



Ortho Clinical Diagnostics Franchise Investigator-Initiated Study Program

The Ortho Clinical Diagnostics (OCD) Franchise, comprised of the three operating companies; Ortho-Clinical Diagnostics, Inc., Therakos, Inc., and Veridex, LLC., proudly provides support for Investigator-Initiated studies to advance scientific knowledge concerning our products and related therapeutic areas. The following basic information and guidance is provided for potential investigators interested in requesting OCD support.

What is an Investigator-Initiated Study?

An Investigator-Initiated Study (IIS) is a research effort in which the investigator designs and implements the study and the investigator or the institution acts as the study sponsor, NOT the OCD operating company. As the sponsor, the investigator assumes all responsibilities for complying with applicable regulatory requirements. IIS may be supported by an OCD operating company in the form of funding and/or company product.

What are the responsibilities of the investigator?

- Designing and conducting the scientific investigation
- Complying with institution requirements where the study will be conducted and all relevant laws, regulations and guidelines for clinical and pre-clinical research
- Reporting safety data to regulatory authorities and the OCD operating company as required
- Registering the clinical study on a public website such as www.clinicaltrials.gov
- Providing the OCD operating company with interim and final research summary reports, a proposed publication plan and a draft manuscript(s) as applicable

How to apply?

To apply for IIS support, please download the IIS Support Request Form from any of the following websites:

Ortho Clinical Diagnostics

www.orthoclinical.com/IIS

Therakos

www.therakos.com/home/about

Veridex

www.veridex.com/About.aspx

or send an e-mail request to IISOTV@its.jnj.com.

In order to enable a timely review, the following documents are required:

- A completed IIS Support Request Form
- A study protocol or proposal that includes at a minimum the study objectives, background and rationale, disease stage, clinical population description and size, and study plan
- Investigator CV
- Itemized budget [when funding is requested]
- Form W-9 Request for TIN [for US studies] or W-8BEN certificate [for outside US studies]

Please refer to the IIS Support Request Form instructions for more details and submit the above documents to IISOTV@its.jnj.com.

What is the review process?

All submitted requests for support will go through an internal review by the OCD Franchise IIS Review Committee consisting of company personnel from relevant disciplines. A decision is based on criteria in the areas of strategic fit with the franchise business plan, investigator research experience, scientific merit, adherence to Good Clinical Practice, etc. The applicant is notified of the committee decision on the study proposal. If your proposed study is approved for OCD support, an IIS study agreement will be provided to you to sign as a requirement to execute prior to study start.

Who can I contact if I have questions?

For additional information, please send an e-mail request to the OCD Franchise IIS Administration Office at IISOTV@its.jnj.com.

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