**Parental Opt-Out Template**

To provide the necessary information to enable parents/guardians to decide whether to allow their children to participate in research, a comprehensive opt-out form is needed. For your convenience, a parental opt-out template is provided on the next page and may be used if the following criteria are met:

* Your study will “[involve] no more than minimal risk to participants”;
* “The research could not practicably be carried out” if a consent form were required (e.g., circumstances would make obtaining signed consent from parents impracticable, like the implementation of a teaching intervention involving entire classes or grades); and
* Not providing a normal consent form “will not adversely affect the rights and welfare of the subjects” (45 CFR 46.116(f)).
* Additionally, if your study will involve children in a school setting, the appropriate district or school official will need to grant permission for you to utilize the opt-out procedure.
* You will still provide study information (i.e., the completed template provided below) to parents but only require it to be signed and returned if they prefer that their students ***not*** participate (i.e., opt-out).

**To reduce the potential for IRB revision requests and delayed study approval, please use our template.**

The contents of the opt-out template have been organized to facilitate comprehension. **Opt-out documents should be written in plain language, excluding technical terms, and generally at an 8th-grade reading level.** For more information on plain language, go to <http://www.plainlanguage.gov/>.

Please note the following:

1. The regulations require consent forms to contain a concise and focused presentation of the key information that is most likely to help potential subjects understand why they might or might not want to participate in a study. The key information must be presented first and must include the following:
	1. Identification of the project as a research study and that participation is voluntary
	2. Purpose of the research, duration of participation, and a description of research procedures
	3. Foreseeable risks or discomforts
	4. Expected benefits to subjects or others
	5. Alternative procedures or treatments that might benefit the subject
2. Text in [brackets] represents information about your study that you must add.
3. A forward slash (/) indicates that you must select an option specific to your study (e.g., “will/will not” or “I/we”) and remove the remaining option(s).
4. Additional instructions or sample text are provided in boxes.
5. Before you submit your consent document to the IRB, delete this cover page(s), all brackets, and the boxes. You’ll also need to remove any extra spaces created when the boxes were removed.
6. Please follow the **instructions in blue** below, revising or providing the information in **red**. You will need to remove the instructions as you go, including these instructions. The font color of your completed document should be **black**.
7. The finished document should reflect what you will give to prospective participants.
8. If your study involves multiple types of participants who will complete different procedures (e.g., students who will be interviewed and take part in a focus group and students who will complete a survey), you will need to create different opt-out forms for each participant group.
9. When you save your newly created opt-out documents, please use a file name that clearly identifies the document and the intended audience (e.g., opt-out, etc.).

For questions about consent, please contact the IRB at irb@liberty.edu.

Choose the applicable heading and remove the remaining options.

**[Parental Opt-Out]**

Provide your study title, **ensuring that it matches the title you listed on your IRB application**. Regarding co-investigators, list any individuals who will be assisting you with your research. If you are a student, do not list your faculty sponsor as a co-investigator. Only list a faculty member if they will serve as part of a study team.

**Title of the Project:** [Title]

**Principal Investigator:** [Your Name, [List your role/affiliation with LU.] [Student/Graduate Student/Doctoral Candidate/Faculty Member/etc.], [Provide the name of your academic school or department (e.g., School of Education, Psychology Department, etc.).] [\_\_\_], Liberty University

[**Co-investigator(s):** Name(s), credentials, institutional affiliation]

**Key Information about the Research Study**

This is the key information section described beside number one on the previous page. Please complete each bullet point by inserting the required information.

[Your child/student] is invited to participate in a research study. To participate, [he or she/he/she] must be [List your participant criteria.] [e.g., a 4th-grade student at Franklin Elementary]. Taking part in this research project is voluntary.

Things you should know:

* The purpose of the study is to [brief, concise study purpose]. If you choose to allow your [child/student] to participate, [she/he] will be asked to [brief, concise study procedures]. This will take approximately [time estimate].
* [Retain and complete the following sentence if your study procedures will involve greater than minimal risk. Otherwise, you may remove it.] Risks or discomforts from this research include [brief, concise description of risks or discomforts].
* [Brief, concise description of potential direct benefits to subjects or statement that subjects are not expected to receive direct benefits].
* Taking part in this research project is voluntary. You do not have to allow your [child/student] to participate, and [he/she] can stop at any time.

Please take time to read this entire form and ask questions before deciding whether to allow your [child/student] to take part in this research project.

**What is the study about and why are we doing it?**

In one to two sentences and in plain language, please list the purpose of your study. Do not include details about your procedures as they will be discussed below.

The purpose of the study is [study purpose].

**What will participants be asked to do in this study?**

\* Next, you will need to list your study procedures **in order** and **include expected time estimates for each**.

