

Expanded Access Template Document

Individual Patient Expanded Access Clinical Treatment Plan Agreement

*This template should be used as an agreement (If Company requires such) between the drug manufacturer and organization (*where organization refers to the organization and should be substituted as such in the agreement) to capture the applicable terms and conditions of the specific treatment plan of the patient under an individual patient expanded access submission, compassionate use, or emergency use request.*



CLINICAL TREATMENT PLAN AGREEMENT

This Clinical Treatment Plan Agreement ("AGREEMENT") is entered into effective the *[day of the month]* day of 20*[year]* ("Effective Date") by and between *[name of organization]*, located in *[city, state]*, and *[manufacturer's name]* ("COMPANY"), a corporation with its principal place of business at *[city, state]*.

WHEREAS, *[name of organization]* has filed an *[Individual Patient IND/Emergency Treatment IND/Compassionate Use IND]* and has requested expanded access to the Investigational Drug (as defined below) for *[compassionate use/emergency treatment/expanded access]* of *[a single patient/group of patients ("Patient/Patients")]* and COMPANY is willing to provide such expanded access subject to the terms and conditions set forth in this AGREEMENT;

WHEREAS, COMPANY has the rights to *[name of investigational product]* ("Investigational Drug") and desires to make the Investigational Drug available to *[name of organization]* for the purpose of conducting the treatment plan entitled "*[name of treatment plan]*" ("TREATMENT PLAN");

WHEREAS, *[name of organization]* has the facilities and the personnel with the requisite skills, experience, and knowledge to undertake such TREATMENT PLAN; and

NOW, THEREFORE, the parties agree as follows:

1. TREATMENT PLAN, PHYSICIAN, IRB. *[name of organization]* agrees to conduct the TREATMENT PLAN according to Protocol No. *[protocol number]* which is attached hereto as Exhibit A (the "Protocol"), and fully details the clinical treatment activities and responsibilities to be undertaken. The treating physician ("PHYSICIAN") shall be *[name of treating physician]*, or the PHYSICIAN's designee, who shall direct the work required under the TREATMENT PLAN. PHYSICIAN shall apply for approval to conduct the TREATMENT PLAN as required by applicable regulations. No treatment will be initiated without such approvals, and *[name of organization]*'s performance of its obligations under this AGREEMENT is expressly conditioned upon the TREATMENT PLAN's approval by its IRB. No changes in the Protocol will be made unless agreed upon by *[name of organization]*, PHYSICIAN, and COMPANY or unless necessary to protect the safety, rights, or welfare of the Patient. In the event of a conflict between this AGREEMENT and the Protocol, the provisions of this AGREEMENT shall control with respect to contractual rights and obligations, and the Protocol shall control with respect to the clinical conduct of the TREATMENT PLAN.

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2. INVESTIGATIONAL DRUG. COMPANY will provide sufficient quantities of the Investigational Drug [and a lump sum funding amount for effort] for use in the TREATMENT PLAN as set forth in the Protocol. [name of organization] will maintain appropriate control of supplies of the Investigational Drug for the TREATMENT PLAN and will not administer or dispense the Investigational Drug except to the Patient, or provide access to Investigational Drug provided for the TREATMENT PLAN to anyone except [name of organization] personnel involved in the conduct of the TREATMENT PLAN.
3. COMPLIANCE WITH LAWS. The TREATMENT PLAN will be conducted in accordance with, and both parties agree to comply with all federal, state, and local laws and regulations applicable to the TREATMENT PLAN.
4. EFFECTIVE DATE AND TERM. This AGREEMENT shall become effective on the Effective Date first written above and shall continue in effect until completion of the TREATMENT PLAN or termination of this AGREEMENT for other reasons as provided herein.
5. RELATIONSHIP OF THE PARTIES. [name of organization]'s relationship to COMPANY under this AGREEMENT shall be that of an independent contractor and not an agent, joint venturer, or partner of COMPANY.
6. TERMINATION. This AGREEMENT shall terminate upon Patient no longer being eligible for treatment. A party may terminate this AGREEMENT effective immediately due to a breach or default of the other party that is not cured within thirty (30) days of written notice being delivered to the other party. [name of organization] may terminate the AGREEMENT upon thirty (30) days written notice if it becomes, for any reason, unable to perform or complete the TREATMENT PLAN. COMPANY or [name of organization] may terminate this AGREEMENT immediately upon written notice to the other party in the event of circumstances that pose risks to the health or well-being of the Patient or regulatory agency actions relating to the TREATMENT PLAN or the Investigational Drug. Articles 6 through 12 shall survive any termination of this AGREEMENT.
7. CLINICAL DATA AND REPORTING.
 - a. A summary of treatment results generated during the TREATMENT PLAN will be promptly and fully disclosed to COMPANY in accordance with the Protocol, and shall be freely usable by COMPANY consistent with applicable laws and regulations, except that any use or disclosure of Protected Health Information, as defined in the Health Insurance Portability and Accountability Act of 1996 and its implementing regulations (HIPAA), shall be subject to the authorization provided by the Patient in the informed

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consent or other authorization document. In addition, COMPANY shall collect, use, store, access and disclose data and materials, including any biological samples, collected from Patient only as allowed by the informed consent, or other authorization, obtained from Patient. COMPANY shall not attempt to identify, or contact, the Patient except as required by law.

