INVESTIGATOR CERTIFICATION/AGREEMENT FOR IN-UTERO ENDOSCOPIC CORRECTION OF MYELOMENINGOCELE

I, Dr. Ruben Quintero, M.D., agree to participate as the Principal Investigator for the performance site located at the Wellington Regional Medical Center ("Study Site") in the clinical investigation of *In-Utero Endoscopic Correction of Myelomeningocele: Laparotomy versus Percutaneous* (*specify investigational device/ intended use*)("Study Device")("clinical investigation").

I have been provided a copy of the following Food and Drug Administration (FDA) regulations: 21 CFR Part 812, Investigational Device Exemptions; 21 CFR Part 50, Protection of Human Subjects; and 21 CFR Part 54, Financial Disclosure by Clinical Investigators.

I agree and/or certify that:

1. I will conduct the clinical investigation in accordance with this agreement, all requirements of the protocol, IDE regulations, other applicable regulations of the FDA, and any conditions of approval imposed by my reviewing Institutional Review Board (IRB) or FDA. I agree to abide by all of the responsibilities of Investigators addressed under 21 CFR Part 812, Subpart E and Subpart G, including but not limited to the following:

a. I will obtain written approval from the authorized IRB for the institution at which this clinical investigation will be conducted. I will submit the certification of IRB approval and any conditions of this approval to the sponsor, Dr. Ruben Quintero at the University of South Florida ("Sponsor-Investigator").

b. I will ensure that Informed Consent is obtained from each subject participating in this clinical investigation in accordance with the informed consent regulation found in 21 CFR Part 50, and that a signed copy of the informed consent is available to the Sponsor-Investigator and the Sponsor-Investigator's designated monitor.

c. I will supervise all uses of the Study Device on human subjects and will allow only those physician co-investigators listed on the last page of this agreement, if any, to administer this Study Device and/or perform follow-up medical evaluations regarding the use of the Study Device.

d. I will be responsible for accountability of the Study Device at the Study Site and I will follow the instructions of the Sponsor-Investigator regarding the return or further use of the Study Device following the completion of the clinical investigation.

e. I will ensure the accurate completion of protocol case report forms and I will submit completed protocol case report forms, progress reports, and a final report to the Sponsor-Investigator upon the time frames specified in the Protocol and/or FDA regulations.

f. I will direct the retention of required records and documents related to the clinical investigation

2. I have the appropriate, relevant qualifications to conduct and to oversee the conduct of the clinical investigation as documented by the following: (*Check applicable statement)*

__x__ My relevant qualifications, including dates, location, extent, and type of experience, are listed in my most recent curriculum vitae (CV), which is attached to this Agreement and which will be maintained by the Sponsor-Investigator of the corresponding IDE application.

____ My curriculum vitae (CV) does not reflect my relevant qualifications, therefore attached to this Agreement is a statement of my relevant experience (including dates, location(s), extent, and type of experience) which will be maintained by the Sponsor-Investigator of the corresponding IDE application.

3. There are no reasons to question my ability to oversee the appropriate conduct of this clinical investigation. (Check applicable statement.)

____ I have never participated in an investigation or other research activity which was terminated (disqualified) by FDA, the IRB (or equivalent), or sponsor of a study due to a non-compliance issue.

__x__ I have participated in an investigation or other research activity which was terminated (disqualified) by FDA, the IRB (or equivalent), or sponsor of a study due to a non-compliance issue. 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 Generic Drug Enforcement Act of 1992, 21 USC §§ 335a and 335b. 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 the Sponsor-Investigator and the authorized IRB for the Study Site.

4. As required by 21 CFR Part 54, Financial Disclosure by Clinical Investigators, I will disclose sufficient and accurate financial information to the Sponsor-Investigator by completing the Certification of Financial Interest form (attached) and if applicable, the Disclosure of Financial Interest form (attached). I will also notify the Sponsor-Investigator if my disclosed financial information changes at any time during the clinical investigation or up to one year following the closure of the study.

