*TEMPLATE YOUTH ASSENT*

* *The Consent Instructions and Youth Assent Starter Version documents give important format instructions and examples. REFER TO THEM as you develop your assent.*
* *Pages MUST be numbered (page x of y).*
* *Reading level MUST be appropriate for the YOUNGEST of your participants.*
* *Check the reading level of each section separately. Do NOT include section headings or verbatim text when checking reading level.*
* *Because full information is given in the Parental Permission, some sections are omitted from the Youth Assent.*
* *Gray text and boxes give extra sections or wording that might apply to some studies. Only use them if appropriate.*

**Youth Assent Form for Research**

**(Ages 12-17 Years)**

**University of Cincinnati**

**Department: *(or Division:)*  *Name***

**Principal Investigator: *Name***

***Faculty Advisor: Name*** *(only needed if the PI is student)*

**Title of Study:** *Name of the study, as it appears on the IRB application/protocol*

*ONLY if the research is conducted at The University Hospital, insert the following:*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant's Name (printed) Date of Birth

**Introduction:**

You are being askedto be in a researchstudy. Please ask questions about anything you do not understand.

**Who is doing this research study?**

The person in charge of this research study is *(Principal Investigator's name).*

*If the PI is a student, use this sentence.*

The people in charge of this research study are *(PI's name)* and *(Faculty Advisor's name)*.

 *If additional people might help the researcher conduct the study, add this sentence.*

There may be other people helping as well***.***

 **What is the purpose of this research study?**

The purpose of this research study is to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

*Complete the sentence. The purpose must be the consistent with the IRB application unless there is a compelling reason for incomplete disclosure or deception that is explained in the IRB application. Wording might need to be simplified.*

**Who will be in this research study?**

About  *(number)* people will take part in this study. You may *(or may not)* be in this study if

*List criteria that make a person eligible (or ineligible) to participate, such as being in a particular course or meeting other criteria. Bullet points or a numbered list might help.*

*ONLY if participants are employees of the site where the research is conducted, include this section:*

**What if you are an employee where the research study is done?**

Taking part in this research study is not part of your job. Refusing to be in the study will not affect your job. You will not be offered any special work-related benefits if you take part in this study.

**What will you be asked to do in this research study, and how long will it take?**

You will be asked to *(do what?)*. It will take about *(how long?)*. The research *(or interview, etc.)* will take place *(where?)*.

* *State the activities the participants will do.*
* *Identify how long each activity will take, for a total of how much time (such as "a survey that will take about 10 minutes and then an interview that will take about an hour").*
* *If more than one study visit will be required, state how long and how often the visits will be.*
* *State where the activities will be done.*
* *Bullet points or a numbered list might help.*
* *Be sure to identify any different steps or phases.*
* *Be sure to mention all kinds of information being collected from/about participants.*
* *If any activities are experimental, be sure to identify them as such.*

**Are there any risks to being in this research study?**

*State any risks that are reasonably expected.*

*If no risk is expected, some phrases that might be used include (but are not limited to):*

* *The researcher does not think there is any risk of being hurt by this research study.*
* *The researcher does not think there is any risk from allowing your \_\_\_\_\_\_\_ (grades, class work, information, etc.) to be used in this research study.*
* *The risk of being hurt by this research study is probably no more than you would have in everyday life.*

*If some risk might be expected, some phrases that might be used include (but are not limited to):*

* *Some questions may make you uncomfortable. You can refuse to answer any questions that you don't want to answer.*
* *Possible risks from being in this research study include the following:*
* *There might be risks that are not known at this time.*
* *To reduce the possibility of risk, \_\_\_\_\_\_\_\_\_\_ (explain what you will do to reduce the possibility of the risk).*
* *If you feel upset because of this research, tell the researcher. He (*or She) *can get help for you.*

**Are there any benefits from being in this research study?**

*If direct benefit to the participant IS expected, use this statement:*

Because of being in this research you might *(state any direct benefits because of participation in the study)*.

