



Initial Submission Detail Form		
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Instructions: Each section must be completed. If a section is not applicable to your submission, state so (“Not Applicable”) and explain exactly why the section is not applicable.

Summary/Synopsis of the Research Project:

This section introduces the reviewers to the study to get a quick understanding of just what is being proposed. If someone who was **not a scientist** asked you to explain what your study is about in **100 words or less**, this is where you put your response.

- Give an overview of what your study is about, a general sense of the strategy and/or techniques involved,
- Why is your study important?
- What issues will be addressed?
- Give an overview of the human subjects or personal data you will use.

Research Plan:

1-Introduction - Should contain the scope and background of the proposed research including the history of research topic. References to pertinent studies and the rationale for the proposed methods should also be presented.

2-Objectives/Specific Aims - Summarize the purpose/goals of the study/data request. State study hypothesis or hypotheses.

Scientific or Public Health Purpose

Specify the Scientific or Public Health Purpose of your study (**100 words or less**)

Risks/Benefits

1-Foreseeable Risks - Detail the foreseeable risks involved in your study and how you will minimize them

2-Potential Benefits - Discuss the risks in relation to the potential benefits and the importance of knowledge that may reasonably be expected to result.

Subject Selection:

1-Study Population - This section should describe the population under study (numbers, gender, geography, ethnicity, etc.), and how the population relates to the purpose of the research. Detail the potential sources and the number and sample size methodology used to determine the proposed sample. If your submission is a data request, include years of data requested. Explain why those specific years of data and data elements are needed.

2-Eligibility Criteria – This section should detail what factors a potential subject needs to meet to be considered for participation in the study. Explain the rationale for the use of special classes of subjects such as fetuses, pregnant women, women of childbearing potential, children, institutionalized mentally disabled, prisoners, or others, especially those whose ability to give voluntary informed consent may be in question.

3-Ineligibility Criteria – This section should detail what factors a potential subject would need to meet to be excluded from the study.

4-Recruitment/Registration - This section should describe how potential subjects would be identified and contacted. This should include the specifics of who will recruit subjects, when, where, and how, and the information to provide to the subject. Advertisements, flyers, and any other materials that will be used to recruit subjects must be reviewed and approved before their use. If a data request has a follow-back component to individuals or their next of kin, describe in detail here.

Informed Consent

If you are consenting subjects, include copies of the consent document with your submission. If you are not consenting subjects or are only



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requesting data, download, complete, and include copies of the Consent Waiver Request form.

Consent Documents included Consent Waiver Request form included

Protocol Details:

1-Research Design and Methods - This section should describe the type of research to be conducted (e.g. experimental, quasi-experimental, case study, evaluation, outcome, etc.) and the methods used to conduct the research such as intervention therapy (e.g. surgery, drugs, radiation, exposure (e.g. media campaign, curriculum, best practice, etc).

2-Subject Assessment - This section should contain the requirements for each assessment to be conducted. The studies to be done and the follow-up times should also be detailed in either outline or graphic format.

3-Data - This section should contain a list of all data items including forms, and the specified timetable for collection. For the release of DSHS program, submit a completed and approved data request form from the DSHS program, if available.

- Include a discussion of the specific steps you will take to provide privacy during interviews.
- Specifically describe all health information that the project will be using and/or requesting (e.g., personal identification information; billing records; medical history; physical findings from exams; lab, pathology and radiology results; results of MRIs, X-Rays, blood test and similar tests; PHI previously collected for research purposes; answers to questionnaires/interviews, etc.).
- Include descriptions of potential uses of the final products that may be created using the data.
- If you are attaching a data request form from a DSHS program, use this section to explain the justification for any request for data elements that are designated as either 'confidential' or 'sensitive.'

4-Statistical Design & Analysis - This section should include a discussion of the end point(s), the difference expected, and the analytical methods to be employed to detect the difference.

Student Investigator/Requestor -

If you are a student, indicate the relationship of the proposal to your program of work and identify your supervising/sponsor faculty member. **Include documentation that the student's committee approved your thesis and dissertation proposals.**

Data Element Use & Management

1-Steps You Will Take to – Store the Data (DO NOT CITE POLICY. Detail the exact steps you will take)

2-Steps You Will Take to – Keep the Data Confidential and Protected (DO NOT CITE POLICY. Detail the exact steps you will take)

3-Steps You Will Take to – Destroy the Data (DO NOT CITE POLICY)

- Name the overwriting software you will use to destroy the electronic records and how many overwrites occur
- Describe exactly how the paper copies and CDs, etc. will be destroyed
- Include the destruction date

Appendices

Attach additional documentation and material, such as questionnaires, surveys, and other assessment tools; brochures, media flyers; certificates of human subject protection training; approval from study sites and/or other IRBs.

Translated materials are not required for review until approval of the English version(s) is obtained.

Funding

If the study will be funded by a federal agency, include a copy of the full grant proposal or a detailed summary.