**Wake Forest University Informed Consent Template and Instructions**

Investigators should use the template to construct a readable consent document that complies with University policies and government regulations, if applicable. Please include all necessary study-specific information that will enable your potential participants to make informed, voluntary decisions about taking part in the study.

Consent forms signed by the participant are required unless the PI provides specific justification for a waiver of documentation or waiver of consent (see eIRB application for more information).

You can type over this template to take advantage of the formatting, suggested language, and the merge field for watermarking of the approved consent document. Please note that in the template below, instructional text is *italicized*. Delete it along with this first page before saving and uploading your informed consent document.

* Include the IRB merge field for watermarking (the electronic approval “stamp”)—see the text box in the footer.
* Avoid scientific jargon and exculpatory language that waives or appears to waive a participant’s rights.
	+ Adapt the language to the average reading level of your participant population. For the general population, aim for a 6th grade reading level.
* Write in the second person in language understandable to the participant. Check the final version for an appropriate reading level.
* Refer to individuals involved in the study as participants, not subjects.
* Use formatting, bullet points, and/or 12-point fonts to make the consent forms easy to read.
* Do not emphasize any part of the consent form over others as all are considered equally important, e.g., do no use italicized, underlined, enlarged or bolded fonts.
* Spell check and proofread to insure correct spelling, sentence construction, information flow, and readability.

After your application is approved:

* Remember that informed consent is a *process* the investigator must follow to ensure that participants fully understand what is involved in the study.
* The investigator must use the *watermarked* informed consent to indicate IRB approval of the protocol. Download the watermarked approved consent form from the link in the “Attachments” tab in the study workspace.
* Investigators should read and go over consent forms with participants (or their legal representatives) and answer any questions they may have prior to their signing the consent forms.

**[Insert Study Title]**

*Incorporate the following required elements in the consent narrative.*

1. ***Study Description***
* *Include a statement in the first paragraph that the study involves research.* You are invited to participate in a research study.
* *Describe the study’s purpose*. *Provide a broad outline of the research.*  We are investigating \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* *Participation description (what you want your participants to do): Generally, a simple summary will suffice.* *Alert participants to any particularly sensitive questions*. In this study, we will ask you to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.Please note that we will be asking questions about \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. Some people may find these questions disturbing or embarrassing.
* *Procedures for declining or withdrawing from participation. Tell participants how to decline to participate or withdraw*. If you do not wish to participate, do not sign this consent form. If you wish to withdraw, please tell a member of the study team. Any data you have provided to date will be destroyed.
* *Indicate the length of time participation will require.* Your participation in the study will take about \_\_\_\_\_\_\_\_\_\_\_\_\_\_.
* *If applicable, identify any procedures that are experimental.*
* *If applicable, disclose any appropriate alternatives to participation that might be advantageous to the participant*. *For example, study procedures such as an exercise intervention may be available outside of the research.*
1. ***Participation is voluntary***
* *Include the following statements within the IC:*

○ Your participation in this research is voluntary.

○ You may discontinue your participation at any time without penalty or loss of benefits.

○ You may choose to not answer any question(s) you do not wish to for any reason.

1. ***Reasonably foreseeable risks or discomforts***
* *Describe reasonably foreseeable risks or discomforts to the participant. Discuss the implications of the risks involved, especially if they are more than minimal*.
* *Studies involving no more than minimal risk should include the statem*ent: The risks from participating in this study are not more than would be encountered in everyday life. *OR* You may become upset while . We do not anticipate any risk in your participating; however, you may become uncomfortable answering some of the questions.
* *If the study has the potential to upset participants, include contact information for help (e.g., the University Counseling Center, Crisis Hotline, etc.).*
* *For research involving more than minimal risk, provide an explanation as to what, if any, treatments are available if injury or harm occurs and where to obtain further information about the treatments. Please contact* *irb@wfu.edu* *for help with appropriate language.*
1. ***Benefits***
	* *Some studies have no direct benefit to the participant. In such cases, you should say so and describe the potential benefits to the public or research community from this research. Compensation (payment or course credit) is not a research benefit and should not be included in this section*. While we cannot promise you any direct benefit from your participation in this study, we hope it will provide you with more information on \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. This information may help us develop \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ in the future. *OR* You may reasonably expect the following direct benefit(s) from your participation: \_\_\_\_\_\_\_.
2. ***Confidentiality and Privacy***
	* *Tell participants if their information and/or participation will be kept confidential or anonymous, the extent of the protection provided, and how it will be accomplished.*
	* *Almost no studies can “guarantee” or “ensure” confidentiality or anonymity so these assurances should only be included in rare circumstances.*

The study team will take the following precautions to protect your privacy and the confidentiality of your information.

