

# Institutional Review Board Checklist for Submitting a New Protocol

## *Protocol Statement Form*

- Signature of investigators (students must include faculty advisor)
- Principal investigator should be first name; be sure to include a PO address
- All sections filled out
- Signatures of all involved chairs and deans (others as appropriate)

## *Protocol*

- Abstract in lay language (generally a brief synopsis of 250 words or less)
- Consent and assent forms (with their own consecutive pagination)
- Authorization or waiver for use or disclosure of protected health information
- Cover letter(s) or telephone text
- Recruitment ad(s)

### Headers, as given below, with appropriate wording

- Introduction
- Purpose
- Description of Procedures
- Risks or Discomforts
- Voluntary Compensation
- Financial Considerations
- Alternatives
- Benefits
- Contact Persons
- Confidentiality
- Voluntary Participation
- Signature Lines
- Discussion items 1-17 as given in Guidelines (Currently Under Revision)
- Attachments
  - Questionnaire
  - Support letter(s)
  - Sponsor protocol(s)
  - Investigator brochure
  - Other