DSHS Institutional Review Board #1
Protocol Checklist

Directions:

Each of these sections must be included in the protocol submission. If a section is missing, the submission will be returned.

____ **Summary/synopsis of the research project.**

This is a critical part of the submission because it introduces the reviewers to the study to get a quick understanding of just what is being proposed. The summary of study objectives should be written as if you were trying to give an overview of your research to someone who is not a scientist or medical professional. Include a brief description of the subject area(s) to be investigated. It is not necessary to include a complete description of the study design in this portion of the submission; rather, give a general sense of the strategy and/or techniques involved.

_____ **Research Plan:**

_____ ***1****-Introduction/Background*

Should contain the history of the disease or condition and current treatment or control measures. References to pertinent studies and the rationale for the proposed modalities should also be presented.

_____ ***2****-Objectives/Specific Aims*

Summarize the purpose of the study/data request and state any public health benefits. State study hypothesis or hypotheses.

_____ **Subject Selection:**

_____ ***1****-Study Population*

This section should describe the population under study, the potential sources and the number and sample size methodology used to determine the proposed sample. If a data request include years of data requested.

_____ ***2-****Eligibility Criteria*

Inclusion criteria, such as: sites, stage of disease/histology, age (lower and upper limits should be stated), performance status, laboratory values, and other evaluations as applicable, etc. 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*

Exclusion criteria, such as: prior treatment, prior other diseases, infection, hematologic, and other values that preclude entry into 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.

_____ **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 [for the release of DSHS data, specific information on the use of individual data fields may be required as defined by DSHS program area – submit a completed and approved data request form from the DSHS program, if available], including forms, and the specified timetable for collection. Specify the type and format of the data requested (i.e. copies of certificates or electronic files, and years needed). Specify if names or other identifying information is needed. Include a discussion of confidentiality safeguards including the specific steps you will take to a) provide privacy during interviews, b) keep forms/data secure, c) keep data confidential, d) prevent release or publication of identifying data, and e) retain and ultimately dispose of records. Specifically describe all health information and/or hospital discharge data 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.). If you will use the entire medical file, then you must mention this fact specifically. Include descriptions of potential uses of the final products that may be created using the data. [For hospital discharge data requests, download, complete, and attach the THCIC data element form. For personal data requests, download, complete and attach the appropriate personal data, data element form(s).]

_____ ***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.

_____ ***5****-Informed Consent Document*

This section should contain all forms to be used; each form should be clearly identified and dated.

An investigator using a consent form and other instruments in a language other than English will need to submit the translated version along with the credentials and qualifications of the translator(s). Non-English version(s) will be requested after approval the English version.

_____ ***6****-Risks/Benefits*

This section should include procedures for protecting against or minimizing risks, the potential benefits to be gained by the subjects, and the benefits that may accrue to society in general because of the planned work. Describe any potential risks--physical, psychological, social, legal, or other--and assess their likelihood and seriousness. Describe alternative methods, if any, that were considered and why they will not be used. Where relevant, describe arrangements for providing medical treatment if needed.

_____ ***7****-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. The student's committee must approve thesis and dissertation proposals before approval by the IRB.

_____ **E) Appendices**

This section should include documentation and material, such as: questionnaires, surveys and other assessment tools; brochures, media flyers; certificates of human subject training; letters of support from data sources and DSHS Program Contacts/approval from study sites and/or other IRBs. Translated materials are not required for review until approval of the English version(s) is obtained.

_____ **F) Funding**

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