

Simmons University IRB
Protocol Checklist

- Have you described your research protocol in as much detail as possible?
- Have you described the subject population from which the sample will be drawn?
- Have you addressed the rationale for including or excluding any specific group of subjects?
- Have you clearly described how the subjects will be recruited?
- Have you considered the issues of voluntariness and coercion in your recruitment process?
- In your proposal and consent form, have you addressed:
 - specific activities required of the subjects;
 - risks to the subjects;
 - benefits to the subjects;
 - how risks are minimized;
 - protection of confidentiality/anonymity;
 - provision of counseling support or intervention if the study causes psychological distress;
 - ability of subjects to refuse participation or withdrawn from the study without penalty;
 - parental/guardian permission and child assent if subject is under 18 years of age?
- Have you considered language and reading comprehension level of the subject population in your consent form?
- Are copies of your research instruments included in your email to the IRB?
- Have you completed, signed and attached your Research Project Cover Sheet?
- If you have a formal proposal that has a precise description of how human subjects will be involved in the research, on which page(s) can this information be found? _____