## Researcher: Read Me First!

***(Delete this section prior to submitting to the IRB for review)***

## Text that is presented in black should be left the same as it appears below – these items are regulatory requirements. The red italicized text should be tailored for your research project.

## Full board and Expedited studies always require a consent process (or a waiver granted by the IRB) per federal regulations. Most exempt research also requires a consent process per institutional policy.

## For Full Board and Expedited studies, your consent form will be stamped with your approval date by ORP and provided to you as a PDF. Your consent form may not be altered after this stamp is applied without submitting a modification to the IRB. This means you should not have extraneous highlighting, notes, or track changes. If you would like to include a copy with these formatting conventions for the reviewer’s convenience, please also provide a “clean” copy in your application that can be stamped and used “as is”.

## This document includes multiple signature blocks for different circumstances. Please include only the signature block relevant for your study. If you will not be capturing signatures for your study, (e.g. for online research where participants will select “I agree” or “I disagree”, do not include a signature block and in that case please be sure to select the “waiver of documentation of consent” option in your IRB application.)

## Assent is required from individuals who cannot legally consent on their own, i.e. children or adults with impaired decision-making capacity. You can find assent templates on the IRB website, irb.villanova.edu. These assent templates are available for ages 5-17, which may be modified as appropriate for the participants in your study. For children below 5 years of age, or for individuals with cognitive capabilities equivalent to a child under 5 years of age, the researcher is responsible for developing an appropriate assent process and describing such a process in the IRB application.

## If your study is determined to be a clinical trial, your approved consent form will be uploaded to a federal public website such as ClinicalTrials.gov.

## If your study involves consenting individuals for whom English is not the main language (whether conducted internationally or domestically), please note that you will need to provide a translated consent form to the IRB for approval and stamping by ORP.

## Consent for Participation in a Human Research Study

## Title of research study: ***[insert title of research study here. This should be identical to the protocol title used in Cayuse IRB]***

## IRB #: ***[IRB-FY20XX-XX]***

## Investigator: ***[insert name of principal investigator]***

## Key Information: This section is intended to provide key information to assist in your decision on whether to participate in this research study.  More detailed information about the topics covered in this section is included below. ***[Include a concise and focused presentation of the key information most likely to assist a prospective subject in deciding whether to participate in the study.***

For example, provide a statement that this study involves research and participation is voluntary. State the expected time commitment including frequency of interactions and describe any possible risks/discomforts, as well as any possible benefits the participant can expect. Include some details about what the participants will be doing, specific to your study (e.g., “You will be asked to complete an online survey about marketing campaigns that idealize women’s appearances”). If remuneration is offered, you may want to include that here.

## ***Use language that is easy to understand and organize this section in the way that will best facilitate comprehension. It’s expected the elements described in this section will be redundant with information presented later in the document; think of this as the “executive summary” of your consent form. If you find that a bulleted list is the most concise way for your to present this information for your study, please format that way.]***

***Part 1: About Research***

## What should I know about a research study?

1. Someone [describe who this will be] will explain this research study to you. ***[You can replace with “You can reach out to the researcher with questions about this study at any time,” for online studies.]***
2. Whether or not you take part is up to you.
3. You can choose not to take part.
4. You can agree to take part and later change your mind.
5. Your decision will not be held against you.
6. You can ask all the questions you want before you decide or at any time.
7. You can be assured that we are committed to best practices for safety and the well-being of all participants.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has harmed you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to the IRB office by calling (610) 519-4228 or writing to irb@villanova.edu if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research subject.
5. You want to get information or provide input about this research.
6. You feel you have been injured or harmed while participating in this research.

You may also call the EthicsPoint hotline, a third party resource unaffiliated with Villanova, toll-free at 1-855-236-1443 if you prefer not to speak to the researcher or the IRB office.

***Part 2: About this Study***

## Why is this study being done?

This study involves research [Tell the subject the purpose of the research using basic language. Explain the background of the research problem. Explain any potential benefits to others.]

## Why am I being invited to take part in this research study?

We invite you to take part in this research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes subjects eligible for the research. You may also indicate exclusion criteria here.]

***What will I see, hear, read, or do in this study?*** [Broadly describe the types of experiences that participants will have in this study and what equipment will be used that they should be aware of before deciding to participate. Particularly take care to describe specific experimental conditions that might be sensitive for some people, (e.g., “You will hear stories about a couple experiencing discrimination during the course of air travel and be asked to reflect on your attitudes” or “you will be given a survey asking about your opinions on gender equality”.)

IF YOUR STUDY WILL BE EXEMPT UNDER CATEGORY 3 (benign behavioral interventions) and includes deception, (deliberately misleading the participant about the nature or purposes of your research, NOT incomplete disclosure or withholding details of hypotheses) you must include a statement to inform participants that they may be misled about the purposes of the research.

This section is not meant to be a detailed procedure, but rather a description of content or information that will be provided.]

