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This Sample Study Agreement ("Agreement") does not constitute Banner Health advice, recommendation or formal instruction. Banner Health does not warrant or represent the accuracy, completeness or compliance-status of this Agreement for a particular study. This Agreement does not constitute legal advice. This Agreement is intended as only a sample for a Sponsor's consideration and should not be filled-in and used for a particular study.

Sample Study Agreement – Version 6-18-09
Assumes Clinical Intervention with Study Subject

STUDY AGREEMENT

[Insert Full Protocol Title]

This Study Agreement ("Agreement"), is made and effective as of the date of the last party to sign this Agreement by and among the [Name of Sponsor/Party retaining Banner Health to perform study site (institution) activity], with place of business at [Sponsor Address] ("Sponsor"), Banner Health, an Arizona nonprofit corporation, , located at 1441 North 12th Street, Phoenix, Arizona 85006("Institution"), and [Name of Investigator], an employee of [Employer Name & Employer Address] ("Principal Investigator" or "Investigator").

The parties desire to conduct the research study ("Trial" or "Study"): *[Insert full Study / Protocol Title]* as described in the Study Protocol delivered to Institution and Investigator from Sponsor ("Study Protocol"). The Study Protocol is hereby incorporated into this Agreement. Institution has determined that the scope of the work identified herein falls within its mission as a nonprofit entity. Therefore, the parties agree as follows:

1. Study
The Institution and Principal Investigator will use their professional expertise to perform the Study at the Institution according to the Study Protocol and this Agreement. In the event of a conflict between the terms of this Agreement and the Study Protocol, the Study Protocol will have precedence with regard to clinical performance and the terms of this Agreement will have precedence with regard to all other matters. The Institution and Principal Investigator will provide the facilities necessary to perform the Study in accordance with the Study Protocol and the Agreement. The Sponsor, Institution and Principal Investigator will comply with all applicable local, state and federal laws and regulations including those relating to research, clinical studies and research.

2. Principal Investigator
The Principal Investigator verifies that they are qualified by training and experience in the research relating to the Study. The Principal Investigator commits to conduct and takes primary responsibility for performing and supervising the Study at the Institution in accordance with the Study Protocol, the terms of the Agreement, and the requirements of the Ethics Committee/Institutional Review Board ("IRB"). In the event that the Principal Investigator ceases to be on the staff of the Institution, the Institution or Principal Investigator will promptly notify the Sponsor in writing and, if such person is available, propose a substitute Principal Investigator. The Principal Investigator will disclose to Institution any financial interest (or other interest), which they or their spouse, domestic partner or dependent children have in the Sponsor

and/or Study. Principal Investigator's responsibilities with regard to the Study shall include, without limitation, collection and reporting of data as described in the Study Protocol.

3. Co/Sub-Investigators
The Principal Investigator may, subject to the approval of Institution and Sponsor, appoint collaborating investigators ("Co/Sub-Investigator(s)") to participate in the Study. Such Co/Sub-Investigator(s) will work under the supervision of the Principal Investigator and agree to be bound by the same terms herein that bind the Principal Investigator.

4. Ethics Committee/IRB Approval
Prior to enrolling any subjects in the Study, the Institution's Ethics Committee/IRB must review the Study Protocol, Informed Consent Form, and such materials which are subject to the approval of the Ethics Committee/IRB under applicable law and regulations. Amendments to the protocol which apply at Institution or to Institution and Principal Investigator will be agreed upon by Sponsor, Institution and the Principal Investigator, and signed by the Institution and Principal Investigator. These amendments will be submitted to the Ethics Committee/IRB for any approval that may be required, and not implemented by the Principal Investigator until receipt of Ethics Committee/IRB approval.

5. Compliance with Laws
In performing, documenting, overseeing and reporting the Study, the Sponsor, Institution, Principal Investigator, shall comply with all applicable local, state and federal laws and regulations, including the requirements of the Ethics Committee/IRB. The Principal Investigator shall send Sponsor a copy of all correspondence with the Ethics Committee/IRB, including correspondence in relation to continuing review. All parties hereby agree that this Agreement shall cover all of the services relating to the Study provided by Institution and Principal Investigator to Sponsor for the term of the Agreement and shall specify the services to be provided by Institution and Principal Investigator (including such services described in **Exhibit A** and the Study Protocol). The services performed under this agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law. The aggregate services contracted for do not exceed those which are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

6. Patient Enrollment
The Principal Investigator will enroll subjects in the Study meeting the eligibility criteria described in the Study Protocol. Only subjects meeting the inclusion criteria may be enrolled. The Principal Investigator shall use reasonable efforts to recruit subjects who meet these eligibility requirements. Sponsor hereby acknowledges that the enrollment of study subjects is contingent upon the availability of eligible study subjects and their willingness to participate in the Study.