- b. To the extent such personal data is provided, COMPANY is responsible for the security of any such data and shall ensure that it and any of its contractors adopt, implement and maintain appropriate security controls, including but not limited to encryption in transit, to protect against unauthorized access of any Protected Health Information (PHI) or Personal Identifiable Information (PII) of the subjects or any [name of organization] employees, agents or customers. COMPANY accepts responsibility and liability for any unauthorized disclosure by it or its contractors and shall notify [name of organization] immediately in the event of any breach of data security or unauthorized release of PHI or PII.
 - c. [name of organization] shall be free to use the data generated and the results of the TREATMENT PLAN for its own internal, teaching, research, education, clinical and publication purposes.
 - d. During and following the completion of the TREATMENT PLAN, COMPANY shall promptly, or in a timely manner appropriate to the level of risk involved, report to PHYSICIAN any information that could directly affect the health or safety of the Patient or influence the conduct of the TREATMENT PLAN. In each case, the PHYSICIAN and [name of organization] shall be free to communicate these findings to Patient and the IRB.
8. **CONFIDENTIAL INFORMATION.** "CONFIDENTIAL INFORMATION" will mean all information provided by one party ("Discloser") to the other ("Recipient") and clearly identified as "Confidential" by the Discloser at the time of disclosure and related to the TREATMENT PLAN. Recipient agrees, for a period of five (5) years following the completion of the TREATMENT PLAN, 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. 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. Specifically excepted from this is all information that: (a) was previously known by the receiving party; (b) is publicly

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disclosed except by breach of this AGREEMENT either prior to or subsequent to the receiving party's receipt of such information; (c) is rightfully received by the receiving party without an express obligation of confidence; (d) is independently developed by personnel of the receiving party without use of or reliance upon information from the transmitting party; or (e) is required to be disclosed pursuant to any judicial or government request, requirement or order, provided that the disclosing party takes reasonable steps to provide the other party with sufficient prior notice in order to allow the other party to contest such request, requirement or order.

9. **INVENTIONS.** It is recognized and understood that certain existing inventions and technologies are the separate property of COMPANY or *[name of organization]* and are not affected by this AGREEMENT, and neither party shall have any claims to or rights in such separate inventions and technologies. In particular, nothing in this AGREEMENT shall be construed to grant *[name of organization]* any claim or interest in COMPANY'S Investigational Drug provided for use in the TREATMENT PLAN.

If the conduct of the TREATMENT PLAN results in any invention or discovery, whether patentable or not ("Invention"), *[name of organization]* will promptly inform COMPANY. Ownership of Inventions will be determined in accordance with U.S. patent law.

10. **INDEMNIFICATION AND INSURANCE.** *[name of organization]* shall indemnify, defend and hold harmless COMPANY against any third party claim, action or suit (each a "Claim") to the extent that such Claim results from *[name of organization]*'s negligence or willful misconduct in the conduct of the TREATMENT PLAN. COMPANY shall indemnify, defend, and hold harmless *[name of organization]* and its employees, officers, directors, agents, and trustees for any Claim to the extent that such Claim results from COMPANY's negligence in the design, preparation, manufacture, or packaging of the INVESTIGATIONAL DRUG.

COMPANY represents that it carries products liability insurance or self-insurance coverage sufficient to cover its obligations under this section. *[name of organization]* represents that it maintains a program of professional liability self-insurance sufficient to cover its obligations under this section. Upon request, both parties will provide a copy of a certificate evidencing such insurance or self-insurance.

11. **USE OF A PARTY'S NAME.** Neither party will, without the prior written consent of the other party, use in advertising, publicity, or otherwise, the name, trademark, logo, symbol, or other image of the other party or that party's employee or agent, except that *[name of organization]* may acknowledge COMPANY's support of the TREATMENT PLAN as required in academic journals.

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12. **NOTICE.** Any notice or other communication required or permitted under the AGREEMENT shall be in writing and will be deemed given as of the date it is received by the receiving party. Notice shall be given to the parties at the addresses listed below:

As to *[name of organization]*:

[name of organization]
[address line 1 organization]
[address line 2 organization]

with copy to PHYSICIAN:

As to COMPANY: _____

Attn: _____

13. **ENTIRE AGREEMENT.** This AGREEMENT and its attached Exhibit represent the entire understanding between the parties, and supersedes all other agreements, express or implied, between the parties as to its subject matter. Any alteration, modification, or amendment to this AGREEMENT must be in writing and signed by both parties.
14. **FORCE MAJEURE.** If either party hereto shall be delayed or hindered in, or prevented from, the performance of any act required hereunder for any reason beyond such party's direct control, including but not limited to, strike, lockouts, labor troubles, governmental or judicial actions or orders, riots, insurrections, war, acts of God, inclement weather or other reason beyond the party's control (a "Disability") then such party's performance shall be excused for the period of the Disability. Any TREATMENT PLAN timelines affected by a Disability shall be extended for a period equal to the delay. The party affected by the Disability shall notify the other party of such Disability as provided for herein.
15. **COUNTERPARTS.** This AGREEMENT may be executed in any number of counterparts, each of which shall be an original and all of which together shall constitute one and the same document, and is binding on all parties notwithstanding that each of the parties may have signed different counterparts. Facsimiles or scanned copies of signatures, electronic or digital signatures or electronic images of signatures shall be considered original signature unless prohibited by applicable law.

WHEREFORE, the parties hereto place their hands and seals:

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[name of organization]

COMPANY:

By:

Printed Name: _____

Title:

Date executed:

By:

Printed Name: _____

Title:

Date executed:

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EXHIBIT A : PROTOCOL

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