

November 11, 2013

Given IIS #13-12: Comparison of the use of Wireless Capsule Endoscopy with Magnetic Resonance Enterography in Children with Inflammatory Bowel Disease

The Children's Mercy Hospital
2401 Gillham Road
Kansas City, MO 64108
Attn: Randall L O'Donnell, PhD
President/CEO

Investigator Initiated Study (IIS) Letter of Offer and Agreement

Dear Dr. O'Donnell:

We are pleased to furnish this letter that confirms our offer of research support and the terms and conditions upon which Given Imaging Ltd. ("Given") will provide assistance to The Children's Mercy Hospital ("Institution"), for use in its performance of a study entitled "Comparison of the use of Wireless Capsule Endoscopy with Magnetic Resonance Enterography in Children with Inflammatory Bowel Disease" (the "Study") for which Institution's employee, Nadia Hijaz, MD, will act as principal investigator ("Investigator"). The Research Protocol for the Study is attached hereto as Appendix A (the "Protocol") and incorporated herein by reference.

Upon satisfaction of the requirements and conditions below, Given agrees to provide Institution with: 34 (thirty-four) PillCam SB Capsules and 34 (thirty-four) Patency Capsules ("Capsules"). No other property or rights are granted under this agreement.

In consideration for our assistance, Institution agrees to use the Capsules exclusively as part of and in the course of the Study and solely in accordance with the Study's protocol. Without limiting the foregoing, Institution and Investigator shall not (i) make any commercial use of the Capsules or submit any bill for the Capsules to any patient, third-party payer or other person, (ii) disassemble or in any way reverse engineer the Capsules, or any part thereof, or (iii) recycle the Capsules.

Institution shall use commercially reasonable efforts to comply with all applicable laws, rules and regulations, including, without limitation: (1) the federal anti-kickback statute (42 U.S.C. §1320a-7b) and related safe harbor regulations; and (2) the Limitation on Certain Physician Referrals also referred to as the "Stark Law" (42 U.S.C. §1395nn). Accordingly, Given and Institution acknowledge that provision of the Capsules hereunder is intended solely for the use in Institution's internal, academic research as described in the Study's protocol and such provision of the Capsules is not dependent upon the volume or value of or any referral of patients by Given to Institution or the referral by Institution of any of Given's products to an Institution patient. Nothing herein shall be intended or implied to require the referral of any patient to Institution or the referral of any of Given's products by

Institution nor shall Institution be obligated to purchase, use, recommend or arrange for the use of Given's products or those of any organization affiliated with Given.

Institution acknowledges and agrees that Given is not the sponsor of the Study and has no liability or responsibility whatsoever concerning the Study or its conduct. Institution shall have sole liability and responsibility for the Study and its conduct and shall indemnify, defend and hold Given and its directors, officers and agent harmless from and against any and all claims, demands, actions, liabilities, losses, damages or expenses relating to the Study. Without limiting the above, Institution shall be responsible to recruit patients, obtain the appropriate patients' consents and comply with all applicable current laws and regulations, including, laws and regulations concerning the collection, use, storage and disclosure of any data and information relating to the Study. Given's liability is solely and completely limited to and by the Product Warranty that comes with the Capsules.

Institution certifies and represents that it maintains an insurance policy or self-insurance with coverage limit of not less than \$1 million per event and \$3 million in the aggregate during the period of the Study to cover its obligations hereunder. If such insurance is based on *Claims Made*, Institution undertakes to maintain valid insurance with at least the foregoing requirements for at least seven (7) years from the completion date of the Study. Any and all settlements of claims by Institution and/or by the insurers shall be free of admission of any liability whatsoever on the part of Given. Institution or Investigator shall promptly notify Given in writing about any complaint, claim or action of which Institution become aware against any insured including Given. **Institution must present Given evidence of such insurance as a preceding condition for Given providing the Capsules.**

During the Study, you agree to provide us, on a quarterly basis, a status report and interim results of the Study if available. Following completion or termination of the Study, you will provide us with a final written report of the Study results. Such final report shall include: (a) Patient videos which have been obtained with Given's RAPID software including the sets of findings obtained with the RAPID software (RAPID report), (b) an excel spreadsheet containing subjects' demographic data. All data supplied to Given must be de-identified and/or compliant with HIPAA and all applicable Clinical Trial and privacy laws. Institution is solely responsible for ensuring that all communications with Given relating to this study are compliant with HIPAA and applicable Clinical Trial and privacy laws.