7. Informing Sponsor
The Principal Investigator shall notify Sponsor if the Ethics Committee/IRB withdraws approval of the Study. The Principal Investigator shall provide a progress report to the Ethics Committee/IRB, as prescribed by and in such frequency as required by the Ethics Committee/IRB, but no less than one year after initiation of the Study and annually thereafter until the Study is completed/terminated.

8. Access
The Institution, and Principal Investigator will allow Sponsor reasonable access to the Institution and Principal Investigator's facilities where the Study is conducted for the purpose of monitoring the Study, reviewing documents, progress reviews, and other matters related to the Study.

9. Confidential Information
All Study data and case report forms generated by the Institution and Investigator in the performance of the Study (the "Study Data") shall be the property of Sponsor, which may utilize the Study Data in any way it deems appropriate, subject to and in accordance with applicable state and federal privacy laws and regulations, this Agreement and any other applicable laws and regulations. The Study Protocol, case report forms and other written instructions provided by Sponsor to Institution and Principal Investigator shall be the property of Sponsor, shall be treated as confidential by Institution and Principal Investigator except as set forth in this Agreement, and shall only be used for the purposes of performing the Study except as set forth in this Agreement.

As a result of the performance of this Agreement, Sponsor agrees and acknowledges that it may have access to and may discover certain valuable information belonging to Institution or which the Institution is the custodian of and Sponsor shall keep all non-public information, letters, and documents of Institution confidential. Sponsor shall keep all security procedures of Institution confidential (including but not limited to procedures relating to electronic data). As a healthcare provider Institution contains information relating to non-subject patients and in the event Sponsor comes into contact with such information Sponsor shall treat all such information as confidential.

Sponsor will protect and maintain the confidentiality of all patient or subject medical records. Sponsor will protect and maintain the confidentiality of all individually identifiable subject information. Sponsor will not use individually identifiable subject information except for purposes of the Study, or as required by law or regulation. Sponsor will not contact a Study subject for non-Study purposes except with the subject's written consent. Sponsor will not disclose individually identifiable subject information to any third party unless required to do so by law, regulation or government order. In the event Sponsor contracts with any agents to whom it provides individually identifiable subject information, it shall include provisions in such agreements whereby its agents agree to the same restrictions and conditions that apply to it with respect to such individually identifiable subject information.

All parties shall act in accordance with all applicable federal, state and local laws governing confidentiality of medical records. Institution is required to comply with the Standards for Privacy of Individually Identifiable Information under the Health Insurance Portability and Accountability Act of 1996 contained in 45 CFR Parts 160 and 164 (the "HIPAA Privacy Standards"). If this Agreement must be amended to secure such compliance, the parties will meet in good faith to agree upon such amendments. If the parties cannot agree upon such amendments, then any party may terminate the Agreement upon thirty days written notice to the other party. Institution and Principal Investigator, in coordination with their IRB/Ethics Committee, may disclose confidential information (including, but not limited to, Study Data, study results from Institution and other study sites, and adverse event reports) to the Study subject in order to protect the health, safety or welfare of the Study subject or where such information is relevant to the Study subject's decision to continue participation in the Study. Sponsor agrees to provide Institution and Principal Investigator with Study results that could affect the safety or medical care of Study subjects enrolled in the Study.

10. Compensation
In return for performing the services described under this agreement, the Sponsor will pay Institution in accordance with the attached **Exhibit A**, which is hereby incorporated into this Agreement. Any change to compensation the Sponsor offers to Investigator(s), research staff or subjects shall constitute an amendment to this Agreement and must be approved in writing by all parties before implementation. The Payee for Institution shall be: [redacted], Study Number [redacted]; Tax ID #: [redacted]. All parties hereby agree that aggregate compensation paid to Institution and Principal Investigator over the term of the Agreement is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties. For purposes of identification of payment, each payment shall include Sponsor's name, the title of the protocol, the protocol number of the Study, the Banner Health ID number issued by Institution and the name of the Investigator. Where invoices are generated by Institution for compensation Sponsor shall return a copy of the Institution's invoice with each payment.

