Clinical Research Investigator Support (CRIS) Application

Please complete all application contents. This information is REQUIRED to process your application. When completed, please email to SReitzler@vertiflexspine.com.

The Review Process:

Vertiflex gives all CRIS applications a comprehensive review based upon scientific, business, and healthcare compliance interests. This process may take 3 to 4 weeks from the submission date to complete, and we ask for your patience. The applications are reviewed to ensure that:

1) The research subjects' well-being is considered of paramount importance;
2) Medical and ethical concerns are identified, considered, and resolved;
3) Proposals are original, and their objectives contribute valid scientific data to the body of knowledge;
4) The proposals are consistent with the educational, business, and/or research interests of Vertiflex®; and
5) Proposals are deemed likely to result in a peer-reviewed publication, or otherwise meet generally accepted public criteria.

Please submit all completed attachments AND a copy of your CV to SReitzler@vertiflexspine.com.

Submission Agreement

1. Study Concept Information

Investigator affirms that Investigator has no financial or proprietary interest in the product(s) or idea being studied. Investigator affirms that Investigator and Investigator's Institution have not been prohibited by law from providing clinical research services and have not been convicted of a criminal offense related to the provision of health care items or clinical research.

Investigator wishes to submit the idea described below for consideration by Vertiflex®, Inc. ("Vertiflex"). Investigator understands and agrees that this idea will be considered only under the terms and conditions set forth below and further agree that these terms and conditions shall also apply to any previous or future disclosures made by the Investigator which relate to the idea described herein.

Vertiflex does not solicit suggestions, and all submissions or disclosures of ideas are voluntary on the part of the Investigator. No confidential relationship is established or implied by Vertiflex's acceptance or consideration of the submitted material.

Investigator acknowledges that all suggestions will be submitted in writing, and Vertiflex shall have the right to retain any material submitted to it in connection with the suggestion. Ideas that are not covered by a patent shall be considered by Vertiflex only with the understanding that the use to be made of such ideas and the compensation, if any, are matters resting solely in the discretion of Vertiflex.
Patented ideas shall be considered only with the understanding that the Investigator agrees to rely for Investigator's protection wholly on such rights as Investigator may have under the patent laws. Pending applications for a patent are to be treated in the same manner as ideas not covered by a patent, as described in paragraph 3, above, unless and until a patent issues.

Vertiflex shall not be obligated to give reasons for its decision or to reveal its past or present activities relating to the submitted idea. Negotiating or offering to purchase an idea will not prejudice Vertiflex nor be deemed an admission of the novelty, priority or originality of the idea. All requests for financial funding must be consistent with Fair Market Value and will not be subject to any institutional overhead costs.

The disclosure which the Investigator makes relates to the attached Protocol.

Investigator represents and warrants to Vertiflex that, except as noted herein, the material disclosed is wholly original with the Investigator; that no interest has been granted to or acquired by others; and that Investigator has full authority to make the disclosure and to execute this release.

2. Disclosure Pursuant to Laws:

The Parties acknowledge that certain laws, such as the he Physician Payments Sunshine Act, may require medical device companies to disclose information on compensation, gifts or other

remuneration provided to physicians and other healthcare professionals. Vertiflex may report information about remuneration provided under this Agreement, as required by law. Once reported, such information may be publicly accessible.

By requesting CRIS support, Investigator consents to the collection, use, and disclosure of the information Investigator has provided, in accordance with this Privacy Statement. Investigator's name, address, e-mail address and other personal information will be used by Vertiflex to support our grant process. Vertiflex may disclose Investigator's personally identifiable information to third parties, located in the United States and/or any other country where required by applicable laws, court orders, or government regulations.

Investigator has the right to reasonable access to Investigator's personal information maintained by Vertiflex, and the right to correct such information, as appropriate. It is the Investigator's responsibility to ensure the accuracy of Investigator's personal information. To keep personally identifiable information accurate, current, and complete, please contact Vertiflex at SReitzler@vertiflexspine.com.

WITNESS WHEREOF, the Investigator, intending to be legally bound, has executed this Agreement as of the day and year written below.

Investigator: Signature: _____
Print: _____
Date: _____

Applicant Information & Requested Support

Date:	
Investigator/Applicant (Name and Title):	
Institution:	
Institution Address:	
Relationship to Institution:	☐ Employee ☐ Contract ☐ Other, please specify:
Office Phone:	
Business Email:	
Preferred Contact:	
Contact Phone:	
Contact Email:	

Collaborators (List if any):

Name	Study Role

Financial Request Information:

	Type	Quantity	Cost
Financial Support Requested			
Product Support Requested			
In-Kind Service Support Requested			
List key budget items (Cash Costs, not in-kind services or products)			Cost
Total Project Cost			

Please list any additional sources of materials, data, or support requested (and cost if applicable):	

Study Information

Project Title:	
Study Type:	☐ Clinical Trial ☐ Animal Study ☐ Health Outcomes ☐ Lit Review ☐ In Vitro ☐ Registry
Study Driven By:	☐ Pilot/Feasibility ☐ Hypothesis
Study Design (Choose best option):	☐ Randomized, Concurrent control with blinding (check one): ☐ Single ☐ Double ☐ Randomized, concurrent control no blinding ☐ Non-randomized, prospective, concurrent control ☐ Non-randomized, prospective, no concurrent control ☐ Case series, retrospective ☐ Review published trials (meta-analysis) ☐ Database mining ☐ Other, please describe:
Estimated Start Date:	
Estimated End Date:	
Subject Visits:	
Total Sample Size:	
Treatment Subject Count:	
Control Subject Count:	
Primary Endpoint/Objective:	
Current Status: Full Protocol Developed?	☐ Yes (attach if yes) ☐ No
IRB/Ethics/Animal Use Committee Status:	☐ Not submitted ☐ Under Review ☐ Approved ☐ N/A (please explain):

Dissemination plans:	☐ Presentation, local/regional meeting ☐ Presentation, national/international meeting ☐ Manuscript suitable for submission to peer reviewed journal	Date: Date: Date:

Describe Study Significance:

Describe Hypothesis:

Primary Endpoint:

Secondary Endpoints:

Inclusion Criteria:

Exclusion Criteria:

Study Procedures:

Steps to protect rights of study subjects:

References:

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