# OCPS Application to Conduct Research
# Informed Consent Guide

## Informed Consent

**Orange County Public Schools (OCPS) requires informed consent forms to be used when conducting research with OCPS staff, students, or families.** Per OCPS guidance, consent must include participant signatures. In addition to informed consent acknowledged by adults, OCPS requires assent by minors. In this case, assent is the agreement by a person not able to give legal consent (e.g., students in grades VPK through 12) to participate in a research activity. Work with children or adults not capable of giving consent (e.g., cognitively impaired person) requires the consent of the parent or legal guardian. Student participant signatures are required as part of the assent process with a few exceptions. Students in voluntary pre-kindergarten (VPK) through grade 5 only require parental consent, signed student assent is not required. Further, student participant signatures are not required for those in grades 6 through 12 when completing an online survey. In this case, student assent is determined using an online platform (e.g., Qualtrics, Survey Monkey, Google Forms) with the use of radio buttons or check boxes, in which a participant can select from either accept or decline options. Other student research activities in grades 6 through 12 require participant assent signatures. Informed consent forms that research participants are required to sign must be written in plain language. Participants should not be asked to waive (or appear to waive) any of their legal rights (i.e., exculpatory language), nor should they be asked to release the investigator or research institution from liability or negligence. Unless otherwise stated, the following required components of informed consent will be reviewed by the Research department. A sample consent form is included at the end of this document.

| Statement of… | Description |
|---|---|
| 1. *INTRODUCTION* or invitation (Optional) | • Describes who is the researcher or investigator of the study (e.g., doctoral student) and conveys opportunity to discuss research participation.<br>• Details participant selection (e.g., why chosen to participate).<br>• Invites participation in research (e.g., reason to join). |
| 2. *PURPOSE* of the research | • Invites participation in research (e.g., reason to join).<br>  ○ Sufficient information is provided about the research project to ensure informed decision-making.<br>• Identifies numbers of participants, if applicable to the decision to participate (e.g., a small number may compromise confidentiality). |

| Statement of… | Description |
|---|---|
| | |
| 3. *METHODS* used in research | • Describes procedures to be followed:<br>  ○ Type of participation (e.g., survey, interview, etc.).<br>  ○ Duration of participation (e.g., time commitments).<br>  ○ Disclosure for audiotaping, videotaping or photographing participants.<br>  ○ Disclosure of how data may be used.<br>  ○ Compensation or costs (e.g., at no cost to you). |
| 4. *RISKS* (reasonable, foreseeable risks or minor discomforts related to research) | • Describes the level of risk to the participant. Specifies significance of physical, psychological, social or economic risk (e.g., minimal risk to participants). Risks must be explicitly stated. It is not plausible to claim that there are no risks involved in participation.<br>• Considers risk "minimal" when the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life. For most observational studies, for example, the level of participatory risk would be minimal. |
| 5. *BENEFITS* (reasonable expectations, not overstated) | • Declares that no direct benefit is anticipated, if this condition applies.<br>• Describes potential participant or societal benefits or accrued benefits to the investigator, sponsor or other relevant stakeholders.<br>• Names incentives (e.g., financial incentives, reimbursements, contributions to research literature, etc.). |
| 6. *VOLUNTARY PARTICIPATION* (right to refuse or withdraw) | • *Refusal.* Refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled (e.g., without negative consequence or disadvantage).<br>• *Withdrawal.* A participant may discontinue at any point in time without penalty or loss of benefits to which the participant is otherwise entitled (e.g., without negative consequence or disadvantage).<br>• *Termination.* Potential circumstances where participation may be terminated by the researcher or investigator without the participant's consent. |
| 7. *CONFIDENTIALITY* of records (data security and privacy) | • Describes the extent to which the researcher or investigator and/or institution intends to maintain confidentiality of records identifying participants (e.g., pseudonyms, data retention and disposal).<br>• Complies with the Family Educational Rights and Privacy Act (FERPA), Protection of Pupil Rights Amendment (PPRA), Health Insurance Portability and Accountability Act (HIPPA) or other federal and state regulation as well as school board policy. |

| Statement of… | Description |
|---|---|
| | • Identifies parties that may gain access to study records. |
| *8. CONTACT INFORMATION* | • States where pertinent questions about the research are directed (e.g., point of contact or primary researcher).<br>• States where further information may be obtained (i.e., more detailed information about the study).<br>• States where adverse events are reported (e.g., University department) and an explanation of research participants' rights (e.g., IRB). |
| *9. CONSENT SIGNATURES* | • Requests the participant or legal representative name both in *print* and *hand-written* or *certified electronic signature* form and is date stamped; Witness, if needed (e.g., oral presentation)<br>• Parental consent requires a signature, either hand-written or digital<br>• Written "active" or "opt in" consent option (e.g., if more than minimal risk, then written active consent is required)<br>• Written "passive" or "opt out" consent (e.g., if minimal risk, then written passive consent is required) |

## Written Active ("opt in") Consent

**Active means action is required.** The participant (or legal representative) of the study must provide documented (i.e., written) agreement to participate in the proposed study. In this case, consent is explicit. For example, active consent requires the parent/legal guardian to signify in writing their permission for their student in grades VPK through 5 to participate in a study.