11. Termination
The Sponsor or Institution may terminate this Agreement, with or without cause, prior to the conclusion of the Study at any time by giving thirty (30) days prior written notice of termination to the other parties. Institution and Principal Investigator shall be compensated for Study-related work actually performed or reimbursed for expenses actually and reasonably incurred through the effective date of termination and any non-cancellable financial obligations incurred prior to receipt of notice of termination from Sponsor (or upon the date of Sponsor's receipt of notice of termination where such termination is initiated by Institution), which Sponsor has agreed to pay as part of the Study under this Agreement. Institution and/or Principal Investigator may temporarily halt or terminate the Study at any time in order to protect the health, safety or welfare of the Study subjects. In the event of a termination or completion of the Study any unused Study drug, device or biologic will be returned to the Sponsor at Sponsor's expense as set forth in **Exhibit A.** In the event of a termination or completion of the Study any unused Study drug, device, or biologic which was purchased by Institution shall be reimbursed by Sponsor to the extent set forth in **Exhibit A**.

All parties acknowledge and agree that this Agreement may not be amended prior to the first (1st) anniversary hereof, or more than once during any twelve (12) month period thereafter, unless the terms of such amendment do not change the terms of this Agreement in any material respect and the compensation for items or services provided hereunder are not changed at all during any such twelve (12) month period. If this Agreement is terminated prior to the first (1st) anniversary hereof for any reason, the parties may not enter into a successor agreement for the same items or services provided hereunder prior to first (1st) anniversary hereof unless such successor agreements contains the same terms and compensation as are set forth in this Agreement.

12. Notices
Any notices under this Agreement shall be in writing and delivered by (i) first class mail – certified return receipt requested or (ii) a recognized overnight delivery service to the parties at the locations that follow:

If to Institution:

[Name]_____ Research Director [Address]_____ _____	With copy to: Jeremy Stoloff Associate General Counsel Banner Health

	1441 North 12th Street Phoenix, Arizona 85006

If to Principal Investigator:

[Name]_____ [Address]_____

If to Sponsor:

[Name]_____ [Address]_____

13. Conflict of Interest

Sponsor certifies that, to the best of its knowledge, it has no financial arrangement with Investigator whereby the value of any compensation to Investigator could be influenced by the outcome of the Study.

14. No Federal Exclusion

All parties represent and warrant that they and all personnel providing services under this Agreement, as applicable, have not been placed on the sanctions list issued by the Office of the Inspector General of the Department of Health and Human Services pursuant to the provisions of 42 U.S.C. § 1320a(7), have not been excluded from government contracts by the General Services Administration ("GSA") and have not been convicted of a felony or any crime relating to healthcare. Further, if during any term of this Agreement, any party is placed on the sanctions list, excluded from government contracts or convicted of a felony or any crime relating to healthcare, such party will immediately notify the other party(ies) in writing of the event and such notice shall contain reasonably sufficient information to allow such party(ies) to determine the nature of the sanction, exclusion or conviction. A party will have the right to terminate this Agreement immediately by written notice to the other party(ies) if another party is placed on the sanctions list, banned from government contracts by GSA or convicted of a felony or any crime relating to healthcare.

15. Amendment

No alteration or amendment of this Agreement shall be valid unless the same is made by an instrument in writing signed by the Institution, the Principal Investigator and Sponsor and no such alteration or amendment shall be construed to alter or amend any other provision of this Agreement unless expressly so stated in such written instrument.

16. Severability

If any provision of the Agreement or the application thereof to any circumstance shall be invalid or unenforceable to any extent, it is the intention of all parties that the remainder of the Agreement and the application of such provision to other circumstances shall not be affected thereby and shall be enforced to the greatest extent permitted by law. In the event that state or federal law or regulations should change, alter or modify any operations of Institution such that terms, benefits and conditions of this Agreement must be changed accordingly in order to realize the original expectations of the parties, the parties shall immediately negotiate in good faith to modify the Agreement as necessary to reflect such changes.

