

16. Protocol Submission Checklist

PROTOCOL TITLE:	
PRINCIPAL INVESTIGATOR'S NAME:	PROPOSAL NO:
INSTITUTION:	

Requirement for All Protocols as Appropriate:

- ___ Research Protocol
- ___ Consent Form(s)
- ___ Curriculum Vitae or Biosketch for Principal Investigator and Medical Monitor
- ___ Documentation of the most current ethics training for all research staff
- ___ Scientific Review/Peer Review Approval(s)
- ___ Letter from the IRB Chairperson with the following protocol information: (a) MPA number, (b) risk level that the IRB classified the protocol (exempt, NGTMR, GTMR), (c) date of IRB approval, (d) next continuing review date, and (e) risk for medical devices (nonsignificant risk or significant risk).
- ___ Recruitment advertisements, posters, and announcements
- ___ Case report form(s), data collection/recording form(s), questionnaires, interview guides, etc.
- ___ Radiation Control Committee/Biosafety Review Report
- ___ Data Collection Forms and Case Report Forms
- ___ If potential commercial use of sample(s) or future use of sample(s) in other studies, a Sample Donation is required to be in the consent form.
- ___ With HIV Testing, documentation of consent for HIV antibody testing, if scheduled, may be addressed in the body of the consent form or as separate HIV test consent form.

Additional Requirements for IND Protocols:

- ___ Documentation of the Investigator's most recent GCP training
- ___ Document specifying IND Number
- ___ Investigator's Brochure
- ___ Copy of Case Report Forms (blank)

Protocol Submission Checklist (cont.)

Additional Requirements for Medical Device Protocols:

- ___ Documentation of the Investigator's most recent GCP training
- ___ Document from manufacturer declaring level of risk for device (non-significant risk or significant risk) and IDE form
- ___ Document specifying IDE Number
- ___ Manufacturer's device manual/ device information

What type of study is proposed?

- | | | |
|------------------------------|----------------------------------|----------------------------|
| ___ Phase I Clinical Trial | ___ Survey/Medical Record Review | ___ Community Intervention |
| ___ Phase II Clinical Trial | ___ Cohort (longitudinal study) | ___ Laboratory Experiment |
| ___ Phase III Clinical Trial | ___ Retrospective (case-control) | ___ Tissue Only |
| ___ Multicenter Trial | ___ Program/Policy Study | ___ Qualitative Study |
| ___ Pilot Study | ___ Cross-Sectional (prevalence) | ___ Other: _____ |

Check all procedures applicable to this protocol:

- | | |
|---|---|
| ___ Experimental Drug/Medications IND# _____ | ___ Prosthetic Orthopedic Devices |
| ___ Marketed Agent, but Unapproved Use IND# _____ | ___ Nutrition/Metabolism Study |
| ___ Experimental Device, IDE# _____ | ___ Tissue/Organ Transplant |
| ___ Immunological Study | ___ Radiation or Radioactive Material |
| ___ Artificial Organ Study | ___ Human Embryos |
| ___ Experimental Treatments | ___ Diagnostic Procedures |
| ___ Experimental Surgery | ___ Anatomical Substances
Biological Specimens |

Other: _____

Drug (s) to be used: _____ Drug Type* _____

*Drug Type may be chosen from the following list or other type may be stated as appropriate:

- | | | | |
|----------------------------------|-------------------------|-----------------------------|----------------------------------|
| Analgesics | Anti-cancer drugs | Cardiac drugs | Hematologic agents |
| Anesthetics | Anti-convulsants | Diuretics | Hormones |
| Anti-allergy drugs | Anti-hypertensive drugs | Drugs affecting respiration | Tranquilizers/psychotropic drugs |
| Anti-arrhythmic drugs | Anti-Parkinson agents | Eye/Optical drugs | Vitamins/Minerals |
| Antibiotics/anti-infective agent | Autonomic drugs | Gastrointestinal drugs | |

Protocol Submission Checklist (cont.)

Human Subject Information:

Age range of subjects: _____

Total number of subjects expected to be enrolled: _____

Total number of subjects at each collaborating site: _____

Check all that apply:

Subject Gender:

Male

Female

Are subjects able to provide their own consent?

Yes

No

Vulnerable Subject Class:

Prisoners

Minorities

HIV positive

Psychologically impaired

Impaired decision-making

Psychiatric patient

Military

Employee/Student

Trauma

Subject Recruitment:

In-patients

Out-patients

Students/employees

Paid volunteers

Other:

Principal Investigator's Signature