NC STATE UNIVERSITY

Parental Permission Form for Research Participation

Title of Study: <Insert title of study>
IRB Protocol <Insert eIRB number>
Principal Investigator(s): <insert name, NC State University email, and phone number>
Funding Source: <insert funding source or, if no funding, state None>
NC State Faculty Point of Contact: <insert name, email, and office phone number or delete faculty point of contact if the PI is NC State faculty>
Collaborating Researchers: <insert institution/organization name and their affiliated researcher(s) name, email, and phone number. Delete this section if there are no collaborators>

Your child is invited to take part in a research study. Here are some important things to know:

- Your child's participation in this study is voluntary. You can choose for your child to not participate without penalty. If you decide your child can participate and change your mind later, your child can stop participating at any time without penalty.
- The purpose of this research study is <describe purpose>.
- Your child will be asked to <briefly summarize your procedures and indicate estimated study time. One to two sentences is enough>.
- Your child is not guaranteed any personal benefits from being in this study. Research studies may pose risks to those who participate.
- You may want your child to participate in this research because <discuss why>. You may not want your child to participate in this research because <discuss why not>.
- If you have questions about your child's participation in this research at any time, do not hesitate to contact the researcher(s) named above.
- If you have questions about your child's rights as a research participant, do not hesitate to contact the NC State University IRB office via email at IRB-Director@ncsu.edu or via phone at 1-919-515-8754.

Please read the rest of this consent form for more specific details of this research. If you do not understand something, please ask the researcher for clarification or more information.

What is the purpose of this study?
The purpose of the study is <briefly describe purpose, 1-2 sentences>.

How many children will be in the study?
There will be approximately <insert estimated participant range> participants in this study.

Is my child eligible to be a participant in this study?
To be a participant in this study, your child must agree to be in the study and <insert inclusion criteria>.

Your child cannot participate in this study if they do not meet the inclusion criteria or <insert exclusion criteria>.

What will happen if your child takes part in the study?
If you agree, your child will be asked to do all of the following:

1. <Insert procedures>
2. <Add as many numbers as needed to describe your procedures>

The total amount of time that your child will be participating in this study is <insert time>.

The following procedures are experimental: <explain any experimental procedures in lay language>.

This study is a clinical trial. A description of it will be available on www.clinicaltrials.gov, as required by U.S. law. A summary of this study's results will be posted to this website a year after the study is completed. However, it will not include any information that can directly identify your child. You can search the clinical trials website at any time to review this study's results once they are posted.

This study involves testing the safety or efficacy of a medical device or testing a medical device for a new indication for use. The <select one: approved or unapproved> medical device is called <insert name of device> and its primary function is <insert primary function information.> The medical device is <select one: commercially available or not yet commercially available and designed by the researchers>. The institutional review board at NC State University, who is responsible for reviewing projects that involve human participants, has reviewed this project and determined that the device being studied is considered a "Not Significant Risk" device.

Recording in research
Participants will <select: be photographed, have their screen recorded, be audio recorded, be video recorded, be audio and video recorded, have their body scanned, have their movement tracked, have their physical activity logged, have their online activity recorded> during the research activities. If you do not want this information collected about your child, they cannot participate in this research.

OR

The research team would like to record your child for research purposes if you agree. The recording will only occur while your child is participating in research activities.
Please <initial next to/select> the sentence(s) that you agree to:
_____ It's okay to photograph my child
_____ It's okay to record my child's computer screen

_____ It's okay to record my child's online activity
_____ It's okay to audio record my child
_____ It's okay to video record my child
_____ It's okay to record audio and video of my child
_____ It's okay to scan my child's body
_____ It's okay to track my child's movement

<I or We> would like to use <these recordings and/or your image> for <describe how you want to use them, e.g., transcription only, sharing audio snippets, their images>. <I or We> will keep these <recordings/images> for <describe how long, e.g. until transcriptions have been verified, at least XX years, indefinitely, etc.>.

Benefits to participating in this research

The direct benefits to your child because of their participation in this research include: <insert the direct benefits>.

OR

There are no direct benefits to your child because of their participation in the research. The indirect benefits are <insert the indirect benefits>.

Risks to participating in this research

There is minimal risk associated with your child's participation in this research.

