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| Instructions and Notes:   * Depending on the nature of what you are doing, some sections may not be applicable to your research. If so, mark as “NA”. * When you write a protocol, keep an electronic copy. You will need a copy if it is necessary to make changes. | |
| 1. **Protocol Title**   Include the full protocol title: | |
| 1. Background and Objectives   Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how will it add to existing knowledge.   * Describe the purpose of the study. * Describe any relevant preliminary data or case studies. * Describe any past studies that are in conjunction to this study. | |
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| 1. Data Use   Describe how the data will be used. Examples include:   * Dissertation, Thesis, Undergraduate honors project * Publication/journal article, conferences/presentations * Results released to agency or organization | * Results released to participants/parents * Results released to employer or school * Other (describe) |
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| 1. Inclusion and Exclusion Criteria   Describe the criteria that define who will be included or excluded in your final study sample. If you are conducting data analysis only describe what is included in the dataset you propose to use.  Indicate specifically whether you will target or exclude each of the following special populations:   * Minors (individuals who are under the age of 18) * Adults who are unable to consent * Pregnant women * Prisoners * Native Americans * Undocumented individuals | |
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| 1. Number of Participants   Indicate the total number of participants to be recruited and enrolled*:* | |
| 1. Recruitment Methods  * Describe who will be doing the recruitment of participants. * Describe when, where, and how potential participants will be identified and recruited. * Describe and attach materials that will be used to recruit participants (attach documents or recruitment script with the application). | |
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| 1. Procedures Involved   Describe all research procedures being performed, who will facilitate the procedures, and when they will be performed. Describe procedures including:   * The duration of time participants will spend in each research activity. * The period or span of time for the collection of data, and any long term follow up. * Surveys or questionnaires that will be administered (Attach all surveys, interview questions, scripts, data collection forms, and instructions for participants to the online application). * Interventions and sessions (Attach supplemental materials to the online application). * Lab procedures and tests and related instructions to participants. * Video or audio recordings of participants. * Previously collected data sets that that will be analyzed and identify the data source (Attach data use agreement(s) to the online application). | |
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| 1. Compensation or Credit  * Describe the amount and timing of any compensation or credit to participants. * Identify the source of the funds to compensate participants * Justify that the amount given to participants is reasonable. * If participants are receiving course credit for participating in research, alternative assignments need to be put in place to avoid coercion. | |
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| 1. Risk to Participants   List the reasonably foreseeable risks, discomforts, or inconveniences related to participation in the research. Consider physical, psychological, social, legal, and economic risks. | |
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| 1. Potential Benefits to Participants   Realistically describe the potential benefits that individual participants may experience from taking part in the research. Indicate if there is no direct benefit. Do **not** include benefits to society or others. | |
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| 1. Privacy and Confidentiality   Describe the steps that will be taken to protect subjects’ privacy interests. “Privacy interest” refers to a person’s desire to place limits on with whom they interact or to whom they provide personal information. Click here for additional guidance on [ASU Data Storage Guidelines.](https://uto.sp10.asu.edu/sites/sec/isodocs/isodocs-asurite/Documents/Data%20Storage%20Guidelines%202012%20Final.pdf)  Describe the following measures to ensure the confidentiality of data:   * Who will have access to the data? * Where and how data will be stored (e.g. ASU secure server, ASU cloud storage, filing cabinets, etc.)? * How long the data will be stored? * Describe the steps that will be taken to secure the data during storage, use, and transmission. (e.g., training, authorization of access, password protection, encryption, physical controls, certificates of confidentiality, and separation of identifiers and data, etc.). * If applicable, how will audio or video recordings will be managed and secured. Add the duration of time these recordings will be kept. * If applicable, how will the consent, assent, and/or parental permission forms be secured. These forms should separate from the rest of the study data. Add the duration of time these forms will be kept. * If applicable, describe how data will be linked or tracked (e.g. masterlist, contact list, reproducible participant ID, randomized ID, etc.).   If your study has previously collected data sets, describe who will be responsible for data security and monitoring. | |
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| 1. Consent Process   Describe the process and procedures process you will use to obtain consent. Include a description of:   * Who will be responsible for consenting participants? * Where will the consent process take place? * How will consent be obtained? * If participants who do not speak English will be enrolled, describe the process to ensure that the oral and/or written information provided to those participants will be in that language. Indicate the language that will be used by those obtaining consent. Translated consent forms should be submitted after the English is approved. | |
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| 1. Training   Provide the date(s) the members of the research team have completed the CITI training for human participants. This training must be taken within the last 4 years. Additional information can be found at: [Training](http://researchintegrity.asu.edu/training/humans). | |
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