CAMPBELL UNIVERSITY	**IRB Guidance:** Informed Consent Process/Documentation of Consent for Registration Projects Approved by FLEX Review

The IRB highly suggests using the IRB approved templates found on the CU IRB website which contain standardized language. There is no required consent template for exempt research or registration projects. However, the following elements of informed consent should be included in a project information handout, survey introduction and script as applicable:

- **Subject rights:** State that the activity involves research, participation is voluntary, *and* that participants may withdraw at any time without penalty or loss of benefits.

- **Purpose of the study:** Provide a brief non-technical explanation of the purpose(s) of the research. Explain why the subject is being asked to participate in the study (e.g., *You are being asked to participate in this research study because*…).

- **Study tasks or procedures:** Provide a complete description of procedures (including the order in which they take place). Identify and distinguish procedures that are being performed solely for research purposes from any activities that would otherwise occur. Include information about audio- or videotaping and/or any records that may be accessed (e.g., educational records).

- **Duration of subject's participation:** Provide expected duration of the subject's participation (e.g., time required to complete surveys). Ensure that the proposed time period is realistic for the procedures to be performed.

- **Confidentiality:** *Note: Do not interchange the terms "confidential" (i.e., maintained in a way that prevents inadvertent or inappropriate disclosure of participants' identifiable information) and "anonymous" (i.e., identifiers were not collected or have been permanently removed).* See language below.

  To be in this research project, the project team needs your permission to access, collect and use some of your personal information. If you say no, you cannot be in the project. This information may come from questions we ask, forms we ask you to fill out, as described below. We will only collect and use information needed for the project. We cannot promise complete privacy and confidentiality. Organizations that may inspect and copy your information include the IRB and other representative of this institution. [Add to this list other organizations that may have access to the participant's records.]

  If identifiers are removed from your identifiable private information, the information may be used for future research or distributed to another investigator for future research without additional informed consent from you or your legally authorized representative. The information might also be used

or released for other purposes without asking you. Results of the project may be presented in public talks or written articles, but no information will be presented that identifies you.

[When applicable, include whether assessment or educational relevant research results, including individual research results, will be disclosed to participants, and if so, under what conditions.]
[For projects taking place in a school, this paragraph must be included:]
Please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232(c)(1)(A), you or your parents have the right to review a copy of the questions asked of or materials that will be used with you or your students. If you would like to do so, you should contact [Principal Investigator] to obtain a copy of the questions or materials.

- **Contacts and Questions:**
  - Provide the name and contact information of the Principal Investigator for questions, concerns, or complaints about the study. Include contact information for research staff, as applicable. The person(s) listed should be knowledgeable about the research. Include area code or international dialing codes for phone and fax numbers.
  - Provide ORRP contact information for questions about subject rights and as a contact who is not part of the study team for participant concerns or complaints about the research: *For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Shawn Leming in the IRB Office at 910-893-7780 or at leming@campbell.edu.*

- **Incentives:** Explain payments or other incentives (e.g., class credit) to participate, including amount and schedule of payments. Compensation should be pro-rated (e.g., per session) and not contingent upon study completion. Explain the effect of a subject's decision to withdraw from the research on compensation (e.g., a participant who is an OSU student will receive extra credit for enrolling in the study even if he/she withdraws). If payments are offered, include the following: *By law, payments to subjects are considered taxable income.*

- **Sponsor:** Provide the name of the sponsor funding the research, when applicable.