INDIANA UNIVERSITY OFFICE OF CLINICAL RESEARCH

INTERNAL ESCALATION POLICY

ABOUT THIS POLICY

Effective Date: 2/21/2023
Last Updated: 2/21/2023
Responsible Unit: Indiana University Office of Clinical Research
Responsible Administrator: J. Carmel Egan. PhD

PURPOSE

The Office of Clinical Research (OCR) provides administrative services that Indiana University (IU) and Indiana University Health investigators may be required to utilize when conducting human subjects clinical research. IU, IU Health, and the OCR have established various policies, procedures, and guidelines to communicate the scope of these requirements. At times, investigators and their study teams may question the applicability or necessity of our services; or be found to be non-compliant with policy expectations. The purpose of this policy is to document OCR internal review and escalation of such concerns.

SCOPE

This policy applies to IU or IU Health investigators conducting human subjects research on prospective, clinical studies involving informed consent and/or provider services that may require the following OCR services:

- Review and negotiation for Industry-Sponsored Confidentialiy and Disclosure Agreements (CDA) and/or Contracts
- Use of the OnCore Clinical Research Management System and other clinical research systems managed/overseen by the OCR.
- Coverage Analysis and Research Billing Compliance Review

POLICY

It is the OCR policy that exception requests and policy/process non-compliance will be escalated according to the escalation policy statements below.

A. Requests for Policy/Procedure Exceptions:

- Requests for exceptions to OCR policies and procedures will first be reviewed and decided by the OCR leadership of the respective research team/division at issue. If the request is not approved and the OCR leadership cannot resolve the investigator's concerns, the request will be escalated as detailed below in Section C.

B. Repeated or Unresolved Non-Compliance:

- When instances of repeated or unresolved non-compliance are encountered, the OCR leadership will attempt to first resolve the non-compliance with the study team. If the study staff cannot resolve the issue, OCR leadership (Director and/or Medical Director) will communicate directly with the project's principal investigator and/or the principal investigator's department/institute research leadership. When OCR leadership is unable to resolve the issue after communication with the investigator, the issue will be escalated as detailed in section C below.

C. Escalation:

- Following attempts to resolve the above-mentioned concerns with the investigator, OCR leadership will escalate these matters to the IU School of Medicine Associate Dean for Clinical and Translational Research, with a copy to the Director of the OCR, for resolution.

- Issues that remain unresolved may then be escalated to the Executive Associate Dean for Research Affairs at Indiana University School of Medicine,and/or the IU Health Chief Compliance Officer, when appropriate, for final resolution. If the situation also impacts human subjects oversight, conflict of interest, or data security, the appropriate Indiana University committee will be notified.

D. Sanctions

Individuals that do not adhere to the OCR policies and procedures could experience delayed study enrollment and may be subject to research-related sanctions, up to and including permanent suspension or debarment from engaging in research at Indiana University as well as additional discipline up to and including termination pursuant to applicable University policies/procedures.

DEFINITIONS

Clinical Studies: A research study using human subjects to evaluate biomedical or health-related outcomes. This includes, but is not limited to, prevention and treatment of a disease/diagnosis or genetic and environmental factors related to disease and health; studies surrounding cost of care or regarding patient satisfaction; observations surrounding a disease/diagnosis and patient health; specimen or tissues collections; and registries.

ADDITIONAL CONTACTS

OCR Team	*Email*
Contracts	ocr@iu.edu
Financial Compliance	ocrfin@iu.edu
Research Systems Support	oncore@iu.edu

RELATED INFORMATION

- IU-OCR Coverage Analysis and Research Billing Policy
- IU Clinical Trials Management System Policy
- IU-OCR OnCore®CRMS Registration Requirements for Clinical Research at Indiana University and IU Health
- IU Health Research Policy
- IU Health Clinical Research Recruitment Policy

HISTORY

This is an inaugural policy.