OR

The risks to your child as a result of participating in this research include <insert risks identified in the IRB application>. These risks are mitigated through <insert details as to how the risks to participants are mitigated>

Researcher obligations

Due to <identify why you are a mandatory reporter (e.g., your professional role as XXX, local/state/federal reporting requirements, etc.>, I have an obligation to report <select or insert what applies (e.g., child neglect and abuse, sexual abuse of an adult ages 28 years old or younger, elder neglect and abuse, sexual discrimination and harassment of students, etc.)>. This means that if I observe instances of, or your child tells me about <insert in lay terms topics that would lead to reporting>, I am obligated to report that information to the appropriate authorities. The risks associated with reporting this information include <insert possible risks to reporting>.

In the rare case that a member of the research team is exposed to your child's blood, your child's blood will be anonymously tested for HIV and hepatitis. This test and the results will not show up in your child's medical records. Though the exposed research team member may know your child, the results of these tests will be anonymous and cannot be reported back to you or your child in accordance with the law."

Emergency medical treatment

If your child is hurt or injured during the study session(s), the researcher will call 911 for necessary care. There is no provision for compensation or free medical care for your child if they are injured because of this study.

Other options

Instead of participating in this research, there are alternative procedures and courses of treatment available to your child. These include <insert text>.

What data will be collected about my child and are there risks associated with that?

The data that are collected about your child include <insert summary of data points>. These data are <select one: directly identifiable, indirectly identifiable, not connected to your child's name or other information that could easily identify either or you, or anonymous>. The risks to your child as a result of collecting this information include <insert relevant risks>. These risks will be mitigated through implementing data protections in accordance with NC State University data protection standards.

This study includes the collection of your child's student records. <I or we> will collect <list all types of student records and data categories accessed>. The purpose of collecting these student records is <list all uses/purposes of the records>. This information will be accessible to <list who can access data-e.g., members of the research team, transcription service, etc.>. The dataset will remain <select one: directly identifiable, indirectly identifiable, de-identified, or anonymous>.

How will my child's identity and the data about them be stored and protected?

After all data is collected, the researchers will go through the data and <select one: remove all direct and indirect identifiers so that the dataset can no longer be connected to your child's identity OR remove all direct and indirect identifiers from the dataset and create a coded list that connects your child's real identity to the dataset OR remove all direct identifiers and retain indirect identifiers with the data>.

This master list connecting code names to real IDs will be stored separately from the data. After the study is over, <I or we> will <select one: permanently delete the master list OR we will retain the master list for __ years>. <Select one: It is unlikely your identity could be deduced from your responses in the dataset without the master list OR it may still be possible for someone to recognize you from your responses>.

<I or We> will go through <select what applies: your responses, the transcripts, etc.> and do <my or our> best to remove or replace any information that can identify you directly. Examples of the information <I or we> will remove are <give examples>. After <I or we> do this, <select one: it may still be possible for someone to recognize you or your child from your child's responses OR it is unlikely your child's identity could be deduced from their data>.

Who can access my child's data and how will their data be shared and used in the future?

For administrative purposes, <I or we> may share you or your child's name with <insert funder, NC State University Accounting/HR, etc.>. The information <I or we> share with them <will/will not> be associated with your child's individual identifiable data.

This study is subject to the FDA regulations because it is <select one: testing a medical device for safety and efficacy or testing a drug or biologic.>. As a result, the FDA or their designee, may review all research information about your child. Should this occur, the FDA representative will comply with applicable confidentiality measures.

Because this study is funded by the NIH, data about your child including <insert data such as whole genome, genomic data such as ___, or other data points> will be shared with the larger research community. Your child's data will not be directly identifiable, but <I or we> cannot guarantee anonymity now or in the future.

Your child's data, with direct identifiers removed, will be stored, used, and shared with others for future research studies without additional consent from you or your child. This may include sharing your child's individual de-identified data with other researchers, journals, data repositories, and/or funding sources.

OR

Your child's data will not be used or shared for future research studies. <I or We> will delete your child's data after <insert time period or range, e.g., the regulations indicate at least 3 years>.

OR

<I or We> would like to keep, use, and share your child's individually identifiable data with others for future unspecified research. To do this, <I or we> need your additional consent which can be found after this document. If you do not provide additional consent, then any data about your child that we store, use, and share with others for future research will not be identifiable.

How will data about my child be reported to the public? Are there risks associated with that?