## What happens if I say yes, I want to be in this research study?

[Tell the subject what to expect using lay language and simple terms. Whenever appropriate include the following items:]

[

* A timeline and description of the procedures that will be performed. If practical, prepare a timeline chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The length and duration of study visits and procedures
* With whom the subject will interact
* When the interaction will happen
* Where the research will be done
* When applicable, indicate that the subject may be contacted for future research and how they will be contacted.
* Provide identification of any experimental procedures. (This means describe any procedures that are being done solely for research purposes and would not ordinarily be involved in standard of care or in classroom activities for example.)
* Indicate whether participants will be paid and if so how much and in what form.

***]***

## What happens if I say yes now, but I change my mind later?

You can leave the research at any time and it will not be held against you.

***[Describe how the participant should proceed with termination of their participation.]***

***[Describe what will happen to data collected to the point of withdrawal. Describe any impact on payment/compensation if applicable.]***

***[If research is part of a clinical trial, indicate what the cutoff point is for participants to remove themselves from the study and still have their data withheld from reporting.]***

## How long will the research last?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event].

## How many people will be studied?

We expect about \_\_\_\_\_ people here will be involved in this research study ***[out of \_\_\_\_\_ people*** in the entire multi-site study, if applicable].

## What happens if I do not want to be in this research?

Your participation in research is completely voluntary. You can decide to participate or not to participate and can leave the study at any time.

[Include if there are alternatives other than participating. Otherwise delete.] Instead of being in this research study, your choices may include: [List alternative procedures. For student subject pools describe alternatives for course credit.]

## Is there any way being in this study could harm me?

 [Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk. These risks should be the same risks you disclose to the IRB in your application. Remember that your goal here is to educate the subject and not to minimize the risks in order to convince them to participate.]

* [Physical risks
* Psychological risks
* Privacy/confidentiality risks
* Legal risks
* Social risks
* Economic risks]

Although unanticipated, it is also possible that there are risks to you we as researchers cannot foresee.

## Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. Include direct benefits to participation if any. Otherwise, list possible indirect benefits to future subjects, science and/or society. First describe any direct benefits to the subject, then any benefits to others. Monetary reimbursement for participation is not a benefit.]

 [Include for research involving prisoners] Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this organization. [Add to this list other organizations that may have access to the subject’s records such as federal regulatory bodies like the Department of Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, sponsor’s agent and other collaborating institutions. Also include if applicable any external services that may access data such as transcriptionists, translators, coders, study staff, etc.]

[Describe any limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover abuse, neglect, or reportable diseases, explain that this information may be disclosed to appropriate authorities.]

***[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the data or specimens will be retained.]***

***[Indicate if you will be securing an NIH Certificate of Confidentiality for the project and the limitations of that protection.]***

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law. ***[Describe when this might be necessary given the circumstances of your study and study population.]***

## Can I be removed from the research without my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the subject may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

Must include this statement with addendum (a) or (b), but not both] Identifiers may be removed from the identifiable private information you provide, and after any such removal,

a. the [information or biospecimens] could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you.

b. your [information or biospecimens] collected as part of this research will not be used or distributed for future research studies, even if we remove identifiable information.

 [Include for sponsored research. Otherwise delete.] This research is being funded by [Insert name of sponsor].

 [Include if subjects will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount and method] for your time and effort. [Indicate if the amount is pro-rated for research visit completion or any other details relevant to partial completion of the research.]

[Include if relevant, otherwise delete.] There will be no additional costs to you as a result of participating in this research.

 [Include if relevant, otherwise delete.] Any significant new findings developed during the course of this research that may relate to your willingness to participate in this research will be provided to you.

[Include if relevant, otherwise delete.] Your biospecimens may be used for commercial profit. [indicate whether participant will or will not share in this commercial profit.]

[Include if relevant, otherwise delete.] Any clinically relevant research results [will or will not] be disclosed to you. [Indicate under what circumstances.]

[Include if relevant, otherwise delete.] The research [will, will not, or may] include whole genome sequencing.

 [Include for more than minimal risk research if relevant, otherwise delete.] There will be [will not be] any compensation to you and/or available medical treatment for you in the event of injury from participating in this research. [Describe where further information may be obtained.]

We will provide you a copy of this form [or you may print this page] for your records.

 [There are three signature pages attached to this template consent. Use the signature page or pages appropriate for your study. The IRB recommends that you make separate consent documents for each signature page to be used.]

[Omit the signature page if there is no written documentation of consent (i.e you have a waiver of documentation of consent.]

**Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your voluntary consent to take part in this research. You affirm you are 18 or older. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |
| Printed name of person obtaining consent |  |  |

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature documents your voluntary consent for the named subject to take part in this research. |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
| Relationship of legally authorized representative to subject |  |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |
| Printed name of person obtaining consent |  |   |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

**Signature Block for Children**

|  |
| --- |
| Your signature documents your voluntary consent for the named child to take part in this research. |
|  |  |  |
| Printed name of child |  |  |
|  |  |  |
| Signature of parent/guardian |  | Date |
|  |  |
| Printed name of parent/guardian |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |
| Printed name of person obtaining consent |  |  |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained using Villanova assent template appropriate for age of child.
* Not obtained because the age appropriate assent process could not be developed.
 |