Flowchart for Industry Sponsored Clinical Trials – Part I

Principal Investigator (PI) Contacted by Sponsor & Receives Confidentiality Agreement (CDA)

Do Not Sign CDA on your own! It must be reviewed and signed by Institutional Officials.

Office of Technology Development
Jill Wagner x8496
jwagner3@psu.edu

The Office of Technology Development negotiates the CDA, obtains necessary signatures, and sends signed CDA to Sponsor

Sponsor Sends Protocol to PI for Review
If Protocol is Acceptable – Begin Process for Budget Feasibility

Protocol must be reviewed for compliance with HMC procedures, labs, and investigational pharmacy

Clinical Trials Office
Terry Novchich x3779
tnovchich@psu.edu

Clinical Trials Office (CTO) meets with PI and Trial Coordinator (CTO creates initial trial budget and assists with budget negotiations)

CTO Reviews Protocol for Budget Feasibility
CTO/PI approve initiation of review process for IRB and Contract
Flowchart for Industry Sponsored Clinical Trials – Part II

IRB Application submitted for IRB Review & Approval***
Budget and Contract Negotiations Initiated

Human Subjects Protection Office
Kathy Hay x5687
khay@psu.edu

Office of Research Affairs
Barb Suchanec x3567
bsuchanec@psu.edu
Brion Lesko x5955
blesko@psu.edu
William Pogash 531-0030 x285839
wpogash@hmc.psu.edu

Clinical Trials Office
Michele Stanton x1388
mstanton@psu.edu

IRB Approval

Finalized Contract & Budget

Internal Budget

Once all three are received, the Award Statement is Issued by Office of Research Affairs and sent to the PI’s Home Department. Study may begin and IBIS Account may be opened.

*** Clinical Trials Office Provides Regulatory Services for IRB Approval