17. Headings

The section headings are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

18. Indemnification
Sponsor agrees to indemnify, defend and hold harmless the Institution, its affiliated hospitals, trustees, officers, agents, staff, employees, IRB and the Principal Investigator (and any co/sub-Investigator and any investigator staff, employee or agent) (collectively "Indemnitees" or individually as an "Indemnitee") against any demands, claims, damages, liabilities, losses, costs, and expenses (including reasonable attorneys' fees and experts' fees) (collectively, a "Claim"), made or instituted against Indemnitees, arising, in whole or in part, out of the performance of the Study, implementation of the Study protocol (including Sponsor's written instructions), the Sponsor's use/disclosure of Study subject information, or Sponsor's handling, use or subsequent transfers of Study subject biological material.

This indemnification obligation does not apply to that portion of the Claim against an Indemnitee that arises from an Indemnitee's: (1) failure to adhere to material terms of the Study Protocol or Sponsor's written instructions, except where such deviation is necessary to protect the health, safety or welfare of the Study subject, (2) failure to comply with applicable FDA or other U.S. government regulations, or (3) negligence or willful misconduct.

In regards to any claim, suit or cause of action described above, Indemnitees shall have the right to be present at any pre-trial litigation, including but not limited to negotiations, mediation, arbitration as well as any trial and appeal arising therefrom, and Sponsor shall provide them with adequate notice of such. Sponsor shall not admit liability on behalf of any Indemnitee without such Indemnitee's prior written consent, which shall not unreasonably be withheld. Sponsor may not agree to a settlement which may result in a report to a state licensing board or the National Practitioner Data Bank, without the Indemnitee's advance written consent.

19. Governing Law
This Agreement shall be governed by the internal substantive law of the state of [State where study site is located], without regard for its conflicts of laws provisions.

20. Insurance
Sponsor will maintain general liability insurance with limits of at least $5 million per occurrence and $10 million in the aggregate. Sponsor also will maintain product liability insurance, including clinical trial coverage, with limits of at least $5 million per occurrence and $10 million in the aggregate. Sponsor's insurance will cover liability assumed under contract, will cover the Study, and will not be materially encumbered by existing claims. Sponsor will maintain such coverage for the duration of this Agreement and if the policy is claims-made, for two years thereafter. Sponsor will provide certificates of insurance to Institution upon request. Sponsor will notify Institution within 20 days of any notice of cancellation or non-renewal of, or material change in, or claim against, its insurance coverage. Insurance carriers will have an AM Best rating of A-VII or better.

21. Use of Name
Sponsor shall not use the name, symbol or image of Institution, Principal Investigator, nor of any member of their staff, in any publicity, advertising, or news release or in any way imply endorsement of Institution and/or Principal Investigator without the prior written approval of an authorized representative of such party. Institution and Principal Investigator shall not use the name, symbol or image of Sponsor, nor any employee of Sponsor, in any publicity, advertising, or news release without the prior written approval of Sponsor. Institution and Principal Investigator are permitted to identify Sponsor in any informed consent document/process, study subject authorization and study subject recruitment materials. Institution and Principal

Investigator are free to disclose the Sponsor's name as required by applicable law or regulation and in accordance with the publication section of this Agreement or other applicable provisions of this Agreement.

22. Independent Contractor Status
In the performance of all services hereunder: (A) Institution and Principal Investigator shall be deemed to be and shall be independent contractors and, as such, they shall not be entitled to any benefits applicable to employees of Sponsor; (B) Institution, Principal Investigator and Sponsor are not authorized or empowered to act as agent for another party for any purpose and shall not on behalf of another party or enter into any contract, warranty, or representation as to any matter; and (C) Institution, Principal Investigator and Sponsor shall not be bound to the acts or conduct of the other parties.

[The following shall be inserted where the Principal Investigator is not an employee of Institution] Principal Investigator shall at all times be deemed to be an independent contractor from Institution. Further, Principal Investigator and its employees, agents and representatives shall not be regarded as employees or agents of Institution with respect to any intentional or negligent activity in which they may be involved or for any other purpose. Nothing in this Agreement shall be construed to create an employment relationship between Principal Investigator and Institution.

23. Assignment
This Agreement may not be assigned by any party without the prior written consent of the other parties. If consent to an assignment is obtained, this Agreement is binding on the successors and assigns of the parties to this Agreement.

24. Survival of Terms
Termination of this Agreement by any party for any reason shall not affect the rights and obligations of the parties accrued prior to the effective date of termination. Additionally, the provisions of Sections 5, 9, 11, 18, 20, 21, 26, 29 and 30 shall survive the termination or expiration of this Agreement.