Your child will be easily recognized by the way <I or we> report the results from our study in publications, presentations, etc. This is because <insert why they are easily recognizable>. As a result of how <I or we> share information about your child, the possible risks to your child, you, or others you know include <insert risks of being associated with the study or having their data directly identifiable>

OR

Even though <I or we> will not directly identify your child when <I or we> share the results of <my or our> study, it's still possible someone could figure out who your child is from the information <I or we> will include. This is because <I or we> will report the data

like <state how you will report the data such as N size or specific demographics and stories>. Because of that, someone may be able to re-identify your child from the project because of <state how they could be re-identified in publications>. As a result of possible re-identification, the risks to your child, you, or others you know include <insert risks of being associated with the study or having their data possibly re-identifiable>.

OR

<I or We> will not include your child's individual responses, such as quotes or specific answers, when <I or we> share the results of our study. Instead, the data will be aggregated or reported as summary statistics. As a result, there are minimal risks to your child as a result of how we report the data.

OR

<I or We> may quote your child or share specific responses from your child in study publications and presentations but <I or we> will not include your child's name or any other information that could easily identify your child. As a result, there are minimal risks to your child as a result of how <I or we> report the data.

If your child is physically in the European Economic Area (EEA)

The GDPR is a European law that details conditions under which it is lawful to collect, use, disclose or process personal data. For this research project, the information being <collected/processed> is <explain the personal and pseudonymized data you're using for research purposes]. [Insert name of researcher> is collecting this data and you can find their contact information at the top of this form.

This information is <collected/processed> by <insert method>. The reason this is being <collected/processed> is <explain why you need the data to answer your research question>. One lawful basis for doing so is your consent. The information will be used for <insert time frame> and will be used for research purposes. The data will be stored for <insert time frame> and the data will be shared with <insert information about with whom data will be shared>. The information will <not> be shared with someone in another country under the lawful basis of your consent and the legitimate interest of research. If the data is shared, it will be shared in <select one: an identifiable format, a format where it's possible to guess who you are, or a completely de-identified format>.

The effect of the <collection/processing> of this data to your child is <explain the possible effect(s) for participants>. The use of your child's information is unlikely to cause harm to your child. If you would like to request access to the information from this project about your child, rectify the information about your child, or remove all of your child's information from this research project, you may do so by contacting the researcher named above unless it is impossible to identify your child's information amongst the other data. The EEA representative that you may contact is <insert individual's name, professional email, and office phone number>.

Right to withdraw your child's participation

Your child's participation is voluntary. Even if you and your child agree initially, consent is an ongoing process. Your child can stop participating at any time for any reason. To do so, <talk about the immediate ways they can withdraw, e.g., close their internet browser, tell the researcher implementing the intervention, etc.>. You can also contact the <student> researcher, <insert name>, at <insert NC State email address> and [insert phone number]. Or you can contact the faculty advisor for this research, <insert name>, at <insert NC State email address> and <insert office phone number>.

If your child withdraws from the study, <I or we> will stop any procedures or data collection that may be happening. <I or We> will also delete any data that's already been collected from your child whenever possible. <I or We> will not be able to delete your data if <I or we> cannot identify which responses are your child's or if the data has already been published. <If applicable, specify when you're de-identifying the data and indicate that after this point, you may not be able to identify which responses are theirs>.

Compensation

There is no compensation for participating in this study.

OR

For your child's participation in this study, they will receive <insert compensation>. If your child withdraws from the study before it ends, your child will <describe whether they will receive any compensation if they withdraw early>.

What if your child is a student?

Your child's participation in this study is not a class requirement. Your child's participation or lack thereof will not affect your child's class standing, grades, or relationship with their instructors or advisors.

What if you are an employee?

Your child's participation in this study is not a requirement of your employment. Your participation or lack thereof will not affect your job.

Research collaborations

This research project is a cooperative effort <select one: between or among> the following entities: <insert names of all participating entities such as universities and organizations>.

Sponsorship and funding

This research is funded by <insert name of funder/sponsor>. This means that the sponsor is paying the research team for completing the research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. If you would like more information, please ask the researcher(s) listed at the top of this form about the funding and sponsorship.

