Orange County Public Schools
Research and Evaluation

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. It must also include participant 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. 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., minor, under the age of 18 years) to participate in a research activity. Work with children or adults not capable of giving consent (e.g., children under the age of 12; cognitively impaired person) requires the consent of the parent or legal guardian. Unless otherwise stated, the following required components of informed consent will be reviewed by the Research and Evaluation department's research review team.

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. • Details participant selection (e.g., why chosen to participate). • Invites participation in research (e.g., reason to join).
2. *PURPOSE* of the research	• Invites participation in research (e.g., reason to join). o Sufficient information is provided about the research project to ensure informed decision-making. • Identifies numbers of participants, if applicable to the decision to participate (e.g., a small number may compromise confidentiality).

3. *METHODS* used in research	• Describes procedures to be followed:
	  o Type of participation (e.g., survey, interview, etc.).
	  o Duration of participation (e.g., time commitments).
	  o Disclosure for audiotaping, videotaping or photographing participants.
	  o Disclosure of how data may be used.
	  o Compensation or costs (e.g., at no cost to you).

Statement of…	Description
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. • 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, 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. • Describes potential participant or societal benefits or accrued benefits to the investigator, sponsor or other relevant stakeholders. • 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). • *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). • *Termination.* Potential circumstances where participation may be terminated by the researcher or investigator without the participant's consent. o An unexplained statement of termination does not adequately inform participants of anticipated circumstances for such withdrawal. o A statement of withdrawal if participants do not "follow study procedures" is not appropriate. However, participants may be informed that they may be withdrawn if they do not follow instructions.
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). • Complies with FERPA, HIPPA or other federal and state regulation as well as school board policy. • 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).

Statement of…	Description
	• States where further information may be obtained (i.e., more detailed information about the study). • States where adverse events are reported (e.g., University department) and an explanation of research participants' rights (e.g., IRB).
9. CONSENT SIGNATURES	• Requests participant or legal representative name both in *print* and *written* (i.e., signature) form and is date stamped; Witness, if needed (e.g., illiterate) • Written Active Consent (e.g., more than minimal risk written active consent is required) • Written Passive Consent (e.g., minimal risk written passive consent is required) • Parental consent requires a signature, written or digital

Written Active 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 the minor to participate in the study.

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

Sample "opt in" language. Typically used for K-8 grade students.

Before your student can participate in this [project, study, survey, etc.], we must obtain written parental or legal guardian consent. You must indicate that your student is able to participate by signing the attached form and returning it to 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 THE RESEARCH DESCRIBED IN THIS CONSENT FORM. THIS MEANS YOU OR YOUR STIDENT 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 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 participates in the proposed study. In this case, consent is implied. For example, passive consent assumes that the parent/legal guardian has agreed for the minor 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. 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.

Sample "opt out" language. Typically used for 9-12 grade 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 allow your student to participate in this [project, study, survey, etc.]. If you do NOT want your student to participate, please sign the attached form to "opt out" of the research and return it to your child's school.

BY SIGNING THIS FORM, I WISH TO "OPT OUT" OF 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. **Active means an action is required to participate.** The participant (or legal representative) of the study must provide documented (i.e., Yes or No) agreement 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, for example, or other planned activity. If "No" is selected, then the individual must not proceed further in the study or any other research activity, and therefore does not participate in the researcher or investigator's data collection.

Online "passive" consent is not an option for OCPS participants.

Sample Photographs, Videos, Audio-tape Recordings language.

You will be [audio-taped, video-taped, 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-tape recordings, videos, or photographs, the following statement should be added.]

Please check one of the boxes below and initial:

□ I agree to be [audio-taped, video-taped, photographed]. Initials _____

□ I do not want to be [audio-taped, video-taped, photographed]. Initials _____

Informed Consent Example

PROJECT TITLE

Name the long and 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 your family and friends, or anyone else you wish to. 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 audio or video recordings will be taken.

Refer to the participants as "you." *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.

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.

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 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 or Passive 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 January 2018.*)