CRO or Lilly or becomes known from an independent source or third party under no obligation to CRO or Lilly or any other third party to keep such information confidential, as can be shown by prior written documentation; or iii) is independently developed, as shown by written documentation, by Recipient's personnel who have not had access to Confidential Information provided by CRO or Lilly.

CRO and/or Lilly may collect information from Recipient or Recipient's personnel including names, titles, and business contact information ("Site Personnel Data") and may provide Site Personnel Data to Lilly's business partners and vendors working with CRO and/or Lilly on matters related to the Lilly study to fulfill Lilly's business purposes including:

a. Compliance with U.S. regulations regarding possible financial conflicts of interest;

b. Assessment of personnel qualifications to conduct the Lilly study;

c. Quality control and Lilly study management; and

d. Disclosures to IRBs or foreign regulatory authorities in connection with their performance of review or oversight responsibilities for the Lilly study.

Site Personnel Data may also be aggregated with data from other CRO and/or Lilly sources and evaluated for business decisions, including those involving future research. Lilly may store or process such Site Personnel Data in the U.S. or other countries at CRO, Lilly or Lilly-associated facilities, as long as a business need or legal obligation exists. CRO and Lilly agree to comply with all applicable laws and regulations regarding CRO and Lilly's use of Site Personnel Data. Recipient or Recipient's personnel may have access to Site Personnel Data about themselves that CRO and Lilly has collected and may have corrections made to Site Personnel Data about themselves that is inaccurate. Recipient may contact Lilly with inquiries regarding Lilly's collection or use of Site Personnel Data.

Recipient shall not distribute, disclose, or disseminate any Confidential Information to anyone except employees, contractors, agents, or affiliates of Recipient who are obligated to the same or substantially similar terms of confidentiality and non-use and have a definable need-to-know for reasons of furthering the Purpose. Recipient shall be responsible for ensuring that employees, contractors, agents, or affiliates of Recipient are obligated to the same or substantially terms of confidentiality and non-use. Institutions or other third parties with which Recipient may be affiliated may have policies applicable to this type of agreement.

Recipient hereby acknowledges that unauthorized disclosure or use of Confidential Information could cause irreparable harm and significant injury to CRO and Lilly, the degree of which would be difficult to ascertain. Accordingly, Recipient agrees that CRO will have the right to seek and obtain immediate injunctive relief to enforce the obligations under this Agreement without proof of actual damages or the necessity of posting bond or other securities, in addition to any other rights and remedies it may have.

This Agreement does not supersede any prior agreements of confidentiality or non-use between Recipient and CRO.

Neither Party is obligated to enter into any further agreements with the other Party by virtue of entering into this Agreement. However, in the event that the Parties enter into a subsequent agreement for a business relationship relating to the Purpose, then the obligations with respect to the confidentiality and non-use shall be governed by that subsequent agreement. _____ may be named as an investigator or consultant in said subsequent agreement.

By executing this Agreement, Recipient agrees that Recipient has a right to enter into this Agreement with CRO and that the Agreement does not violate policies, if any, of institutions with which Recipient is affiliated or any other contract or relationship.

CRO acknowledges and confirms its acceptance of its obligations under this Agreement by providing the Confidential Information to Recipient. Recipient, by execution of this Agreement, acknowledges that one copy will be delivered via e-mail to: RA-Branch@healthcore.com

| AGREED AND ACCEPTED: | READ AND ACKNOWLEDGED: (OPTIONAL - COMPLETE AND OBTAIN SIGNATURE ONLY IF (1) RECIPIENT IS THE INSTITUTION AND (2) INSTITUTION POLICIES REQUIRE PI/CONSULTANT OR OTHER APPROVER SIGN) |
|---|---|
| _____ | |
| (Signature of Individual Recipient or of Authorized Representative of Institution or Corporate Recipient) | (Signature of Investigator/Consultant or Other Approver) |
| (Typed or Printed Name and Title) | (Typed or Printed Name and Title) |
| Date | Date |

***Additional signature is OPTIONAL and not required unless matter of Institution Policy***