* *Direct benefit might include things like getting extra tutoring, or getting emotional support from others in a similar situation, or using an innovative tool, etc.*
* *Do not exaggerate benefit to the individual. For example, a few tutoring sessions will probably not cause the participant to pass the course with an "A".*
* *Feeling good about helping the researcher is NOT a benefit.*
* *Receiving payment or extra credit is NOT a benefit.*

*If no direct benefit to the participant is expected, use this statement:*

You will probably not get any benefit from being in this study. But, being in this study may help *(what group or what part of society?)* understand *(the research topic)*.

**What will you get because of being in this research study?**

*Explain any PAYMENTS the participant will receive.*

*EITHER:* You will not be paid *(or given anything)* to take part in this study.

*OR:* You will be paid *(or given)* *(how much and in what form?) (why?)*

* *Payment might be financial, research credit, extra class credit, some kind of gift, etc.*
* *The amount must be included.*
* *If money is paid, the method must be stated (such as cash, gift card, etc.).*
* *The reason for payment (such as "to thank you for being in the study" or "for your time and travel") must be stated.*
* *If payment, research credit, etc. will be pro-rated based on amount of participation, the schedule of pro-rating should be given (such as "$5 if only one survey is done but the full $10 if both surveys are done" or "a $3 McDonald's coupon each time you come for a study visit" or "1 extra credit if you only do some of the activities but 2 extra credits if you finish all of them").*

*ONLY if the total payment is significant (more than $50), include the following statement (verbatim):*

If you receive money for being in this study, you may have to fill out a form for the Internal Revenue Service (IRS). The money you receive may affect your income taxes. You will have to put your social security number on the IRS form.

**Do you have choices about taking part in this research study?**

If you do not want to take part in this research study you *(what else could they do?)*.

* *If participants will receive some kind of direct benefit, describe alternative ways the participant could receive the same level of benefit.*
* *Some phrases that might be used include (but are not limited to):*
* *may simply not participate.*
* *may work on other class assignments at your desk.*
* *may leave the room quietly.*
* *may turn in a blank survey.*
* *will receive the same services you already get.*
* *will not be treated any differently.*
* *will have other opportunities to earn extra credit.*
* *may still take part in the meetings.*

*ONLY if participants have choices about research activities (such as whether or not an interview may be audiotaped), state them in this section.*

You have a choice whether or not to take part in the *(state the choice)*. There is a place at the end of this paper to mark your choice.

* *Add "yes" and "no" choices above the signature lines at the end of the consent.*

*ONLY if the study involves prisoners (incarcerated, involuntarily detained, or assigned to a program as an alternative to incarceration), the following section MUST be included (verbatim).*

**How will this research study affect your legal status?**

Being in this study or refusing to be in this study will have no effect on your court case or parole. You will NOT get in trouble for saying no. You will NOT get treated better if you say yes.

**How will your research information be kept confidential?**

Information about you will be kept private by *(how?)*.

*Plans that may be used include, but are not limited to:*

* *using a study ID number instead of the participant's name on the research forms*
* *keeping the master list of names and study ID numbers in a separate location from the research forms*
* *limiting access to research data to the research team*
* *not including the participant's name on the typed transcript*
* *erasing audiotapes as soon as they are transcribed*
* *keeping research data on a password-protected computer*

Your information will be kept *(where?)* for *(how long?)*. After that it will be *(destroyed, or de-identified?)* by *(how will you do it?)*.

*Explain**how you will make sure the participant's identity and his/her research data are not disclosed beyond the research team. Topics that MUST be mentioned are:*

1. *LOCATION where information is stored.*
	1. *This is usually in a locked cabinet in the faculty researcher's campus office (storage at home is not acceptable).*
	2. *Signed consent documents and master lists of participant names and ID numbers should NOT be stored in the same place as identifiable data.*
2. *HOW LONG the research data and consent documents will be kept before removal of identifiers and/or destruction.*
	1. *NOTE: identifiers such as name, birth date, M-number, etc. should be deleted as soon as possible.*
	2. *NOTE: federal regulations require that signed consent documents must be kept for a minimum of three years after the study is closed.*
	3. *UC recommends that raw data should be kept for a minimum of two years after the study is closed (UC Investigator SOP 4-2, last point under Procedures).*
3. *HOW records will be de-identified or destroyed in a confidential manner, such as:*
4. *removing participant's name from all research data*
5. *deleting computerized records*
6. *shredding paper research files when the study is complete*
7. *USE of identifiers in publication/presentation. For most studies, the following statement is appropriate:*

The data from this research study may be published; but you will not be identified by name.