\* If you plan to implement an intervention and will be using a control and experimental group(s), you must notify parents and participants of how groups will be assigned (randomly or otherwise) and that participants may or may not receive the intervention as part of their participation. If control group participants will have the opportunity to receive the intervention after the study has concluded, provide related information.

\* If you choose to withhold information about study groups and group assignments, your study will involve deception, and you will need to note this on the Consent page of your IRB application and potentially create and submit a debriefing statement for IRB review.

\* For qualitative studies, if participants will be asked to review their interview transcripts, the developed themes, etc. to check for accuracy or confirm agreement (i.e., member checking), please list this as a procedure and include a time estimate. If you use the term *member checking*, be sure to include a description to allow for participant understanding.

\* Screening is not considered a study procedure, so **it should not** be listed in the below paragraph.

\* Please **do not list reading/signing the opt-out form as a procedure**.

\* If your study will involve the collection of photographs/video/artifacts (pictures, drawings, etc.) of or from participants, and you plan to include the photographs/video/artifacts or images of the artifacts in your paper/thesis/dissertation/publication or as part of a future presentation(s), your participants will need to sign a release form allowing you to do so.

If you agree to allow your [child/student] to be in this study, I will ask [her/him/her or him] to do the following:

1. [First task/procedure (e.g., Participate in an in-person, audio-recorded interview that will take no more than 1 hour.)] [**Be sure to include a time estimate**, and if applicable, information about any plans to record (audio/video) participants.]
2. [Second task/procedure (or delete this text)] [**Be sure to include a time estimate**, and if applicable, information about any plans to record (audio/video) participants.]
3. [Additional tasks/procedures as needed (or delete this text)] [**Be sure to include a time estimate**, and if applicable, information about any plans to record (audio/video) participants.]

**How could participants or others benefit from this study?**

\* Select the appropriate option below. Participants should not expect to receive a direct benefit simply from taking a survey or participating in an interview; however, they may receive a direct benefit if the study procedures involve a teaching or therapy intervention, the opportunity to obtain training they would not receive if they did not participate, etc.

\* You will also need to provide information about the expected benefits to society/your discipline/the literature.

[Option 1: No Direct Benefits] Participants should not expect to receive a direct benefit from taking part in this study.

[Option 2: Direct Benefits] The direct benefits participants should expect to receive from taking part in this study are [description of the expected benefits].

Benefits to society include [description or expected benefits to society/your discipline/the literature].

**What risks might participants experience from being in this study?**

Select the appropriate option below, keeping in mind that risk can be psychological, physical, legal, social, and economic.

\* No study is without risk, but studies involving the collection of data through surveys or interviews are generally considered minimal risk, so option 1 should be retained.

\* Individuals participating in studies involving physical activity may risk injury, but if the participants will be healthy, fit individuals, such risks are still considered minimal. For this scenario, option 2 should be retained and completed.

\* For guidance regarding procedures that may involve greater than minimal risk (Option 3), please contact the IRB.

[Option 1: Minimal risk] The expected risks from participating in this study are minimal, which means they are equal to the risks your [child/student] would encounter in everyday life.

[Option 2: Minimal risk, but the possibility of psychological stress exists.] The expected risks from participating in this study are minimal, which means they are equal to the risks your [child/student] would encounter in everyday life. The risks involved in this study include [Describe any risks, including the likelihood of them occurring.] [(e.g., the possibility of psychological stress from being asked to recall and discuss prior trauma.)]. To reduce risk, [I/the study team] will [Describe the steps you will take to mitigate the risks.] [(e.g., monitor participants, discontinue the interview if needed, and contact you.)].

[If your study will involve direct communication with participants and you are a mandatory reporter, this must be disclosed as a risk to participants. Please include the following language:] [I am a mandatory reporter. During this study, if I receive information about child abuse, child neglect, elder abuse, or intent to harm self or others, I will be required to report it to the appropriate authorities.]

**How will personal information be protected?**

**Please read the below definitions before completing this section:**

**\*Anonymous** means **you, the researcher,** **will not be able** to link your data (e.g., survey responses, grades, etc.) to the specific participants who provided or are associated with the data. \***Confidential** means **you will be able** to link individual participants to the information they provide or are associated with, but you will not disclose participant identities or how named or identifiable individuals responded.

The records of this study will be kept private. [Include the following sentence if the data will NOT be anonymous.] [Published reports will not include any information that will make it possible to identify a subject.] Research records will be stored securely, and only the researcher[s] will have access to the records.

