INDIANA UNIVERSITY
SCHOOL OF MEDICINE

Office of Clinical Research for Indiana Fees

ra-cr-0001

About This Policy

Effective Dates:
01-01-2024

Last Updated:
01-24-2024

Responsible University Administrator:
J. Carmel Egan. PhD Associate Dean, Research Affairs, IU School of Medicine Operations Director, Precision Health Initiative Director of the Office of Clinical Research for Indiana

Policy Contact:
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Scope

This policy applies to:

Anyone engaged in the conduct of industry-funded clinical research where the authority for review and negotiation of the clinical study agreement rests with the Office of Clinical Research for Indiana (OCR), including those whose home department is outside of the IU School of Medicine or Indiana University.

Policy Statement

1. All industry-funded clinical study agreements reviewed by the OCR will be assessed a one-time, non-negotiable OCR New Study Initiation Fee according to the OCR Schedule of Standard Fees for Industry-sponsored Studies.
2. Each major amendment to a clinical study agreement that is routed to the OCR and will impact the overall budget of the study, will be assessed a non-negotiable CTA Amendment Fee according to the OCR Schedule of Standard Fees for Industry-sponsored Studies.
3. The IU Melvin and Bren Simon Comprehensive Cancer Center is delegated to perform several of the administrative functions of the OCR, and therefore will incur reduced fees.
4. Research teams are expected to include these fees during their initial or amended sponsor budget development and negotiation processes. The fees will be charged regardless of whether they are approved by the sponsor.
5. These fees are exempt from indirect cost and are included in the OCR Industry Fee Schedule.

Reason For Policy

The OCR provides essential services and support to clinical researchers working within Indiana University, IU Health, and Eskenazi Health systems. The OCR performs contracting and financial compliance reviews, maintains a robust Clinical Research Management System (OnCore) and provides additional companion services to support recruitment and the state-wide expansion of research. Indirect cost recovery offsets a portion of the study management costs but does not fund the substantial front-end investment to activate new studies. Therefore, the

OCR will charge additional fees for all new industry-sponsored clinical study agreements and subsequent major amendments.

Procedure

1. The OCR will track the submission and negotiation of new industry-funded clinical study agreements and major amendments through to execution.
2. Monthly, the OCR will compile a list of clinical study agreements and major amendments that were fully executed in the previous month.
3. Billing for these fees will be managed through the OCR Core in iLab.

Definitions

Clinical Study Agreement: Clinical study agreement is one of many names for such a document and is intended to encompass all variations including, but not limited to, clinical trial agreements, clinical research agreements, clinical project agreements, and riders, task orders, study letters, or addendums to master clinical trial agreements.

Major Amendments: The OCR is defining major amendments as those that are routed to the OCR and will impact the study's overall budget.

iLab: iLab is a web-based management service designed to provide a unique platform for core facilities to efficiently support the management of service requests, equipment scheduling, project tracking, communication, billing, and reporting.

History

1. Policy ra-cr-0001 first drafted 05 January 2024.
2. Policy ra-cr-0001 updated 24 January 2024.