25. Term
This Agreement shall be effective as of as of the effective date set forth on page one of this Agreement and shall end upon completion of the Study (including the completion of all data queries and financial reconciliation); unless terminated earlier in accordance with this Agreement. The term of this Agreement shall be for no less than one year.

26. Publications
Institution and Investigator agree that Sponsor may make public Study results from all Study sites, including, without limitation, by posting a summary of Study results before or after publication by any other method. In the event Sponsor coordinates a publication or presentation of Study results from all Study sites (a "Multicenter Publication"), the participation of Principal Investigator or other representatives of Institution as a named author shall be determined in accordance with Sponsor policy and generally accepted standards for authorship. If the Principal Investigator or other representative of Institution is a named author of the Multicenter Publication, such person shall have access to the Study data from all Study sites as necessary to fully participate in the development of the Multicenter Publication.

Institution and Principal Investigator, consistent with scientific standards and in a scientific forum, may publish or present the Study results from Institution's Study data (an

"Institution/Investigator Publication"), provided that the Institution/Investigator Publication does not also disclose any of Sponsor's confidential information other than the Study results from Institution's Study data. Institution and Principal Investigator, as applicable, shall submit to Sponsor for review and comment any proposed Institution/Investigator Publication at least thirty (30) days prior to submitting the Institution/Investigator Publication to any third party. If Sponsor requests a delay in order to file patent applications relating to an Invention, Institution and Principal Investigator agree to delay submitting the Institution/Investigator Publication to any third party for up to one hundred twenty (120) days after Sponsor's request. Institution and Principal Investigator also agree that any Institution/Investigator Publication shall only be made after the Multicenter Publication, provided that the Multicenter Publication is submitted within twelve (12) months after conclusion of the Study at Institution.

27. Representations and Warranties

All parties hereby represent and warrant, respectively, that they have the authority to enter into and perform this Agreement, and their performances hereunder will not result in the breach or violation of any contract, arrangement or understanding such party may have with any third party.

28. No Referral or Product Use Requirement

The parties hereto acknowledge that the compensation paid hereunder has been determined though good faith and arms-length negotiation to be the fair market value of the services rendered. No amount paid or reimbursed hereunder is intended to be, nor shall it be construed as, an offer or payment made, whether directly or indirectly, to induce the referral of patients, the purchase, lease or order of any item or service, or the recommending or arranging for the purchase, lease or order of any item or service.

29. Subject Medical Care Reimbursement

Sponsor agrees to pay for the cost of reasonable and customary medical treatment (including diagnosis) of any illness or injury sustained by a Study subject as a result of the administration of the Study, Study drug or Study device in accordance with the Study Protocol (except to the extent such costs are covered by the subject's insurance or other third party coverage). Notwithstanding the foregoing, where the insurance provider or other third party coverage forbids billing for non-covered services, Institution and Principal Investigator shall not bill such providers or insurers for the foregoing services and Sponsor agrees to pay for such services. Sponsor agrees, to pay Institution directly on the Study subject's behalf for the care provided where directed by Institution.

30. No Warranties Regarding Study Results

Institution and Principal Investigator make no warranties, express, or implied, concerning the results of the Study (e.g.: Study data) or merchantability, or fitness for a particular purpose of such results. Institution and Principal Investigator shall not be liable for any direct, consequential, or other damages suffered by Sponsor or any others which arise out of such Study results. Where biologic or other materials are provided by Institution and Principal Investigator under this Agreement such items are provided as-is without any warrantees of any kind including warranties of merchantability, fitness for a particular purpose, or non-infringement of intellectual property rights.

IN WITNESS WHEREOF, Sponsor, Institution, and Principal Investigator, have caused this Agreement to be executed by their duly authorized representative. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original but all of which together shall constitute one and the same instrument. Facsimile signatures and signatures transmitted by email after having been scanned shall be accepted as originals for the purposes of this Agreement.

INSTITUTION-Banner Health:

Signature:

Printed Name:

Title:

Date Signed:

PRINCIPAL INVESTIGATOR:

Signature:

Printed Name: [INSERT Authorized Representative of PI's Employer]

Date Signed:

Signature:

Printed Name: [INSERT PI'S NAME]

Date Signed:

SPONSOR- [INSERT SPONSOR'S NAME]:

Signature:

Printed Name:

Title:

Date Signed:

EXHIBIT A

[Insert full/comprehensive payment provisions for all services to be provided under this Agreement]