Some Quick Tips for completing your IRB Application

Please note: There is a wealth of information about doing research involving human subjects on the U.S. Department of Health and Human Services website for the Office for Human Research Protections (OHRP) at: http://www.hhs.gov/ohrp/

READABILITY
Please proof-read your application and documents for grammar and spelling errors, avoid the use of jargon or highly technical terms and write the full name of any acronym the first time you use it.

ANONYMOUS vs. CONFIDENTIAL
The IRB makes a distinction between the words ‘anonymous’ and ‘confidential’ in terms of research. An anonymous study would mean that no identifying information would be collected and subjects would not be known to the researcher/s. A study involving interviews or any contact between subject/s and researcher/s cannot be considered anonymous, but can be considered confidential if measures are taken to protect subjects’ identities and de-couple personal identifiers from collected data (e.g. through the use of codes or pseudonyms throughout the research process).

RISKS: Focus groups
Any study which involves using a focus group is currently required to go through an Expedited Review. There is an inherent risk in using focus groups, since individuals will know each other and will be sharing personal opinions or information. You should explain how you will work to minimize such risk and state that confidentiality cannot be guaranteed, on your Informed Consent form/s.

RISKS: Small pool of participants
If your study will draw from a small group of participants and you are requesting information that may identify certain members of this community, you should clearly state the risk on your Informed Consent form/s and explain how you will minimize this risk [e.g. by aggregating data or by disguising, masking or not including identifying information in any final or published materials].

BENEFITS
Please do not overstate the benefits of your study, as this can be considered coercive if it sounds like you are trying to ‘sell’ your study to potential participants. A potential direct benefit should refer to a personal or specific benefit that a participant may gain by participating in a study. If there are no direct benefits to participation, you should state this on your Informed Consent form/s. Potential general benefits of a research study may be (briefly) described as indirect benefits.

COERCION and UNDUE INFLUENCE:
If your study involves any potential issues of coercion or undue influence, these should be clearly addressed on your Informed Consent form/s, and you should include a statement that participation is voluntary and that subjects may refuse to participate or withdraw from the study at any time with no negative or positive consequences in terms of student grades, class standing or other entitlements.

EXEMPT Studies: Informed Consent
Exempt research is not subject to federal regulations but the IRB strongly recommends that you provide participants with the basic elements of Informed Consent: describe the research and procedures involved in your study, the risks, benefits, how confidentiality will be protected and state that participation is voluntary and participants may withdraw from the study at any time without penalty. Contact information for the PI and the TC IRB office should also be provided (per Participant’s Rights template).

EXEMPT Studies: Category #4
If you are claiming this exemption (Research involving the collection or study of existing data, documents or records), answer all questions on the application, even if you only indicate ‘Not applicable’, but answer any question relating to your study in order for the IRB to understand the purpose of your research and your research questions. Please state whether your data includes identifiers that can be linked to subjects, provide information about the source of your data, note if it’s publicly available or provide proof that you have permission to use the data.