

Expanded Access Template Document

Individual Patient Expanded Access Mutual Confidential Disclosure Agreement

*This template should be used as an agreement between the drug manufacturer and organization (*where organization refers to the treating entity and should be substituted as such in the agreement) to capture the confidentiality terms of the provided product and protection of use of patient PHI under an individual patient expanded access submission, compassionate use, or emergency use request. *Please note that often a Company prefers to capture both confidentiality and treatment plan terms and conditions in one agreement, by-passing the need for separate agreements.*



MUTUAL CONFIDENTIAL DISCLOSURE AGREEMENT

This Mutual Confidential Disclosure Agreement (“**Agreement**”) is entered into effective as of the [day of month] day of [name of month], 2021 (“Effective Date”) by and between [name of organization], located in [city, state], and [company name] located in [city, state] (“**Company**”) (collectively the “**Parties**” and singularly, a “**Party**”).

WHEREAS, [organization] and Company possess certain confidential and proprietary information relating to the {name of drug as a potential treatment for name of condition under [name of organization] request for expanded access, including emergency use} IRB# [protocol number] (the Study”) (“**Confidential Information**”);

WHEREAS, Each Party is willing to provide, and wishes to receive, such Confidential Information so that Company can evaluate [name of organization] request for individual patient treatment under expanded access (the “**Purpose**”);

NOW, THEREFORE, the Parties hereby agree to the following terms and conditions:

1. A Party shall disclose certain Confidential Information (“Discloser”) to the other Party (“Recipient”) to enable the Parties to perform the Purpose. Discloser shall clearly identify, at the time of disclosure, the confidential nature of any Confidential Information, including, but not limited to, Protected Health Information (PHI), that it discloses, and shall, insofar as is practicable, disclose such information in a writing marked “Confidential” or, if not so marked, that a reasonable person knowledgeable in the field of clinical research or medical practice would conclude was the confidential or proprietary information of the Discloser.
2. Recipient agrees, for a period of five (5) years from the Effective Date hereof, that it will treat the Confidential Information as it would its own similar proprietary and confidential information, and shall take reasonable care to avoid disclosure of the Confidential Information to any third party, person, firm or corporation. Recipient shall be responsible for unauthorized disclosure or failure to exercise such reasonable care. Notwithstanding the foregoing, if Recipient receives information which constitutes

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Protected Health Information as defined in the Health Insurance Portability Act of 1996, as amended, ("PHI") the PHI or information related to adverse events shall be kept in strict confidence without limitation of time.

3. Recipient shall have no obligation, with respect to the Confidential Information, or any part thereof, that:
 - (a) is already known to the Recipient at the time of the disclosure;
 - (b) is or becomes publicly known without the wrongful act or breach of this Agreement by the Recipient;
 - (c) is rightfully received by Recipient from a third party on a nonconfidential basis;
 - (d) is approved for release by written authorization from Discloser; or
 - (e) is subsequently and independently developed by employees of Recipient without use of or reliance upon the Confidential Information provided by Discloser.
4. Nothing herein shall prevent the Recipient from disclosing Confidential Information to the extent required pursuant to a judicial or government request, requirement or order, provided that Recipient takes reasonable steps to provide Discloser with sufficient prior written notice in order for Discloser to contest such request, requirement or order.
5. The Confidential Information is disclosed for evaluation purposes only, and solely for the Purpose. No additional rights are provided to Recipient under any patents, patent applications, trade secrets, or other proprietary or intellectual property rights of Discloser. Recipient shall not be entitled to make any use of the Confidential Information, except as explicitly set forth herein, without separate written agreement to that effect.

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6. Recipient agrees to return to Discloser all hard copies of written Confidential Information received hereunder upon completion of its use or upon written request from Discloser; provided, however, one (1) copy of such Confidential Information may be retained by Recipient in its secure files to preserve a record of the same and subject to the obligations set forth herein. Further, Recipient shall not be obligated to delete copies of Confidential Information that may be captured by Recipient's normal electronic file backup practices in accordance with Recipient's security and/or disaster recovery procedures, but any such electronic back up files containing Confidential Information shall remain subject to the confidentiality and non-use restrictions as set forth under this Agreement.
7. This Agreement shall not be assigned, in whole or in part, by any Party hereto without the written consent of the other Party.
8. Copies transmitted electronically such as by facsimile or portable document format (pdf) shall be considered equivalent to originals as shall signatures applied to such documents and transmitted digitally or electronically. The parties agree that such signed electronic copies shall be binding upon them the same as though they were hardcopies with original signatures.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

[name of organization]

COMPANY: _____

By: _____

By: _____

[name of organization Signatory]

Name: _____

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[title of organization Signatory]

Title: _____

[office of organization Signatory]

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