**Guidelines & Template for Exempt Studies Informed Consent**

The following instructions and examples are provided to assist in the development of Informed Consents distributed via e-mail or electronic survey administration tools.

The following should be considered when developing the consent form:

* Consent forms **must** include clear identification of the responsible institution.
	+ Include the SMU logo at the top of the consent or on a cover letter with the consent document.
	+ If including the consent as the initial section of an electronic survey, the University header must be on the survey.
* Consent forms when printed, need to use a readable 12-point font with standard margins (1 inch). Print single-sided.
* Each page of the consent form should be full without large, blank areas. Sections can be divided and split across multiple pages.
* The informed consent form must be written in the second person. Utilization of the second person personalizes the content and better reflects the existence of a voluntary decision regarding participation choice.
* The information presented under any given element should be reasonably complete and restricted to content appropriate to that element. Do not mix information nor repeat content unless necessary for understanding.
	+ Providing the content separately helps the prospective subject focus on each individual element of consent thereby increasing the validity of the consent process.
* The consent form must be written in simple enough language so that it is readily understood by the least educated of the subjects invited to participate.
	+ Standard reading level of eighth grade is considered the norm.
	+ Avoid use of scientific terms and when needed, use the lay term or provide a definition.
* Age of majority in California is 18 years old. Anyone younger than 18 requires parental consent AND assent with few exceptions. A waiver of parental consent must be approved by the IRB.

*You can use the element headings on the next page to format your Informed Consent. Be sure to delete any instructions or examples provided as well as this first page of guidelines,*

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**Informed Consent**

**Study Title & IRB ID**

* ***List the title exactly as it appears on the IRB application***
* ***Provide the IRB ID***

**Invitation**

* Introduce yourself and explain broadly what your research is about.
* **Example**
	+ *My name is [name] and I am a [role and institution] conducting a study on [general issue].*
	+ *The information in this form is meant to help you decide whether or not to participate. If you have any questions, please ask.*

**Why are you being asked to be in this research study?**

* **Explain the inclusion criteria** and why the person is being invited
* **Example**
	+ *You are being asked to be in this study because you are a leader in the healthcare industry. You must be 30 years of age or older and have at least five years of experience in a management role for a US based healthcare delivery organization.*

**What is the reason for conducting this research study?**

* This section should state the purpose of the study. If appropriate, brief background information may be provided to help a potential participant understand why the research is being conducted. The information should be provided in simple, lay language without any citation to literature.
* **Example**
	+ *The purpose of this study is to understand successful strategies for strengthening knowledge about …*

**What will be done during this research study?**

* In this section, thoroughly describe the activities involved in the study including the expected duration of each activity, explained in chronological order. Use simple language, short sentences or short paragraphs.
* **Examples**
	+ *Participation in this study will involve the completion of an on-line survey that can be completed in less than 10 minutes.*
	+ *Participation will include a 45-60 minute virtual interview that will be audio recorded*

**What are the possible risks of being in this study?**

* Explain clearly the minimal risks involved and what you are doing to mitigate and minimize the risks
* **Example**
	+ *This research presents minimal risk that may include fatigue, boredom, or anxiety as a result of participating in the [interview or survey] process. You*

*will be able to stop the [interview or survey] at any time or skip any questions you are not comfortable answering. There is the potential for a breach in confidentiality, however steps for protecting your identity include…*

**What are the possible benefits to you for participating?**

* Explain either individual benefit for participating **or** state there is no direct benefit to you for participating however explain the broader benefit to the organization or profession for their participation
* **Example**
	+ *There are no direct benefits for participating however understanding your experiences and perceptions may improve our educational practices for …*

**What are the alternatives to being in this research study?**

* Explain whether there are any alternatives for participation. If there are none, state this.
* Example
	+ *Participation in this study is voluntary. There are no alternatives to participating other than deciding not to participate.*

**Are there any costs or compensation for participating in this study?**

* Explain any costs for participating in the research or state there are no costs associated. Explain any compensation or state there is no compensation.
* **Examples**
	+ *There is no cost for you to participate.*
	+ *There is no compensation for participating in this study*
	+ *You will be provided a 5$ giftcard as a thankyou for your time*

**How will information about you be protected?**

* Explain whether participation will be anonymous (for example with a survey process) or if not anonymous, how their identity will be protected with confidentiality practices.
* **Examples**
	+ *Reasonable steps will be taken to protect your privacy and the confidentiality of your study data. The data will be deidentified and stored electronically through a secure server and will only be seen by the research team during and until the study is complete.*
	+ *The only persons who will have access to your research records are the study personnel, the Institutional Review Board (IRB), and any other person, agency, or sponsor as required by law. The information from this study may be published in scientific journals or presented at scientific meetings, but the data will be reported as a group or summarized data, and your identity will be kept strictly confidential.*

**What are your rights as a research subject?**

* Use the following standard clauses:
	+ *You may ask any questions concerning this research and have those questions answered before agreeing to participate in or during the study.*
	+ *For study related questions, please contact me at [insert contact information] or my Faculty Advisor (insert contact information].*
	+ *For questions concerning your rights or complaints about this research, contact the SMU IRB Administrator Jamie Hirota at* *jhirota@samuelmerritt.edu**.*

**What will happen if you decide to not participate?**

* Use the following standard clauses:
	+ *You can decide not to be in this research study, or you can stop being in this research study (“withdraw’) at any time before, during, or after the research begins for any reason.*
	+ *Deciding not to be in this research study or deciding to exit the study early will not affect your relationship with the investigators or with Samuel Merritt University (list others as applicable). You will not lose any benefits to which you are entitled.*

**Documentation of Informed Consent**

* **Capture of subject signatures are not required for minimal risk research.**
* For e-mail or web-based communication of consent use the following standard clause
	+ *You are voluntarily making a decision whether or not to participate in this research study. By completing and submitting your [survey responses or setting up an interview appointment], you have given your consent to participate in this research. You should print a copy of this page for your records.*
* If using an electronic survey for data collection, embed the above consent information up to the Documentation of Informed Consent section; end with the following standard clause
	+ *You are voluntarily making a decision whether or not to participate in this research study. By clicking on the* ***I Agree*** *button below, your consent to participate is implied.*