**Institutional Review Board**

**Consent Form Guidance**

***Instructions****:* Use the text and information in this document to build your consent forms. You may copy and paste the materials relevant to your study into your consent document. Two sample consent documents are available online as additional references. **All numbered elements are required unless otherwise indicated. Use the headings that appear in this document.**

1. **Project Title** (this should be the same as the title of your IRB proposal. If there is a need to alter it, explain this in your proposal).
2. **Purpose of the Research**
	* Identify the researchers, roles (faculty, student, etc.), and their affiliations (e.g. Delaware Valley University).
	* Explain why the reader is being asked to participate (e.g. how or why they were chosen)
	* Briefly describe the general purpose of the study (no more than 3 sentences)
3. **Participation Process**
	* Describe what you will ask participants to do. This should include:
		1. The steps involved in chronological order
		2. The location of participation (in a lab, online, etc.)
		3. Number of waves of data collection (for longitudinal studies)
		4. Duration of participation per wave of data collection (minutes it will take them to participate)
		5. Brief description of the type of data being collected (e.g., basic aims of surveys or interviews).
		6. If multiple groups are being used (such as a treatment and a control group) describe them.
		7. Describe any alternative procedures or courses of treatment, if applicable
4. **Privacy & Confidentiality**
	* Identify if your study is **anonymous** (no possible way to identify data) or **confidential** (data is identifiable but protections are put in place to prevent this from happening).
	* Describe the procedures to maintain anonymity/confidentiality
		1. In data collection
		2. In data storage
		3. In data analysis
		4. In reporting of results
	* If you are collected data online, share how confidentiality is maintained through your survey hosting site.
	* Always include the following language: “Your information may be shared with representatives of Delaware Valley University or governmental authorities if you or someone else is in danger or if we are required to do so by law.”
5. **Risks**
	* All research has risks, describe them here. Risks of research include, but are not limited to psychical, psychological, social, legal, or financial harm; discomfort or embarrassment from asking sensitive questions; coercion, especially if you are studying students or vulnerable populations.
	* Describe how you are minimizing those risks to protect participants, if possible
	* **DO NOT** state that there are “no risks” or “minimal risks” – you must be specific.
6. **Benefits**
	* Describe any direct benefits participants may experience from being in the study. Reimbursement, raffles, and other incentives should not be listed here.
	* Most studies will have no direct benefits to the participants, that is OK.
	* Describe how participation will benefit the field, the community, society, or other stakeholders at large.
7. **Deception**
	* ***You may omit this section if your study does not involve deception****.*
	* If you are using deception in your study, we suggested using the following statement in this section.
		1. I/We will discuss the full purpose of this study with you at the end of your participation today. I/We do not expect any detrimental effects to you during participation.
8. **Voluntary Participation**
	* Be clear that participation is voluntary and the participant may withdraw, without penalty, at any time.
	* We suggest the following language:
		1. Your participation in this research is completely voluntary. You may choose not to take part at all. If you decide to participate in this research, you may stop participating at any time. If you decide not to participate in this study, or if you stop participating at any time, you will not be penalized or lose any benefits to which you otherwise qualify.
	* If there are circumstances where the researchers might choose to terminate a person’s participation, or if there are consequences for withdrawing from participation, describe those clearly.
9. **Medical Treatment**
	* **You may omit this section if your study has minimal risk (exempt or expedited reviews) or if the risk is not health-related.**
	* If your study has greater than minimal risk, or if that risk is health-related, include the following language:
		1. Delaware Valley University does not provide any medical, hospitalization, or other insurance for participants in this research, nor will Delaware Valley University provide any medical treatment or compensation for any injury sustained as a result of participation in this research, except as required by law.
10. **Questions?**
	* Encourage participants to reach out if they have questions, concerns, or issues.
	* Provide contact information for the Principal Investigator, their advisor (if the PI is a student), and the IRB chair.
	* Recommended language:
		1. This research is being conducted by **[PI Name and Department]** at Delaware Valley University. If you have any questions about the research, please contact them at **[email address and phone number]**.
		2. This research has been reviewed according to the Delaware Valley University Institutional Review Board (IRB) procedures for ethical research involving human participants. If you have any questions about the ethics of this study, or if you feel you have been injured through your participation in this study, please contact the IRB chair, **[Name]**, at **[phone number]** or irb@delval.edu.
		3. Until July 2021, the IRB chair is Dr. Matthew Mutchler, 215-489-4188
11. **Video/Audio Recording; Photographs**
	* **You may omit this section if you are not recording/photographing participants**
	* Choose the headings that best apply to your recordings
	* Clearly explain the purpose for making the recordings and how they will be used.
	* Acknowledge that the recording creates a link to their identity via their voice and/or image.
	* Explain procedure for storage and destruction of the recordings.
	* The researcher(s) has/have explained to me that my participation will be video/audio recorded or photographed. I understand there is a possibility that my identity could be revealed through my voice or image. The purpose of this recording has been made clear and I give my permission as indicated by my initials below:
		1. Provide options for the participants to initial:
			1. I agree to be recorded for this study and for my recordings to be used in presentations of this research
			2. I agree to be recorded for research purposes **ONLY** – my recording may **NOT** be used in presentations of this research
			3. I **DO NOT** consent to be recorded during my participation in this study.
12. **Statement of Age of Participant and Consent**
	* The exact wording will vary depending on the mode of consent. Use a version of the following language:
		1. Your signature below indicates that you are at least 18 years of age, the research has been explained to you, your questions have been fully answered, and you freely and voluntarily choose to participate in this research.
13. **Signature or affirmation**
	* For hard copy, signed consent, include lines for signature, printed name, and date.
	* For online surveys, include a required affirmation before the participant can advance to the first page of your survey
	* **For unsigned consent/information sheets, no signature/affirmation line is needed.**

**Important Points to Consider**

* Participants should be able to keep a copy of your consent form – provide 2 copies for signed in person – one to sign and one for them to keep. For online consent, include a link to a PDF of your document so they can download if they choose.
* If your study is low/minimal risk, an unsigned consent form may be appropriate, especially if the consent form would be the only identifiable piece of information (from the signature). The required remains the same, however.
* Writing to an 8th grade reading level is recommended. Avoid the use of jargon, unless your target population will be familiar with it.
* Your consent form will likely fill more than 1 page. In the footer of each page, include the page number formatted as “Page x of y.” For signed consent forms, also include fields for participant initials & date.
* Make sure you are clear and that you spell check your document. This is one of your first interactions with participants, and you want to make a good impression.
* **If your study includes minor (under 18) participants:**
	+ Create a parental consent form that is phrased as “we are inviting your child to participate.” It should contain all the required information above. This form **must** be signed.
	+ Create an assent form for the participant that explains your request of them in clear age-appropriate language. These may be signed or unsigned.
	+ **These participants can only be included if you have BOTH parental signed consent and verbal or written participant consent.**
* **If your study includes participants with impaired decision-making capacity:**
	+ Create a consent form written to an authorized representative of your participants. This document should be phrased as “we are asking this person to” rather than “you.” It should contain all the required information above. This form **must** be signed.
	+ Create an assent form for the participant that explains your request of them in clear language appropriate to the audience. These may be signed or unsigned.
	+ **These participants can only be included if you have BOTH signed representative consent and verbal or written participant consent.**
* Two sample consent forms are available online – one aimed at an online survey and one for a signed hard copy. Feel free to refer to these as you build your own consent documents.
* Reach out to the IRB chair at irb@delval.edu if you have any questions.