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| University of Florida IRB-02  Protocol Template Guidelines    The “protocol” is similar in form to a brief research proposal. It should be as concise as possible. It should, however, contain all information relevant to the proposed research project not specifically covered in the SmartForms. (Not every item will be relevant for every project, of course, and you may limit responses as appropriate in such cases, but if you’re uncertain as to what to include, be “inclusive” as that makes it less likely we’ll have requests for additional information.) |
| 1. **Project Title** |
| 1. **Investigators** |
| 1. **Background:**  * Describe in a few sentences the scientific or scholarly context in which the work is situated. * Include a synopsis of the *most immediately relevant* previous studies, if any, that have been conducted. * State how your research project is a logical step in studying the topic. Do not simply cut and paste from a grant proposal or thesis/dissertation, and limit your response to 1000 words. |
| 1. **Specific Aims:**  * State the purpose, hypotheses or objectives of the project. What do you hope to learn from the research? |
| 1. **Research Plan / Study Description:**  * Provide a detailed description of what you intend to do throughout the course of the study, and with particular participants or datasets, in a logical and sequential format. Please remember, that some IRB board members are non-scientists, so they will not be familiar with the jargon used by people in your field. Also, spell out any acronyms the first time they are used. * Provide a clear and concise description of any intervention or observation to be carried out in the study. If there is a control group, describe its nature.   + Describe the rationale for any inclusion and exclusion criteria for participants over and above membership in the target population.     - If you intend to use a vulnerable population, describe the reasons for including them and what, if any, additional safeguards are needed to protect them.     - Briefly outline the data analyses that are proposed and who will do the analysis. |
| 1. **Possible Discomforts and Risks:**    * Identify any discomforts and risks (physical, psychological, social, and/or economic or financial) that study participants may encounter, listing more common risks first, then less common risks.    * Describe whether disclosure of identifiable information about the participants presents any additional risks to them.      + Describe procedures to protect against or minimize potential discomforts and risks. |
| 1. **Possible Benefits:**    * + Describe the potential benefits to participants or to others that may be reasonably expected to result from the research. If there is no potential for direct benefits to participants, state this here and in the informed consent form/script.    * Discuss why the risks to participants are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may reasonably be gained. Will the research study benefit future populations? |
| 1. **Conflict of Interest:**    * Describe any real or potential conflict of interest you or any other investigators may have with regard to this specific research project.      + Real or potential COIs should be specified in all consent forms/scripts.    * When deciding whether a conflict may exist, consider the following:      + - Do you, the University of Florida, or any of the sub-investigators hold, or have under review, a patent, copyright or license for any material, object, or process used in this project?        - Do you, the University of Florida, or any of the sub-investigators own stock in or have a relationship with a company or agency sponsoring or hosting the project?        - Do you or any of the sub-investigators have any other possible conflict of interest, or any relation with agencies or organizations that may be sponsoring, or be the topic of, the research? If there are such organizations identified in the consent, either describe your relationship with them or state that you have no relationship with them other than that of researcher. |