*If a participant will be identified by name, this entire section should be adjusted to reflect it.*

*Sometimes confidentiality cannot be assured because other participants might disclose information, such as discussion in a focus group. ONLY if it is appropriate, include the following statement.*

The researcher will ask for things said in the focus group to be kept private. People in the group might talk about it anyway.

*Sometimes confidentiality cannot be assured because of technology limitations, such as on-line surveys or email correspondence. ONLY if it is appropriate, include the following statement.*

The researcher cannot promise that things sent by internet or email will be private.

*Sometimes confidentiality must be broken to protect participants or others. ONLY if it is appropriate, include the following statement (verbatim).*

The identity of participants and information about them will be kept confidential, unless the authorities have to be notified about abuse or immediate harm that may come to the participant or others.

*ONLY if the study is funded by the U.S. Department of Justice and meets the requirements found in the US Criminal Statutes under 42 USCS 3789g (a), include the following statement (verbatim).*

Because this research study is federally funded, the law says the information collected about participants cannot be used for any other purpose, including legal action.

*ONLY if a Certificate of Confidentiality has been (or will be) obtained from the National Institutes of Health (NIH), include the following three paragraphs (verbatim).*

To further protect your privacy, the researchers have obtained a Certificate of Confidentiality from the Department of Health and Human Services (DHHS). With this certificate, the researchers may not disclose information (for example by court order or subpoena) that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

Even with the Certificate of Confidentiality, if the investigator learns about abuse of a child or elderly person or that you intend to harm yourself or someone else, or about certain communicable diseases, they will report that to the proper authorities. If keeping information private would immediately put you or someone else in danger, the researchers would release information to protect you or another person.

**What are your legal rights in this research study?**

Nothing in this assent form takes away your rights.

**What if you have questions about this research study?**

If you have any questions about this research study, you should contact *(PI's name)* at *(PI's contact information)*.

*If the PI is a student or if there is a second PI, also include the following.*

Or, you may contact *(Co-PI's name)* at *(Co-PI's contact information)*.

**Do you HAVE to take part in this research study?**

No one has to be in this research study. You will not get in any trouble if you say no.

*If appropriate, add: You may skip any questions that you don't want to answer.*

You may start and then change your mind and stop at any time. To stop being in the study, you should tell *(contact person's name and contact information)*.

**Agreement:** I have read this information. I want to be in this research study.

*ONLY if participants have choices about research activities (such as whether or not an interview may be audiotaped), add "yes" and "no" choices above the signature lines. For example:*

*\_\_ YES, you may audiotape my interview (or use my real name, etc.)*

*\_\_ NO, I do NOT want you to audiotape my interview (or use my real name, etc.)*

Your Name (please print) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Your Date of Birth \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ (Month / Day / Year)

Your Signature \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_

*ONLY include the "oral presentation" statement and signature if some participants might be unable to read the assent for themselves.*

*\_\_\_Oral presentation of the assent was given to the participant, who was not able to read the written assent. By signing, I certify that the oral presentation was consistent with this written document.*

*\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_*

*Impartial Witness Signature (oral presentation only) Date*

Signature of Person Obtaining Assent \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date \_\_\_\_\_\_\_\_\_\_\_

*ONLY if waiver of the signature requirement is requested, use this alternate Agreement section.*

TURNING IN YOUR COMPLETED SURVEY *(or BY TAKING PART IN THESE ACTIVITIES)* MEANS YOU WANT TO BE IN THIS RESEARCH STUDY.

PLEASE KEEP THIS INFORMATION SHEET FOR YOUR REFERENCE.