GUIDE FOR PREPARING INFORMED CONSENT FORMS

When soliciting human subjects as participants in research projects, target subjects must be made aware of certain information before they can consent to participate. This includes:

***Research Purpose**:* State the purpose of the research and give a fair explanation of your research procedures; what you hope this study will accomplish and why it's important.

***Research Procedures**:* Explain tasks and procedures from the target subject's point of view (what will he or she be expected to do?). Estimate the total amount of time for the person involved in the study. Explain the frequency of procedures and include any additional costs or charges for the research procedures with estimated amounts. State why the subject is eligible to participate or what criteria will be used to determine eligibility.

***Release of Archival Data**:* All data collected by the district or on behalf of the district in pursuance of the district's mission are considered **private records**. These records include student demographics, participation in special programs, academic performance, and medical history. Data from these records are released to researchers **only with the parent's or eligible student's active consent**. Researchers requesting release of archival data must itemize each data they are requesting and specify for which time period. The informed consent form should include a statement such as:

> I grant permission to Prince George's County Schools (PGCPS) to release the data itemized below to the researchers at [*name of organization*] for use in the [*title of research study*]. I affirm that the data will be used sorely for this research study.
>
> - Data 1 for spring 2017
> - Participation in Program A during SY2016, SY20

***Risks**:* Describe any foreseeable risks or discomforts the student will bear. Include all reasonably common risks as well as potentially serious risks and, if possible, indicate the likelihood of occurrence. Risks may range from inconvenience to bodily pain. Do not overlook "soft" risks such as confidentiality and embarrassment. Decisions about invasive procedures will always involve a degree of uncertainty regarding the harmful effects. Calculating the probability that these situations will occur can aid in explaining the risks.

The view of the nature of a risk will vary from participant to participant. Be sensitive to the difficult task of determining if the participant is more of a risk taker, is ignoring the risk(s), or has not adequately understood the probability of the risk(s).

***Benefits**:* Describe any benefits to the participant or others that can reasonably be expected. Benefits may range from feeling good about participation, contributing to important research to monetary compensation. Be careful, however, not to oversell any benefits. The consent document must describe the terms of any payments used to compensate individuals for their participation. This includes the conditions under which research participants would receive partial payment or no payment at all.

***Confidentiality**:* The informed consent process must describe the level of confidentiality of the research data and the measures that you plan to take to ensure that confidentiality is maintained. Describe the steps that will be taken to protect the participant's privacy. Also describe under what circumstances records will be made available and to whom. Include any techniques you may use for identifying data, such as creation of a numeric code. Subjects should be assured that their identity will not be disclosed. However, in special circumstances, such as for reportable conditions like child abuse, absolute confidentiality may not be possible. If this or a similar possibility exists, then explain the circumstances under which information must be disclosed and to whom.

***Disclosure of Potential Conflict of Interest**:* Researchers must inform their subjects of any conflicts of interest they have in the research, such as a stake in a company that might benefit from the research.

***Contact Information**:* Give the names of people who can answer questions about the research; include the principal investigator (i.e., you). Because you are a student, include the names and phone numbers of your faculty supervisor as well. Furnish the contact name of a neutral third party who can explain the rights of research participants if the participant has any questions i.e., your university IRB contact.

***Withdrawal**:* Always stress the fact that participation is voluntary. State that refusing to participate will involve no penalty or decrease in benefits to which the participant is otherwise entitled. Emphasize that the student or parent may discontinue participation at any time without penalty or loss of benefits. If there are limitations or risks involved in withdrawal, such as a danger to the participant's well-being, these must also be clearly explained.

***Subject**:* Full Name of target subject for whom consent to participate in research applies. If archival data are being requested, space for PGCPS student identification number or employee identification number (EIN) must be included on the consent/assent form

***Information on Individual Giving Consent**:* Full Name and signature of person granting consent. If it is a parent or guardian giving consent for a student, the relationship to the student must also be included.

Date

NOTE:

If the consent form/letter is more than one page long, it must be paginated using the format Page X of Y. Further, all pages, except the signature page, must have a space for the individual granting the consent to initial.