IRB eProtocol Protocol-Submission Checklist

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| Topic or Protocol Section | Comments/Resource | Yes | No | NA |
| Personnel listed correctly? \*S*tud*ents, your advisor must be PI | CSU defines "Investigator" as an individual who conducts a research study. If the study is conducted by a team of individuals, the Investigator is the responsible leader of the team. Students, fellows and residents may not act as a Principal Investigator. |  |  |  |
| Training up-to-date? | Check with your CITI Program account:  <https://about.citiprogram.org/en/homepage/>  <https://www.research.colostate.edu/ricro/irb/researcher-training/> (this site is not in ‘real’ time. |  |  |  |
| Do you describe your study using language that is clear, easily understood by individuals outside of your expertise; avoid jargon? | Throughout the protocol, but especially in the study summary (requested to be in lay language), study procedures, and consent/assent sections. |  |  |  |
| Subject population – 4a | Did you provide the **number** of participants you are asking to recruit? The number of participants approved to recruit will be included in your IRB approval letter; this number can easily be increased with an amendment post-approval, if necessary. |  |  |  |
| Subject population – 4c  Are you requesting to include or exclude <18 year old students? When recruiting within certain populations, this must be addressed. | Are you recruiting freshman students? Psychology 100 students? When recruiting within certain populations, there may be students who are <18 years old. If this is a minimal risk study, the IRB may waive the requirement to obtain parental permission, but you must request this. If you will exclude students <18, this should be clearly stated on the consent.  Check out these resources: <https://www.research.colostate.edu/ricro/irb/templates/consent-assent/>  Request to waive the requirement for parental permission by selecting “Waiver of consent” and answering the questions from the drop-down menu. |  |  |  |
| Recruitment – 4f | Have you clearly outlined your recruitment plan & included **all** recruitment documents in the attachment section? For example, if you state “Recruitment will occur through word of mouth, flyers, and e-mails,” the reviewers will expect to see a verbal script, flyer and email in your attachment section. Use our recruitment worksheet and templates for your recruitment documents: <https://www.research.colostate.edu/ricro/irb/templates/recruitment/> |  |  |  |
| Subject Population – 4i | Consistency in time commitment? Please state how long your participant should expect to be involved. The reviewers will be looking for consistency in listed time commitment from this section of your protocol, to the time commitment listed in your recruitment, and the time commitment listed on the consent. |  |  |  |
| Risks – 5 | Do not overstate or underestimate potential risks. The IRB assesses psychological, employment, and social risks as well as physical/medical risks. If you will be asking sensitive questions, for example, address how you will minimize the psychological risk to the participants; a response of NA or none would not be appropriate. |  |  |  |
| Benefits – 6a | Most research is about developing generalizable knowledge that might be valuable at some point in the future; the research being done at the moment will most likely not directly benefit the participant. State this and include a potential overall benefit that may be associated with the study. **Note regarding compensation:** The IRB *does not* consider compensation to be a benefit. This should not be listed here or described as a benefit to participants. |  |  |  |
| Confidentiality – 7a | Do you need to keep a linked-list with identifying information once the data have been collected? Our default is that if researchers must keep identifying information, it should be kept as far away from data as possible; if such steps are necessary (and sometimes they are), there needs to be a very careful justification.  \*\***Note**: The term “anonymous” should only be used if no one, not even members of the research team, can link the data to an individual. When referring to data, you will keep your participant’s identity and data “confidential.” Reporting data without a name does not mean that you will keep it “anonymous,” if you know the identity of the participant. |  |  |  |
| Confidentiality – 7c | Is your data management plan in line with the Federal Regulations? Federal Regulations require that study data and consent documents be kept securely for a minimum of three (3) years after the completion of the study by the Principal Investigator at Colorado State University campus. Note that some sponsors require that data be kept for more than 3 years. |  |  |  |
| Obligations - 8 | Has this screen been reviewed and signed (box checked) by the PI of the protocol? |  |  |  |
| Consent – 9 | Consent is the cornerstone of human research protection. Consent begins with your recruitment and continues throughout the study. How you consent your participants & the consent form used are critical elements of your protocol submission. Please use our templates; check the readability of your consent (we are looking for <10th grade); and use **lay language**.  Review the description associated with each template, and select a consent format that makes the most sense when you consider the risk level for the participant, research activities, and location. For example, if you are conducting a low-risk study entirely at a distance with phone interviews, would it make sense to submit a consent form that must be signed? How would your participants be expected to sign and return this to you? Would your participants be better protected if they signed a form and mailed it back to you? For a study that is minimal risk, if requested with adequate justification, the IRB may grant a waiver of documented consent, and you would then be able to consent your participants with a cover letter, email, or verbal script.  Are you recruiting different groups who may require different consents? For example, a teacher’s participation in the research may be different from a parent’s participation. Please submit a consent document customized for each group of participants.  Consent templates: <https://www.research.colostate.edu/ricro/irb/templates/> |  |  |  |
| Assent - 10 | Consider the age of the children or participants you are seeking assent from and describe the method you will use to obtain their assent to participate. Refer to our *templates listed above* for some ideas. Did you know that if a parent gives permission for their child to participate and the child does NOT give their assent, the child should NOT participate? |  |  |  |
| Attachments - 11 | Remember that the IRB needs to see the documents associated with the entire project. You will be uploading your recruitment, surveys, interview questions, methodology chapter for student projects, grant submission, letters of cooperation, etc. |  |  |  |
| Tips from the IRB Reviewers | --Look at your study materials through the lens of a participant. |  |  |  |
| Tips from the coordinators | --Address the status of letters/emails of cooperation - When sites are included in the study that are assisting in the research (e.g., providing mailing lists/names & addresses/handing out or forwarding recruitment flyers/emails to selected clients), documentation that this location understands the project and agrees to assist the Investigator must be received from each site. The IRB can review and approve while you seek to obtain these letters or emails, but inform the IRB with your submission that you understand this requirement, and where you are in the process of receiving these supporting documents.  See: <https://www.research.colostate.edu/ricro/irb/templates/miscellaneous/>--Resist the temptation to copy and paste from your methodology chapter. Also, if the recruitment, consent, interview questions, etc. are contained within the methodology chapter, save them as separate files and upload individually. This helps the reviewers, coordinators, and you when comments are returned.  --Plan for a minimum of 4-5 weeks from submission to approval.  --The details count! Proofread and be consistent.  --Look at your study materials through the lens of a participant. |  |  |  |
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