RISKS AND BENEFITS IN DEVELOPING SPONSORED CLINICAL TRIALS

Doug Mounce MS

Cancer Research And Biostatistics

Pancreatic Cancer Research Team

CRAB
CANCER RESEARCH AND BIOSTATISTICS

PCRT
PANCREATIC CANCER RESEARCH TEAM

21 CFR 312, SUBPART B - THE IND

INVESTIGATIONAL NEW DRUG

§ 312.20
Requirement for an IND
§ 312.30
Protocol amendments
§ 312.31
Information amendments
§ 312.32
IND safety reporting
§ 312.33
Annual reports
§ 312.38
Withdrawl of an IND

SPONSOR RESPONSIBILITIES

§ 312.50
General responsibilities
§ 312.52
Transfer of obligations
§ 312.53
Selecting investigators and monitors
§ 312.54
Emergency research
§ 312.55
Informing investigators
§ 312.56
Review of ongoing investigations
§ 312.57
Recordkeeping/retention
§ 312.58
Inspection of records and reports
§ 312.59
Disposition of unused drug

INVESTIGATOR RESPONSIBILITIES

§ 312.60
General Responsibilities
§ 312.61
Control of the investigational drug
§ 312.62
Investigator recordkeeping/ retention
§ 312.64
Investigator reports
§ 312.66
Assurance of IRB review
§ 312.68
Inspection of investigator's records
§ 312.69
Handling of controlled substances
§ 312.70
Disqualification of an investigator

DEPARTMENTS TO DEVELOP

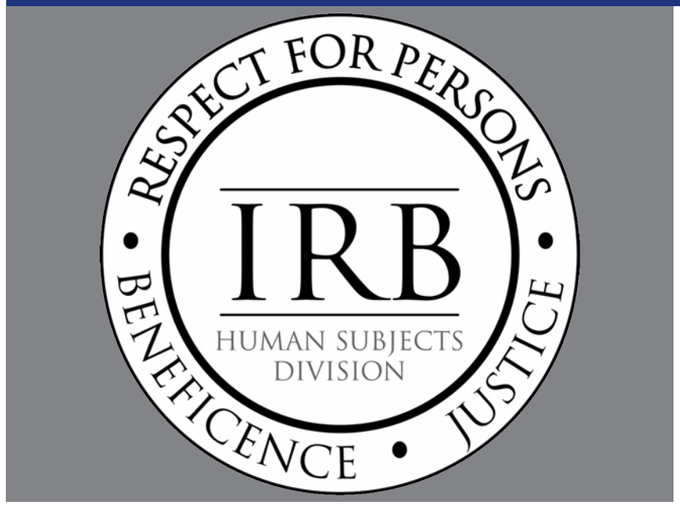
CRM & FEASIBILITY	SPONSOR/CRO CONTACTS	SUBMISSION NEW STUDY PROPOSAL	FEASIBILITY EVALUATION	FEASIBILITY CHECKLIST	
IRB SUPPORT	CTA SUBMISSION	CHECK BY SECRETARIAT	MEETING ORGANIZATION	IRB EVALUATION AND DECISION	IRB POST APPROVAL MONITORING
BUDGET & BILLING	PROFITS AND COSTS	BILLING SCHEDULING	INVOICES AND PAYMENTS	REVENUE ALLOCATION	RESEARCH FUNDING
MONITORING & SAFETY	RECRUITMENT	PATIENT VISITS AND HEALTH SERVICES	STUDY CLOSURE	RESULTS AND PUBLICATIONS	SAE/SUSAR/DSUR
DOCUMENT MANAGEMENT	STUDY DOCUMENTATION (PROTOCOL, IB, ...)	CONTRACT AND INSURANCE	AUTHORIZATION AND SIGNATURE WORKFLOWS	DIGITAL SIGNATURE	
PHARMACY	DRUGS / DEVICES HANDLING	TRACKING DRUGS LOADING AND UNLOADING	DRUGS / DEVICES WITHDRAWAL OR DISPOSAL	ADDITIONAL COSTS TO PHARMACY	

SPONSOR-INVESTIGATOR RISKS

DO YOU TRUST YOUR INVESTIGATOR?

WHAT IS A SPONSOR-INVESTIGATOR?

IRB - HOW MUCH OVERSITE IS NEEDED?



INFORMED CONSENT

ANY ADVANTAGES TO LOSING MONEY?

ISTS ARE UNDER-FUNDED. CLINICAL TRIALS DO ATTRACT PATIENTS AND SHOW THAT YOUR INSTITUTION IS A LEADER.

DO YOU OWN MORE BECAUSE IT'S YOUR PROTOCOL?

IS IT WORTH ARGUING WITH PHARMA OVER IP?

COURT CASES

KERNKE V. THE MENNINGER CLINIC

- Duty to supervise and care for the patient normally lies with the investigator conducting the study
- Sponsor is not automatically shielded from any liability
- Sponsor has duty to adequately warn the patient's prescribing physician of the risks and dangerous side effects associated with the drug

DARKE V. ESTATE OF ISNER

- A sponsor's control over clinical protocol does not demonstrate control over the conduct of the investigators
- In this case, the court left open the critical possibility that a sponsor might be vicariously liable for the tortious acts of an investigator

ABNEY V. AMGEN, INC

- Fiduciary duty is only created when two parties agree that one will act in the interest of the other
- Amgen asserted its right to terminate trials that were found to present a risk

SUTHERS V. AMGEN, INC

- There is no basis to impose "fiduciary duty" on the sponsor
- The consent form made no promise of continued drug supply