EXHIBIT A

INVESTIGATOR AGREEMENT (US)

**Protocol Title: CONFORM Pivotal Study (“Study”)**

I agree and/or certify that:

1. I will conduct the Study in accordance with this agreement, the Clinical Trial Agreement for the Study, all requirements of the Study Protocol, all applicable laws, rules, regulations and guidelines adopted into law relating to the conduct of clinical investigations, and good clinical practice (“GCP”) principles, all regulations of the FDA, and any conditions of approval imposed by my reviewing Institutional Review Board (IRB) or FDA.
2. I have read and acknowledged my responsibilities under the Clinical Trial Agreement for the Study and agree to be bound by the terms of the Clinical Trial Agreement, including but not limited to the confidentiality terms set forth therein.
3. I agree to abide by all of the responsibilities of Investigators addressed under [21 CFR Part 812](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=812&showFR=1), Subpart E and Subpart G for the Study, including but not limited to the following:

* I will obtain written approval from the authorized IRB for the institution at which this Study will be conducted and submit certification of IRB approval and any conditions of this approval to Conformal Medical, Inc.
* I will ensure that Informed Consent and HIPAA Authorization are obtained from each subject participating in this Study in accordance with the informed consent regulation found in [21 CFR Part 50](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=50&showFR=1), and that a signed copy of the Informed Consent and HIPAA Authorization Form for each subject is available to Conformal Medical and its designated monitor and/or representatives.
* I will supervise all elements of the Study involving human subjects and will allow only those physician co-investigators listed on the Delegation of Responsibility Log to participate and/or perform activities for the purposes of the Study.
* I will ensure the accurate completion of protocol case report forms and I will submit completed protocol electronic case report forms, progress reports, and a final report to the sponsor at the time frames specified in the Protocol.
* I will direct the retention of required records and documents related to the Study during the investigation and for a minimum of two (2) years after the later of termination or completion of the Study or the date the records are no longer required to be maintained by Applicable Law.
* I agree to cooperate in the event of any study-related audit by Conformal Medical or other regulatory agencies, as applicable. I agree to reasonably assist Conformal Medical or Conformal Medical’s representatives in conducting audits and resolving any discrepancies or errors with respect to the Study and all study-related documentation.

4. I have attached my most recent curriculum vitae (CV) to this Agreement, signed and dated by me. My relevant qualifications, including dates, location, extent, and type of experience, are described in my CV, or in a separate statement that is attached, along with my CV, to this Agreement.

5. Regarding my previous participation in investigational or research activities **(check applicable statement)**:

\_\_\_\_ I have never participated in an investigation or other research activity which was terminated by FDA, the IRB (or equivalent), or sponsor of a study

\_\_\_\_ I have participated in an investigation or other research activity which was terminated by FDA, the IRB (or equivalent), or sponsor of a study. The specific circumstances leading to this termination and my role in the respective problems or issues and the resolution of these problems or issues are summarized in an attachment to this Agreement.

I further certify that I have not been debarred under the Food, Drug and Cosmetic Act. In the event that I become debarred or receive notice of an action or threat of an action with respect to my debarment during the term of this Agreement, I agree to immediately notify Conformal Medical and the authorized IRB for my study site.

6. I will certify and disclose sufficient and accurate financial information to allow Conformal Medical to submit a complete and accurate disclosure statement as required under 21 CFR Part 54. I will also notify Conformal Medical if my certified and disclosed financial information changes at any time during the Study and for one (1) year following completion of the Study.

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| **PRINCIPAL INVESTIGATOR AGREEMENT** | |
| Investigator Name |  |
| Institution |  |
| Office (Mailing Address) |  |
| City/State/Zip |  |
| Email |  |
| Telephone (Primary) |  |

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Principal Investigator Signature Date

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| **SUB-INVESTIGATOR AGREEMENT** |

**Protocol Title: CONFORM Pivotal Study**

As a physician sub-investigator for above mentioned study, I have read the foregoing and agree to be bound by its terms.

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Name of Sub-Investigator (Print)

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|  |  |  |

Signature Date

*Please print additional copies of this page, as needed, for additional sub-investigators.*

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