**Rationale for use.** If the study involves more than minimal risk (e.g., given consideration to vulnerable populations), children in grades VPK through 5 or is of a sensitive nature, then active consent is required. In this case, active consent provides some assurance that the individual or parent/legal guardian has read the study information and gives approval to participate.

### The following sample "opt in" language is typically used for grade VPK-5 students:

*Before you (your student) can participate in this [project, study, survey, etc.], we must obtain your (parental/legal guardian) written consent. You must indicate that you are (your student is) able to participate by signing the attached form and returning it to the researcher (your child's school).*

*I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.*

**BY SIGNING THIS FORM, I AGREE TO TAKE PART IN OR ALLOW MY STUDENT TO PARTICIPATE IN THE RESEARCH DESCRIBED IN THIS CONSENT FORM. THIS MEANS YOU OR YOUR STUDENT IS ELIGIBLE TO PARTICIPATE IN THIS RESEARCH OPPORTUNITY.**

_____
Name of Participant

_____
Name of Legally Authorized Representative (if applicable)

_____ _____
Signature of Participant or Legally Authorized Representative Date

## Written Passive ("opt out") Consent

**Passive means NO action is required.** UNLESS the participant (or legal representative) does NOT want to participate in the research study, the participant of the study merely takes part in the proposed study. In this case, consent is implied. For example, passive consent for students in grades 6 through 12 assumes that their parent/legal guardian has agreed for their student to participate in the study UNLESS some action is taken to refuse. Here, the action taken would be to provide documented (i.e., written) refusal to participate.

**Rationale for use.** Passive consent can be used for EXEMPT research (e.g., Title 45, Code of Federal Regulations, Part 46, the "Common Rule" or "Protection of Human Subjects Regulations"). However, please note that potential participants must still be informed. The assumption taken with passive consent is that there is likely to be no objection to participate in the study as it poses minimal risk to participants. Signatures are collected ONLY if the participant DECLINES to participate or the parent declines on their student's behalf. One advantage of using passive consent procedures is that they tend to produce a higher response rate and are more likely to yield a representative sample.

### The following sample "opt out" language is typically used for grade 6-12 students:

*I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction.*

*No action is required on your behalf to participate (to allow your student to participate) in this [project, study, survey, etc.]. If you do NOT want to participate (your student to participate), please sign the attached form to "opt out" of the research and return it to the researcher (or your child's school).*

**BY SIGNING THIS FORM, I WISH TO "OPT OUT" OF OR NOT ALLOW MY STUDENT TO PARTICIPATE IN THE RESEARCH DESCRIBED IN THIS CONSENT FORM. THIS MEANS YOU OR YOUR STUDENT IS <u>NOT</u> ELIGIBLE TO PARTICIPATE IN THIS RESEARCH OPPORTUNITY.**

_____
Name of Participant

_____
Name of Legally Authorized Representative (if applicable)

_____ _____
Signature of Participant or Legally Authorized Representative Date

## Online Active Consent for Surveys

**Online active consent captured through survey format is typically used for grade 6-12 students and is also suitable for adults. Active means an action is required to participate.** The participant (or legal representative) of the study must provide documented agreement (i.e., Yes, I agree or No, I don't agree) to participate in the proposed study. In this case, consent is explicit. For example, an active online consent requires the participant to signify their agreement to participate in the study by selecting a "Yes" or "No" radio button or check box within an online platform. Selecting "Yes" provides the active consent or assent by the individual, and the agreeing party proceeds to the next page of a survey. If "No" is selected, then the individual must not proceed further in the survey, and therefore does not participate in the researcher or investigator's data collection.

Online "passive" consent for surveys without selection buttons/check boxes is not an option for OCPS participants. You must provide a clear choice for the participant to indicate that that they agree or disagree to participate.

## Sample Photographs, Videos, Audio Recordings Language

*You will be [audiotaped, videotaped, photographed] in this study. The [audiotapes, videotapes, photographs] will be used for [teaching or research] purposes only and your identity will not be disclosed. [Describe who will have access to recordings, and when they will be erased or destroyed. Describe how personal identities will be shielded, disguised, etc.]*

*If the participant is identifiable from the audio recordings, videos, or photographs, the following statement should be added.*

Please check one of the boxes below:

- □ I agree to be [audiotaped, videotaped, photographed].

- □ I do not want to be [audiotaped, videotaped, photographed].

# Informed Consent Example

## PROJECT TITLE

*Name the long or short title of your research study, as applicable.*

## INTRODUCTION/INVITATION

You are invited to join a research study to look at _____. Please take whatever time you need to discuss the study with the researcher/investigator or anyone else you deem appropriate. The decision to join, or not to join, is up to you.

In this research study, we are investigating/testing/comparing/evaluating _____.

*The information here should be a clear and short description of the "bottom line" of the study. Hold details of the study until later in the document. Briefly give the participants some background information about why this study is being done, this can include information about what is already known and what you hope to learn*.