[Include the following in this section:]

* [Based on your study procedures and the definitions provided above, retain the applicable statement, and remove the inapplicable statement. If your study will involve both anonymous (e.g., an anonymous online survey) and confidential data (e.g., an interview and focus group), retain both statements and specify which forms of data will be applicable to each (e.g., Participant responses *to the online survey* will be anonymous.).] Participant responses [will be anonymous./will be kept confidential by replacing names with pseudonyms/numbers.]
* [Retain the following sentence if you plan to conduct interviews.] [Interviews will be conducted in a location where others will not easily overhear the conversation.].
* [Retain the following information if you will be conducting a focus group(s).] [Confidentiality cannot be guaranteed in focus group settings. While discouraged, other members of the focus group may share what was discussed with persons outside of the group.]
* [Include the following sentence if the data will NOT be anonymous and the possibility of using the data for future research or sharing the data with another/other researcher(s) exists. If neither is the case, you may delete it.] [Data collected from your [child/student] may be [used in future research studies] [and/or] [shared with other researchers]. If data collected from your [child/student] is reused or shared, any information that could identify your [child/student], if applicable, will be removed beforehand.]
* [Describe how and where data will be stored, who will have access to it, and if and how the data will be disposed of. If you will have both electronic and hardcopy data, include information associated with both.] Data will be stored [on a password-locked computer/in a locked [drawer/file cabinet]/etc.]. The [researcher/the researcher and members of [his/her] doctoral committee/the study team/etc.] will have access to the data. [After [three/five/seven] years, [all electronic records will be deleted] [and/or] [all hardcopy records will be shredded.]/Data will be retained indefinitely.] [**Note**: Data should be retained for at least three years after the completion of your study.]
* [Include the following if you will record participants. Describe where and for how long recordings will be stored, who will have access to them, and when they will be erased.] Recordings will be stored [on a password-locked computer/etc.]. The [researcher/the researcher and members of [his/her] doctoral committee/the study team/etc.] will have access to the recordings. [After [three/five/seven] years/once participants have reviewed and confirmed the accuracy of the recording transcripts], [the recordings will be [deleted/erased.]/Recordings will be retained indefinitely.]

**How will participants be compensated for being part of the study?**

\* You may delete this section if participants will not be compensated, and you prefer not to mention the possibility of compensation on this form.

\* Please note, the purpose of compensation is to reimburse participants for their time, effort, or actual costs (e.g., fuel used to travel to and from an interview) spent completing your study procedures.

\* If you do plan to compensate participants, include payment/reimbursement/incentive information here. If participants will receive class points or some other token, include that information here.

\* Include information about when participants will be compensated, the conditions of payment, and whether monetary benefits will be pro-rated if a participant does not complete the study. Because participation in research is voluntary and participants have the right to end their participation during the study if they so choose, if a study involves more than one procedure, compensation should be prorated or even staggered (e.g., $5 to $10 per procedure as opposed to receiving a single payment of $20 or $25 after all procedures are completed.)

\* If you are conducting an anonymous, online survey and plan to request participant email addresses using a platform that will pull participants’ email addresses from the survey for the purpose of compensation and provide them to you in a separate data sheet from the survey responses, include details about how this will occur.

\* If you will provide a meal, snack, or refreshments for your participants, include related information below.

Participants [will/will not] be compensated for participating in this study. [If participants will be compensated, include payment/reimbursement/incentive information. Otherwise, remove the remaining information in this paragraph.] [At the conclusion of the [survey/interview/focus group/each procedure/etc.] participants will receive [a $\_\_ [Chick-fil-A/etc.] gift card/set of colored pencils/etc.]. [If participants will not be compensated for each procedure, but compensation will instead be pro-rated, include the following sentence.] [Any participant who chooses to withdraw from the study after beginning but before completing all study procedures will receive [a $\_\_ [Chick-fil-A/etc.] gift card/etc.] [If you will be conducting an anonymous survey and plan to compensate participants, include information about how you will do so **without linking participants to their data**. Examples include using a survey platform that you can program to pull participant emails from the compensation response field and provide them to you in a separate data form from the survey responses, including a link at the end of the study survey to a separate survey where participant will enter their email addresses for compensation, or including instructions at the end of the survey for participants to email you if they wish to be compensated. ] [Email addresses will be requested for compensation purposes; however, they [will be pulled and separated from your [child’s/student’s] responses by the survey software/will be collected through a separate survey from the study survey/will be collected by email at the conclusion of the survey] to maintain your [child’s/student’s] anonymity.]

**What are the costs to be a part of the study?**

Delete this section if it is not applicable to the study.

For your [child/student] to participate in the research, [you/your child/student] will need to pay for [expected costs (e.g., parking)].