Institution agrees that any proposed publication or presentation relating to the Study will be submitted to Given for review at least thirty (30) days prior to submission for publication or presentation. Institution further agree to consider in good faith Given's comments or recommendations concerning manuscripts or text in preparing final scientific documents and to remove any confidential or proprietary information of Given prior to such publication or presentation. In the event that the proposed publication or presentation contains patentable subject matter belonging to Given that needs protection, then upon Given's written request within the thirty (30) day review period, Investigator shall delay the publication or presentation for a maximum of an additional sixty (60) days to allow Given to file a patent application or other proprietary protection.

Institution further agrees that Instituion will not grant anyone other than Given any right to use the results of the Study for commercial purposes and hereby grants Given an

exclusive, perpetual, irrevocable and royalty-free license to use the results of the Study for commercial purposes in any manner we deem lawful and appropriate.

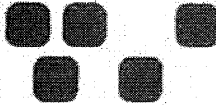
Institution understands that Given may be required to publicly disclose the existence and limited terms of this Agreement, including any payments, transfer or exchange of value in cash or kind made to Institution hereunder, and Institution assents to Given making such disclosure to the extent required under applicable law. Furthermore, Institution (and Principal Investigator, if applicable) agrees to keep all books, contracts, records, documents and other evidence (collectively, "Financial Transparency Records") regarding reportable recipients of the value conferred by this offer, and shall provide Sponsor with information and supporting evidence regarding the disbursement of such value within thirty (30) days after Sponsor's request. Institution shall make the Financial Transparency Records available to Sponsor and its representatives for inspection and audit to enable Sponsor to comply with applicable federal or state financial disclosure obligations, including without limitation the Physician Payment Sunshine Act set forth in Section 6002 of the Patient Protection and Affordable Care Act of 2010. Research Institution and Investigators shall retain the Financial Transparency Records for a period of seven (7) years or for a longer period if and as provided by the applicable laws and regulations. In the event of any legislative change or determination, whether federal or state, that has or would have a significant impact upon either party in connection with the required disclosure or in the performance of this Agreement, or should either party be deemed in violation of any statute or regulation for any reason arising out of this Agreement, then this Agreement shall be amended to comply with the then current law.

All parties expressly acknowledge that it is the intent of each party to comply fully with all federal, state, and local laws, rules, and regulations including, but not limited to, anti-corruption and anti-bribery laws, fraud and abuse prevention laws, transparency reporting laws and privacy laws.

Nothing in this letter shall be deemed to create any form of principal-agent relationship, partnership, employer-employee relationship or joint venture between the parties.

Nothing in this letter obligates Institution to purchase, lease or order (or arrange for or recommend the purchase, lease or order) any product or service of Given. This letter contains the entire agreement between Given and Institution and Investigator with respect to this Study and any transactions that pertain to it. This letter may be only be changed, amended or otherwise modified in writing and must be executed by both parties in order to have effect. Neither party shall assign this Agreement without the prior written consent of the non-assigning party.


SIGNATURES ON NEXT PAGE




If you wish to accept this offer and you agree to the terms and conditions of this letter, please sign in the space provided below and return one copy of this letter, by fax, to the undersigned. We are pleased to support your independent research.

Very truly yours,


Given Imaging.

By: 
Jennifer Doyle, MD
VP Director, Medical Affairs
GI Solutions, Covidien
Early Technologies

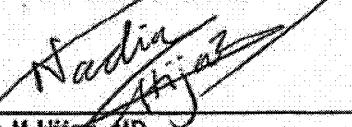
By: 
Erin Carter
Director, Finance
GI Solutions, Covidien

APPROVED AND ACCEPTED

The Children's Mercy Hospital

By: 
Name: Karen S.
Title: EXEC V P O X R W P H D

READ AND ACKNOWLEDGED:


Nadia M Hijaz, MD
Principal Investigator