## STUDY INVOLVEMENT

If you decide to participate you will be asked to _____. We think this will take you _____minutes/hours/days. No photos, audio or video recordings will be taken.

*Refer to the participants as "you*" or "your student," if seeking parental consent.

*Tell participants* **exactly** *what to expect. Explain what will happen during the study and how the study will work. Include* **everything** *that participants will be asked to do. Describe all surveys and data collection instruments that participants will experience. Indicate how long each survey or procedure will take and state how long (e.g. minutes, hours, days, months, until a certain event or endpoint) the participants will be part of the study. Indicate if photos, audio or tape recordings are needed.*

The investigators may stop the study or take you out of the study at any time if they judge it is in your best interest. They may also remove you from the study for various other reasons. They can do this without your consent.

*If appropriate, list any additional reasons why participants might be taken out of the study.*

You can stop participating at any time. If you stop you will not lose any benefits to which you are otherwise entitled.

## RISKS TO TAKING PART IN THE STUDY

This study involves the following risks: _____.

There may also be other risks that we cannot predict.

*List the physical and non-physical risks of participating in the study above. Non-physical risks may include social, psychological, or economic harm; risk of criminal or civil liability; or damage to financial standing, employability, or reputation. Every study poses some risk, however minimal, so indicate that the risks are minimal and no more than might be encountered in everyday life rather than state there are no risks.*

## BENEFITS TO TAKING PART IN THE STUDY

It is reasonable to expect the following benefits from this research: _____.

However, we can't guarantee that you will personally experience benefits from participating in this study. Others may benefit in the future from the information we find in this study.

*List all the benefits that might* **reasonably** *be expected from participating in the study. First describe benefits to participants, then describe benefits to others. If there are no benefits from participating in the research, state that fact.*

## CONFIDENTIALITY

We will take the following steps to keep information about you confidential, and to protect it from unauthorized disclosure, tampering, or damage: _____.

*List all individuals and agencies who will have access to the data and records, and how data will be described if published or shared with others. Will you be using direct quotes which could be traced to an individual? Will you be aggregating the data so that no personally identifiable information can be traced to a single individual?*

*Describe confidentiality protections here. Explain how you are protecting the participant's information. Give details as appropriate: for example, are paper files kept in locked cabinets, are electronic data kept on a secured computer, is a password required for getting onto the system; who has access to the data, etc. How will confidentiality be handled if pictures or recordings are taken? Are online platforms used for data collection safe and secure?*

## INCENTIVES

*Indicate if participants will receive anything in return for participating. As a general rule, incentives for schools are allowed. In most cases, incentives for teachers are* ***not*** *allowed. For research studies sponsored by a grant, federal or state agency, teacher incentives may be permissible.*

## YOUR RIGHTS AS A RESEARCH PARTICIPANT

Participation in this study is voluntary. You have the right not to participate at all or to leave the study at any time. Deciding not to participate or choosing to leave the study will not result in any penalty or loss of benefits to which you are entitled, and it will not harm your relationship with (*Orange County Public Schools*).

*Describe procedures for withdrawing and any follow-up actions that you will request of participants who withdraw early. Follow-up such as questionnaires that are part of the research cannot be forced upon participants who wish to withdraw.*

## CONTACTS FOR QUESTIONS OR PROBLEMS

Call (*Researcher or Principal Investigator name*) at (*Phone number*) or email at (*Email address*) if you have questions about the study, any problems, unexpected physical or psychological discomforts occur, or any injuries result from participation in the study, or you think that something unusual or unexpected is happening. Or you may contact (*Research Chair/Academic Advisor*) at (*Phone number*) or (*Email address*).

*Provide the name of one or more researchers who can be reached for assistance. If you are a student, provide your academic advisor's contact information, too.*

Contact (*Name of Advisor/Research Chair*) of (*Department*) at (*Phone number*) or (*Email address*) if you have any questions or concerns about your rights as a research participant. *For example, this could be your IRB contact information or your Research Chair/Academic Advisor contact information.*

## CONSENT OF PARTICIPANT (or Legally Authorized Representative)

*See Active ("opt in") or Passive ("opt out") Consent samples for helpful text as described earlier in this guidance document.*

Name of Participant or Legal Representative

_____

Signature of Participant or Legal Representative Date

_____ _____

*Upon signing, the participant, or the legally authorized representative, will receive a copy of this form, and the original will be held in the participant's research record.*

(*Adapted from Informed Consent Document Sample with Tips, Ethical and Safe Research, Office of Human Subjects Research, Rochester Institute of Technology, Rochester, NY; retrieved July 2021 from* https://www-staging.rit.edu/research/hsro/informed_consent_document_sample_tips)

# References

Rochester Institute of Technology [RIT] (n.d.). Basic Elements of a Consent Form for Non-Exempt Research. https://www.rit.edu/research/hsro/basic_elements_consent_form

Protection of Human Subjects. 45 C.F.R. § 46 (2021). https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=d2b04625189f40d9cfdc4cd6465e8a7f&mc=true&n=pt45.1.46&r=PART&ty=HTML#se45.1.46_1116