Table of Elements for Protocol and Protocol Summary

1) Name, title, program, address, phone number, fax number and e-mail address of principal investigator and co-investigators).

Principal Investigator

Name:

Address of Investigator:

E-Mail Address:

Phone Number:

2) Title of protocol

3) Anticipated start date and project duration.

4) Purpose of research project.

5) Description of human subject participation:

- **age-range and gender of preferred subjects**
- **how subjects will be selected and solicited for participation**
- **the number of subjects expected to be involved**
- **incentive, if any, for subject participation**
- **description of special classes of subjects, such as human fetus, in utero and ex utero, fetal material and placenta; pregnant women; children and minors; cognitively impaired persons; prisoners or incarcerated juveniles; traumatized or terminally ill patients; elderly/aged persons; minorities; students or employees; and international subjects**
- **criteria for potential subjects to be included or excluded from the subject pool**

6) Procedure: brief explanation of the research procedures including (describe only points that apply to the submitted protocol):

- **description of subjects' participation and what subjects will be expected to do**
- **If applicable, description of what non-participants will do while other subjects participate in the research procedures (for example, in a classroom where some children may not have parental consent to participate or choose not to participate)**
- **details of what subjects will be told about the research project**
- **description of deception, if any, and procedures to debrief subjects**
- **reasonable estimate of time involved including frequency and duration**
- **where research will take place**
- **method of data collection (survey, instruments, interview questions, etc.)**
- **when and how subjects may terminate participation, and/or under what circumstances procedures may be stopped**
- **description of biological samples to be taken, if any, procedures to obtain samples, and qualification of person(s) obtaining samples**
- **description of equipment, if any, to be used on or by subjects**

7) Description of the extent to which subjects will be identified, directly or indirectly through codes or identifiers, including:

- **whether or not subjects will be identified, either by name, appearance, or nature of data**
- **procedure to protect privacy and confidentiality**
- **how and where collected data will be stored and for how long**
- **who will have access to the data and under what circumstances**
- **any other aspects regarding confidentiality**

8) Description of any benefits to the subjects or to others which may reasonably be expected from the research, including:

- **direct benefits to subjects (including any medical and/or monetary compensation)**
- **indirect benefits (to class of participants represented, general body of knowledge, or society-at-large)**

9) Description of any reasonably foreseeable risks or discomforts to the subjects as a result of each procedure, including exposure to minor pain, discomfort, injury from invasive medical procedures, or harm from possible side effects of drugs. All projects are deemed to involve some level of risk to human subjects, however obvious or obscure. Even studies involving data collection through survey or questionnaire involve some risk to the subject either through the process of filling out the questionnaire or release of their personal information, remembering a painful event or discussing a lost relative, all those activities should be considered as potentially risk evoking for the participant, thus there is always some risk to the subjects of a study, the risk should be considered as minimal at least, but may be greater based on the study elements.

Describe only points that apply to the submitted protocol:

- **that minimal risk is involved when the proposed research is viewed as involving little or no risk to human subjects. A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.**
- **whether the research may involve greater than minimal risk, and what protection and/or treatment will be provided to subjects in the event of a research-related injury, including who will pay for necessary treatment and the availability of other financial compensation.**
- **the likelihood, severity, duration, and effects of each potential risk. Common risks may include physical injury or harm; psychological trauma, stress or harm; social (invasion of privacy or breach of confidentiality) and/or related economic harm; legal risks (such as state or local law requirement to report child abuse or neglect).**
- **description of methods to minimize risks, including how and by whom treatment may be offered, and qualifications of persons performing procedures or collecting data**
- **description of treatment available, referrals for treatment and/or counseling, including estimate of costs involved and who will be responsible for those costs**

10) Description of procedure to obtain informed consent, if applicable, or other information to be provided to participant in lieu of obtaining a signed consent form in instances where one may not be required, or if requirement to obtain informed consent is requested to be waived, including

- **how and by whom will subjects be approached to obtain consent**
- **how information will be relayed to subject (read to, allowed to read, audiotaped, videotaped)**
- **description of feedback, debriefing, or counseling referral to be provided**
- **procedure to obtain assent of children of an age and mental capacity deemed capable of providing such**

11) Attach copies of survey instruments, interview questions, tests, and other pertinent documentation that will be used to conduct the research. The name and phone number of an appropriate person to contact for more information about the study must appear on information letters or survey instruments for projects where a consent form is not required or the requirement is waived.

12) If subjects will be solicited through an institution such as a school, hospital, medical clinic, state agency, or if the research will be conducted at such an institution, provide a letter of agreement/approval to do so from an authorized representative of that institution. Clinical/hospital data obtained by the Dept of Health authorized by Wyoming statute requires approval of the WDH program manager. Letters of agreement/approval from the individuals at the institution that will work directly with the researcher either by allowing access to the subjects (i.e. teacher allowing access to classroom, physician office at which subjects will be interviewed) or actively participating by collecting consent forms, distributing surveys, or collecting data are also desirable.