**Is the researcher in a position of authority over participants, or does the researcher have a financial conflict of interest?**

Include the above heading and applicable below statement if you are in a perceived or actual position of authority over your planned participants (e.g., You are a teacher, and participants will be students in the same district.), or you or the organization funding the study may receive a direct financial benefit from the study results (e.g., **Delete this section if it is not applicable to your study.**

[Option 1: Professional/Grading Authority] The researcher serves as [a leader/teacher/etc.] at [organization/school/etc.]. [Retain and revise the following sentence if your data collection will be anonymous. Otherwise, remove it.] [To limit a potential or perceived conflict, [Retain the applicable option.] [data collection will be anonymous, so I will not know who participated/your [child’s/student’s] teacher will ensure that all data is stripped of identifiers before I receive it.] This disclosure is made so that you can decide if this relationship will affect your willingness to allow your [child/student] to participate. No action will be taken against an individual based on her or his decision to allow his or her [child/student] to participate in this study.

[Option 2: Financial Interests] The researcher has a financial interest in the outcome of this study. The researcher [Retain the applicable option.] [is a [paid/unpaid] board member of the sponsoring organization/has stock in the sponsoring organization/is listed on a patent associated with this study/has received honoraria or travel reimbursement from the sponsoring organization during the last 12 months]. This study is funded by [sponsoring organization/firm/etc.]. [Sponsoring organization/firm/etc.] is providing [equipment/etc.] for the study. This disclosure is made so that you can decide if this relationship will affect your willingness to allow your [child/student] to participate in this study.

**Is study participation voluntary?**

The voluntary-participation wording **is required** for all research. Please review the options in red and select the appropriate options based on your study design.

Participation in this study is voluntary. Your decision whether to allow your [child/student] to participate will not affect your or [his/her/his or her] current or future relations with Liberty University [Include the name(s) of any other institution(s) associated with your study from whom you had to gain permission or IRB approval.] [or \_\_\_\_\_]. If you decide to allow your [child/student] to participate, [she/he/she or he] is free to not answer any question or withdraw at any time [Insert the following statement if you are **only** conducting an anonymous survey:] [prior to submitting the survey] [Delete the statement if your data collection includes additional/other procedures than an anonymous survey.] without affecting those relationships.

**What should be done if a participant wishes to withdraw from the study?**

The how-to-withdraw section **is required** for all research. Please review the above options and select the appropriate option based on your study design.

[Option 1: Anonymous Survey Research] If you choose to withdraw your [child/student] from the study or your [child/student] chooses to withdraw, please [Retain the following statement if the survey will be online.] [have [him/her/him or her] exit the survey and close [her/his/her or his] internet browser.]—OR—[Retain the following statement if the survey will be on pen and paper.] [inform the researcher that [you/your child/student] wish[es] to discontinue [his/her/his or her] participation, and [you/your child/student] should not submit the study materials.] Your [child’s/student’s] responses will not be recorded or included in the study.

[Option 2: All Other Research] If you choose to withdraw your [child/student] from the study or your [child/student] chooses to withdraw, please contact the researcher at the email address/phone number included in the next paragraph. Should you choose to withdraw [her/him/her or him] or should your [child/student] choose to withdraw, data collected from your [child/student] [Retain the following information in red if you are conducting a focus group.] [, apart from focus group data,] will be destroyed immediately and will not be included in this study. [Retain the following information in red if you are conducting a focus group.] [Focus group data will not be destroyed, but your [child’s/student’s] contributions to the focus group will not be included in the study if [you choose to withdraw [him/her/him or her]/[your child/student] chooses to withdraw.]

**Whom do you contact if you have questions or concerns about the study?**

If the researcher is a faculty member, the sponsor’s name and email information may be removed. Otherwise, **it is required**.

The researcher[s] conducting this study [is/are] [your name and the name(s) of any co-researcher(s)]. You may ask any questions you have now. If you have questions later, **you are encouraged** to contact [her/him/them] at [phone number and/or email]. You may also contact the researcher’s faculty sponsor, [name], at [email].

**Whom do you contact if you have questions about rights as a research participant?**

**Do not** remove or alter the IRB’s contact information or the disclaimer.

If you have any questions or concerns regarding this study and would like to talk to someone other than the researcher[s], **you are encouraged** to contact the IRB. Our physical address is Institutional Review Board, 1971 University Blvd., Green Hall Ste. 2845, Lynchburg, VA, 24515; our phone number is 434-592-5530, and our email address is irb@liberty.edu.

*Disclaimer: The Institutional Review Board (IRB) is tasked with ensuring that human subjects research will be conducted in an ethical manner as defined and required by federal regulations. The topics covered and viewpoints expressed or alluded to by student and faculty researchers are those of the researchers and do not necessarily reflect the official policies or positions of Liberty University.*

**Your Opt-Out**

If you would prefer that your child NOT PARTICIPATE in this study, please sign this document, and return it to [your child’s teacher/school office/etc.] by [date]. If you consent to your child’s participation, do not sign and return this document.

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Printed Child’s/Student’s Name

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Parent/Guardian’s Signature Date