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Description automatically generated**IRB PROTOCOL GUIDANCE AND CHECKLIST FOR APPLICATION SUBMISSIONS**

**INSTITUTIONAL REVIEW BOARD**

**TEACHERS COLLEGE**

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| **IRB Protocol Guidance and Checklist for Application Submissions** | |
| **Purpose of Your Research with Human Subjects** | **Yes, No, or N/A** | |
| * State the [purpose of your research](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/before-you-begin/) and provide a clear description of the study. * [List your research question(s) and what you hope to discover](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/). * Define any technical terms and/or acronyms. Avoid jargon, complex phrases, or confusing descriptions. |  | |
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| **Study Activities** | |
| * In the application and on the [consent form(s),](https://www.tc.columbia.edu/institutional-review-board/irb-blog/prepare-present--polish/) clearly describe each activity the participants will be asked to do, how long each activity will take, how often they will engage in them, and over what period of time (provide an estimated total time). This time allotment should be consistent across all documentation. * [Describe what data you will collect](https://www.tc.columbia.edu/media/administration/institutional-review-board-/irb-submission---documents/Published_Study-Material-Examples.pdf) (e.g., responses to an online survey). * Itemize how often and for how long participants will be asked to do each study activity. * Describe the duration of the study (e.g., one week). |  | |
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| **Research Participants** | |
| * Describe in detail the characteristics of your participant population, including relevant information such as age, gender, ethnic background, language(s) spoken, any disabilities, health, and/or socio-economic status (SES). * Indicate the maximum number of participants that will be in your study. * Include a statement about your study population and how your research applies to them. |  | |
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| **Your Role in the Research** | |
| * Describe your research role, the research site(s), or the institutions involved with your study. * State in the application and on the consent form(s) how you will minimize the risk of coercion, bias, conflict of interest, or undue influence. * Ensure that the distribution of time per study activity is reasonable and justified.   + For classroom research, avoid taking away from typical classroom learning.   + For intervention research, explain how the study activity differs from daily routines. |  | |
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| **Participant Recruitment** | |
| * Describe your [recruitment methods and procedures](https://www.tc.columbia.edu/media/administration/institutional-review-board-/irb-submission---documents/_IRB-Flyer-Example1.pdf) in detail, and explain on what basis you will select participants. * Provide any [recruitment materials you plan to use](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/notes-on-recruitment-materials/), including email or online text, posts, letters, flyers, or a script for announcements or phone calls. |  |
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| **Payment for Study Activities and Time Involvement** | |
| * + When paying participants, describe when and how they will be paid (e.g., at the end of the study, a gift card will be sent via email).   + When using a raffle, describe the odds of receiving the gift (e.g., “*At the end of the survey, you will have the option to enter your email address into a raffle for a $30 Amazon gift card. Your email address and survey responses will be stored separately. Your chances of receiving the gift card are 1/100. Only the person whose name is drawn for the raffle will be contacted via email*.”) |  |
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| **Risks and Benefits** | |
| * Clearly [describe potential risks](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/understanding-potential-risks-for-human-subjects-research/) (physical, psychological, social, legal, or other), and indicate the likelihood of these risks occurring. Boredom is not a risk. * Explain how you will mitigate risks. * Do not overstate study benefits. Direct benefits to participants are tangible and are equally available to all. Most research has no *direct* benefit. |  |
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| **Informed Consent Procedures** | |
| * Language used on consent form(s), letters, or any other documents for parents/guardians and participants should be [clearly written at an age-appropriate reading level.](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/the-assent-process-with-minors/) An 8th grade reading level is considered standard for adults. Use the Flesch-Kincaid Grade Level test to evaluate reading level.   + If an online survey is being used, the stamped IRB-approved consent form should be downloadable through the survey link.   + The online survey should not include forced responses (i.e., respondents should be allowed to skip questions). * Clearly state that participation is **voluntary**, participants are free to stop or withdraw from the study at any time, and individuals (including parents) have the right to remove themselves (or their child) from the study at any point without damage to their academic standing or access to services or benefits.   + If the study includes minors (under the age of 18) parents/guardians may inquire about the progress of their child or any changes in their child’s reaction to the procedure at any point. |  |
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| **Research Sites** | |
| * Describe the study location.   + If you are conducting research or recruiting subjects from a school or other institution, a **site** **permission form must be obtained** from the appropriate administrator (a site permission form is available in Mentor IRB/Documentation or from a representative of that institution). A site permission form can be signed *after TC IRB approves* the study and uploaded to the protocol via a modification.   + [If the study is being conducted in-person, indicate any details about safety and hygiene that relate to the study](https://www.tc.columbia.edu/preparedness/campus-life-during-covid-19/research-compliance-and-safety/). * Detail any unique characteristics about the study site (e.g., no reliable WIFI). |  |
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| **Proofread, Be Consistent, Self-Check** | |
| * [Ensure your IRB protocol is complete, consistent, and written for ease-of-read](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/writing-for-an-irb-review/). * Name files in a clear and easily identifiable way by developing a naming convention. For example, “IRB Protocol#\_Document Title\_Date.” * [Review resources on TC IRB’s website like the TC Reviewer Questions](https://www.tc.columbia.edu/media/administration/institutional-review-board-/checklists-submission-guides---docs-ppts/Published_TCReviewerQuestions.pdf). |  |
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| **Weblink Resources** | |
| * [Teachers College Institutional Review Board (IRB)](https://www.tc.columbia.edu/institutional-review-board/) * [Life Cycle of a Protocol | IRB Blog | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/irb-blog/life-cycle-of-a-protocol/) * [FAQs | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/faqs/) * [Training & Certification | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/training--certification/) * [Submitting a New Protocol | How to Submit | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/submitting-a-new-protocol/) * [Review Categories | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/review-categories/) * [Guides & Resources | How to Submit | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/how-to-submit/guides--resources/) * [IRB Blog | Institutional Review Board](https://www.tc.columbia.edu/institutional-review-board/irb-blog/) * [Research Compliance and Safety | Campus Life During COVID-19 | Preparedness](https://www.tc.columbia.edu/preparedness/campus-life-during-covid-19/research-compliance-and-safety/policies--procedures/requirements-and-guidance-for-research-ramp-down/) | |
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