Clinical Trials Management System

CA-01

About This Policy

Effective Dates:
04-21-2016

Last Updated:
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Responsible University Administrator:
Vice President for Clinical Affairs

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Scope

This policy applies to all Indiana University employees and affiliated staff, including IU Health, who engage in clinical research (as defined below), which originates from any location.

Policy Statement

It is the policy of Indiana University that all clinical studies shall be registered in OnCore, a clinical trials management system. For the purpose of this policy, “clinical study” shall mean any prospective research study using human subjects to evaluate biomedical or health-related outcomes. This term encompasses interventional and expanded access trials as well as observational studies requiring informed consent and long term adverse event reporting.

This policy applies in all situations and activities of the University where human subjects are used in research regardless of the source(s) of support and/or funding.

Reason For Policy

The use of a single clinical trials management system will promote the safety of study subjects and allow for greater efficiency in conducting studies. This policy provides guidance to ensure consistency and best practices in the management of clinical studies.

Procedure

http://medicine.iu.edu/research/clinical-trials/clinical-trials-industry-partners/oncore/

https://oncore.indianactsi.org/login

Definitions

Clinical Studies: any prospective research study using human subjects to evaluate biomedical or health-related outcomes. This term encompasses interventional and expanded access trials as well as observational studies requiring informed consent and long term adverse event reporting.

Sanctions

Failure to adhere to the principles and procedures of this policy may result in the delay of patient enrollment in clinical studies.