



**CHECKLIST FOR IRB MEMBERS**

**Project Title:**

**Meeting Date:**

- Purpose of the study
- Description of procedures to be performed
  - Are the procedures adequate to maintain confidentiality and anonymity
- Methods for recruitment of subjects defined and appropriate
  - Permission from research location
- Assessment of level of risk:
  - minimal risk [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.]
  - greater than minimal risk but has potential direct benefit
  - greater than minimal risk and no direct benefit but has potential to yield generalizable knowledge about the subjects disorder or condition:
  - If risk is greater than minimal, are the risks reasonable in relation to the potential benefits?
- Are the risks:    Physical                  Psychological                  Social                  Economic
- Have risks for all subjects been minimized via use of an appropriate research design?
- Has safety been maximized for all subjects?
- Is the proposed subject population equitably distributed?
- Are inclusion and exclusion criteria appropriate?
- Does the study include vulnerable subjects?
  - minors                  prisoners                  mentally disabled individuals
  - economically or educationally disadvantaged persons
- Are additional safeguards in place to protect vulnerable subjects?
- Compensation to subject for participation
- Are all subjects' rights and welfare protected?
- If minors are to be enrolled in the study will assent be obtained?
  - Permission of parents provided
- Will privacy and confidentiality of research records be adequately protected?
- PHI to be collected
- Is plan adequate for protecting confidentiality of PHI?
- Is private medical/psychiatric information being requested (e.g. in questionnaires) about Individuals other than the subjects

**Consent Document:**

- Are the basic elements of informed consent incorporated (see below)?
- Will the consent document be understandable to an individual with a 8th grade education
- Are ALL procedures in protocol stated in consent
- Are ALL risks and Adverse Events in protocol stated in consent
- Has the PI requested a modification in the consent process?
- If project approved, should approval be:
  - for one year
  - if no, limited to \_\_\_\_\_ duration or # subjects