* *A confidential study means that, while participants’ identities potentially could be determined from the information they give, the researcher has taken steps to protect their information. Briefly describe to participants the steps you are taking*. The data collected will be kept in a secure location. Only authorized people will have access to the research records and passwords for office computers and networks will be protected.
* *Include one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:*
	+ The study team may remove the identifiers from your private information [biospecimens] collected for this study and use it or share it with other investigators for future research studies without obtaining your additional informed consent. *OR* In keeping with best practices in science, our deidentified dataset will be publicly available when the study is complete. Generally, only other scientists choose to access these data and, even then, that will be rare. Nevertheless, it will be possible for anyone to download the dataset from this study. However, the dataset will not contain any information that will allow people to identify you or your responses in this study. In reports of the results, there will be no way of identifying your responses or you personally.
	+ Your information [biospecimens] collected as part of this research, even if identifiers are removed, will not be used or distributed for future research studies.
* *An anonymous study means there is no way to tell if a particular person participated in the study and no way to identify the participant from the information given to the investigator.*
* *In some cases, confidentiality will be broken to protect the research participant or others (e.g., if information arises in the course of the research that suggests a participant may intend harm to him/herself or others). In such cases, this potential breach of confidentiality should be clearly stated in the informed consent.*
1. ***Contact Information***
* *Contact names and numbers should be provided in case participants have questions/concerns about the study and in the event of a research-related injury to the participant. The investigator’s name, phone number and/or email address should be clearly indicated. Investigators (especially students) are discouraged from providing a personal cell phone number.*
* *Keep the study population in mind. Do not provide a long distance number (e.g., cell phone number) to senior participants from the community or email addresses to participants without easy internet access.*
* *For international research, the consent form should include the PI’s in-country phone number and/or a local contact’s name and phone number as well.*
* *Include the following:* If you have questions about your rights as a research participant, contact the Office of Research and Sponsored Programs, 336/758-5888, irb@wfu.edu.
1. ***Signatures***
* *Include the following statement above the signature lines:* By signing below, you indicate that you are willing to participate in this research project.
* *The printed name of the participant and dated signature of the person obtaining consent are not required; however, including them is considered best practice.*
* *Some research is eligible for a waiver of documentation, i.e., signature is not required. In some cases, a cover page or handout with all or some of the elements of the consent form will suffice.*
* *Minor assent form. Since minors cannot give consent, an assent form is often required that includes all the elements of a consent form in language understandable to the child.* *Please see the Assent Templates.*

***When appropriate, include the following elements:***

* *A statement that the research may involve risks to the participant that are currently unforeseeable.*
* *Anticipated circumstances under which participation may be terminated by the investigator.*
* *Any additional costs to the participant that may result from participation in the research.*
* *The consequences of a participant’s decision to withdraw from the research and procedures for orderly withdrawal of the participant.*
* *A statement that significant new findings developed during the course of the research which may relate to the participant’s willingness to continue participation will be provided.*
* *The approximate number of participants involved in the study.*

***Special Considerations:***

* *Compensation—payments or course credit. Include the amount of payment/course credit, any conditions, and how it will be dispensed (gift card, cash, check, mail, in person, etc.).* You will receive \_\_\_\_\_\_\_\_\_\_\_\_\_\_ for your participation. *OR* You will receive \_\_\_\_\_\_\_\_\_ for each study visit you attend. You will receive an additional bonus for attending all visits. A check for the total amount will be mailed to your home within two weeks of your last visit. *OR* Participants will be awarded \_\_\_\_ course credit for their participation.
	+ *If the compensation is more than $50:* To receive payment, you must provide your social security number, name, and address so that we can comply with Internal Revenue Service (IRS) reporting requirements. When we report payments to the IRS we do not let them know what the payment is for, only that you were paid. If you do not wish to provide this information, you can still take part in this study but you will not be paid.
	+ *If the study is expected to yield product development of commercial value:* The findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.
* *Online studies. The following should usually be included in the IC when the study is conducted online:*
	+ *Study Description, Procedures for Declining or Withdrawing--*You may discontinue your participation at any time without penalty by closing your browser window. Any responses entered to that point will be deleted.
	+ *Confidentiality section—*When completing the survey, please choose a location with adequate privacy and internet security. Please note, however, that while in transmission on the internet, your responses may not be entirely secure.
		- *For some Qualtrics studies*--The study team has taken the following precautions to protect the confidentiality of your information. We will not record your identity or any personal identifiers. We have chosen the option to “anonymize responses” within Qualtrics to remove the link between your email address and your responses.
	+ *Add to the Contact Information-*- Please reference the study number, IRB000xxxxx, in your message.
	+ *After the Contact Information—*We encourage you to print or save a copy of this page for future reference.
	+ *In lieu of Signatures—*By continuing on to the next portion of this survey, you indicate that you are at least 18 years old and that you agree to participate in this research project. You will advance to the survey. If you do not wish to participate, please close your browser window.
* *Taping (audio/video). If you are audio/video taping, you have two options:*

*1) If you require participants to consent to the taping in order to participate, clearly state this in the consent form under the study description section.*

*2) If participants can refuse taping and still participate, include a separate section on taping information with a separate signature line for consent to the taping.*

* *Treatment studies. Describe the treatment participants will receive, any previous knowledge of the effects of the treatment and any alternatives available.*
* *Studies conducted in classrooms/school settings. Indicate to participants that participation in the research will not affect their grades or class standings.*
* *Studies involving deception. Suggest including the following*. Although not all the aspects of the research can be fully described at this time, a full explanation will be provided at the conclusion of the study.

Participant Name (Printed): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_

Signature of Person Obtaining Consent: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_