PRINCIPAL INVESTIGATOR

Ruben Quintero, MD

Name of Principal Investigator (please print or type)

3850 Bird Rd., Suite 401

Office (Mailing Address)

Coral Gables, FL 33146 Q@the-fetal-institute.com

City/State/Zip E-mail

720-753-3825 786-780-2060

Telephone FAX

6/22/18

Signature of Principal Investigator Date

PHYSICIAN CO-INVESTIGATORS (i.e., physicians participating as co- or sub-investigators on this clinical investigation under supervision of the Principal Investigator): A current CV or statement of relevant experience and a completed Certification of Financial Interest form and, if applicable, Financial Interest Disclosure form is required to be submitted to the sponsor (sponsor-investigator) for each physician co-investigator listed below.

As a physician co-investigator for this investigation, I have read the foregoing and agree to be bound by its terms.

Name of Physician Co-Investigator (please print or type)

Signature Date

Name of Physician Co-Investigator (please print or type)

Signature Date

Name of Physician Co-Investigator (please print or type)

Signature Date

Certification of Financial Interest of Clinical Investigators

Title of Clinical Study: *In-Utero Endoscopic Correction of Myelomeningocele: Laparotomy versus Percutaneous*

Principal Investigator: Ruben Quintero, MD

Identity of Investigational Device: Instruments and Devices for Use in In-Utero Endoscopic Correction of Myelomeningocele

As a clinical investigator who will be participating in the above-named clinical study being conducted under a University-based (i.e., investigator-sponsored) IDE application, I certify that *(check the appropriate box for each statement):*

[ ] I do [x] I do not Have an ownership interest, stock options, or other financial interest (i.e., *equity interest*) in the company (public or non-public) that owns the investigational device being evaluated in the clinical study.

[ ] I do [x] do not Have property or other financial interest (i.e., *proprietary interest*) in the investigational device being evaluated in the clinical study; including, but not limited to, a patent or patent interest, trademark, copyright, licensing agreement, or any arrangement tied to a current or future right to receive royalties associated with the development or eventual commercialization of device.

[ ] I will [x] I will not Receive payments from the company that owns the respective investigational device during the term of the conduct of the clinical study; nor do I anticipate receiving payments from the company during a 1 year period following completion of the clinical study. Applicable payments (i.e., *financial interest*) include, but are not limited to, grants to fund projects or research or compensation in the form of monetary payments, equipment, or retainers for consultation or honoraria.

If the response to any of the above statements is affirmative, completion of the Disclosure of Financial Interest of Clinical Investigators is required.

_Ruben Quintero, MD_____

Name of Clinical Investigator (Printed or Typed)

_____ 6/22/18_____

Signature of Clinical Investigator Date

Disclosure of Financial Interest of Clinical Investigators

Title of Clinical Study: *In-Utero Endoscopic Correction of Myelomeningocele: Laparotomy versus Percutaneous*

_____

Principal Investigator: Ruben Quintero, MD_____

Identity of Investigational Device: Instruments and Devices for Use in In-Utero Endoscopic Correction of Myelomeningocele_____

In compliance with the provisions of 21 CFR Part 54, Financial Disclosure by Clinical Investigators, I hereby disclose that I have participated in financial arrangements or hold financial interests as follows: *(Check all applicable boxes.)*

[ ] any financial arrangement entered into between the company that owns the investigational device being evaluated in the above-named clinical study, whereby the value of the compensation to me for conducting or participating in the clinical study could be influenced by the outcome of the study;

[ ] any significant payments (i.e. *financial interests*) of other sorts from the company that owns the investigational device being evaluated in the above-named clinical

study; such as a grant to fund ongoing research, compensation in the form of equipment, retainer for ongoing consultation, or honoraria;

[ ] any *proprietary* interest in the investigational device being evaluated in the above-named clinical study;

[ ] any significant[1] *equity interest* held by me in the company that owns the investigational device being evaluated in the above-named clinical study.

Attach to this form the details of your financial arrangements and interests. Also attach to this form, a description of the steps (i.e., management plan) taken by your department chair and/or dean, the University, or the principal investigator of the clinical study to minimize the potential bias of clinical study results related to your disclosed financial arrangements or interests.

Ruben Quintero, MD_____

Name of Clinical Investigator (Printed or Typed)

_____ 6/22/18_____

Signature of Clinical Investigator

[1] A significant *equity interest* is defined under 21 CFR Sec. 54.2(b) as any ownership interest, stock options, or other financial interest in a non-public company that owns the investigational drug or device, or equity worth more than $50,000 in any public company that owns the investigational drug or device.