New Member Review Guide

What you should see:

For Expedited IRB Review (no greater than minimal risk review package)
☐ Cover page – Signature of PI and Dept Chair (or PI and research advisor if student)
☐ Proposal narrative
☐ Certification of Investigator responsibilities (Signature of PI or PI and research advisor if student)
☐ Human subjects training certificate (Each individual who handles or has access to data, on or off campus)
☐ Informed consent (written or transcript of oral) (see informed consent checklist for content)
   ☐ If minors used – parental consent and minor assent
   ☐ If protected medical information accessed – HIPAA consent
☐ Copies of all questionnaires, survey instruments, interview questions, discussion guides and/or data collection instruments that will be used. If database search, parameters of search.
☐ Letter of cooperation from any other institution where data is collected
☐ Recruitment material (email, poster, flyer or other)
☐ Sometimes additional materials will be attached relevant to the project

Review Guide: There is not a checklist or defined review for IRB’s. The committee declined to product a standard review checklist. The expertise and thoughtful reading by the experienced researchers and reviewers is valuable to the process and could be hampered by a checklist approach.

Does the experiment involve Minimal Risk? ______ (yes) ______ (no)
(If no, the proposal must be reviewed by full-board.)

Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Cover page - Content –
   a. Researcher contact information – should match training certificates
   b. brief summary of project
   c. Identification of other committee approvals required or pending
   d. Number of research subjects requested
   e. Signature or PI and Advisor or Chair
   f. Research title matches informed consent and if funded grant title.

2. Proposal Narrative content
   a. Personnel – describes who will be involved in the research and have contact with data. This should match training certifications provided. Methodology should provide data security description.
   b. Purpose - brief
      i. Study Hypothesis and Specific Aims (purpose, objectives)
      ii. Relevant Literature
      iii. Background and Significance
   c. Outcome – Teaching protocols require less justification than faculty research
      i. Expected outcome.
      ii. Who will benefit from the study (Individual and global)
   d. Subjects
      i. Justification for inclusion of any special or vulnerable populations
      ii. How recruitment will occur
      iii. What personal information is required to participate?
      iv. Is the population appropriate to the study? Are there unprotected power relationships?
      v. Description of incentives – fairly distributed and nominal in nature.
      vi. Management of power relationships or potential coercion.
         1. E.g., Employer/employee; teacher/student relationship
         2. Potential fixes
            a. Conduct the study in another venue (school or grade level)
b. Use a research assistant who does not share the power relationship to recruit subjects, collect the data or
c. Collect the data in an anonymous fashion with provision to allow non-participants to remain unidentified. (e.g., drop a blank copy of the survey in the box so the researcher does not identify who did not participate.)
d. Collect data from transient students (College course) and hold for analysis after grade submission.

e. Methodology
   i. Research Design
   ii. Eligibility Criteria
   iii. Plans for subject selection, recruitment, and documentation of informed consent
   iv. Description of Procedures
   v. Statistical Methods
      1. Planned statistical analysis
      2. Rationale for selection of subject
   vi. Safety Monitoring and Assessment (if relevant, include provisions for managing adverse reactions)
   vii. Data management (when relevant, address measures of privacy protection, coding, storage of information)
      1. Must maintain for 7 years following end of study for faculty (BOR) or 3 years for students (NIH, et al.).
      2. Identify storage in secure location.
   viii. Data collection instrument
      1. Appropriate to the research
      2. Content matches risks described in informed consent
      3. Faculty research – addresses validation  Student research – use judgment

f. Special Conditions
   i. Risk – greater than minimal risk from physical, mental, economic or social discomfort. (Should not say no risk – not likely unless the study is unnecessary to begin with.)
   ii. Minors – how will interactions with children and parent/guardians be handled to assure communication and informed participation
   iii. Deception – description of debriefing.
   iv. Medical procedures (Physical or Protected Health Information (PHI) - Complete description of patient safety and security of medical data.
   v. Match to the checklist on cover page to assure all special risk items were addressed.

g. Informed Consent (See checklist)
   i. Applicant’s affiliation with GSU clear (GSU letterhead)
   ii. Title of the study (as it appears on IRB proposal)
   iii. Applicant’s affiliation with Georgia Southern (GSU letterhead)
   iv. Investigator contact information (and advisor contact information, if a student)
   v. Purpose of the study
   vi. Procedures to be followed
   vii. Discomforts or risks (if none are known, state as such)
   viii. Description of compensation if any and what happens if subject withdraws (If student subjects, alternate method of obtaining compensation – e.g., extra credit)

3. Recruitment Material:
   a. Copy of the poster, email, letter or other communication that invites or recruits participants
   b. All recruitment texts must include a statement like “This research has been reviewed and approved by the GSU IRB under the protocol number HXXXXX.”

4. Informed Consent – See checklist