NC STATE UNIVERSITY

Inventions and patents

<Insert name> is an inventor of <insert information> that is part of this research <note if being evaluated, being used, etc.>. <Insert name> is also a part owner of <insert information> to whom the patent for <insert information> has been licensed. If the technology is licensed at NC State University, a ICF disclosure in Sophia (the Office of Research Commercialization database at the University) must state that the University and the inventor may benefit from the invention. If this patent or approach is successful at some point in the future, NC State University and <insert name> may receive financial benefits. If you would like more information, please ask the researcher(s) listed at the top of this form.

What if you have questions about this study?

If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the <student> researcher, <insert name>, at <insert NC State email address> and <insert phone number>. You can also contact the faculty advisor for this research, <insert name>, at <insert NC State email address> and <insert office phone number>.

What if you have questions about your child's rights as a research participant?

If you feel your child has not been treated according to the descriptions in this form, or their rights as a participant in research have been violated during the course of this project, you may contact the NC State IRB (Institutional Review Board) office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State University IRB office at IRB-Director@ncsu.edu, 919-515-8754, or fill out a confidential form online at https://research.ncsu.edu/administration/participant-concern-and-complaint-form/

Consent for your child to participate

By signing this consent form, I am affirming that I have read the above information. All of the questions that I had about this research have been answered. If I give permission for my child to participate, I understand that my child can stop participating at any time without penalty or loss of benefits to which they are otherwise entitled. I am aware that I may revoke my permission for my child to participate in research at any time.

☐ **Yes, I give permission for my child to be in this research study.**

Name: _____
Today's Date: _____
Child's Name: _____

☐ **No, I do not want my child to be in this research study.**
Thank you for your consideration.

NC STATE UNIVERSITY

Parental Permission Form for the Use of Secondary Data in Research

Title of Study: <Insert title of study>
IRB Protocol <Insert eIRB number>
Principal Investigator(s): <insert name, NC State University email, and phone number>
Funding Source: <insert funding source or, if no funding, state None>
NC State Faculty Point of Contact: <insert name, email, and office phone number or delete faculty point of contact if the PI is NC State faculty>
Collaborating Researchers: <insert institution/organization name and their affiliated researcher(s) name, email, and phone number. Delete this section if there are no collaborators>

Your child is invited to take part in a research study. Here are some important things to know:

- Your child's participation in this study is voluntary. You can choose for your child to not participate without penalty. If you decide your child can participate and later change your mind, your child can stop participating at any time without penalty unless all of the data has been de-identified or published.
- The purpose of this research study is <describe purpose>.
- You are asked to allow your child's information from <insert the activity that the information will be accessed and used from> to be used as data for research purposes.
- You and your child are not guaranteed any personal benefits from allowing your child's information to be used as data in this study.
- Research studies may pose confidentiality risks to those who participate.
- You may want to allow your child's information to be used as data in this research because <discuss why>.
- You may not want to allow your child's information to be used as data in this research because <discuss why not>.
- If you have questions about your child's participation in this research at any time, do not hesitate to contact the researcher(s) named above.
- If you have questions about your child's rights as a research participant, do not hesitate to contact the NC State IRB office via email at IRB-Director@ncsu.edu or via phone at 1-919-515-8754

Please read the rest of this consent form for more specific details of this research. If you do not understand something, please ask the researcher for clarification or more information.

What is the purpose of this study?
The purpose of the study is <briefly describe purpose, 1-2 sentences>.

How many children will be in the study?

Information from approximately <insert estimated participant range> children will be used as data for research in this study.

Is my child eligible to be a participant in this study?
In order to be a participant in this study, you must agree to allow your child's information to be used as data for research purposes and <insert inclusion criteria>.

What will happen if your child takes part in the study?
If you agree that your child can participate in this study, you will be asked to allow the following information about your child to be used as data for research:

1. <List all data categories that will be used for research such as age, race, zip code, address, full name, email, GPA, ACT, medical ID, student ID number, etc.> from <insert record type> record.
2. The purpose of accessing these records is <list all uses/purposes of the accessed records>.
3. This information will be accessible to <list who can access data - e.g., members of the research team, transcription service, etc.>.
4. The information that you agree to share about your child for research will be combined with other information that could re-identify your child from the data.
5. Once a dataset is created, the dataset will remain <select one: directly identifiable, indirectly identifiable, de-identified with a master list linking codes to your child's identity, or de-identified with no master list linking codes to your child's identity>.

Benefits to your child for participating in this research
The direct benefits to your child as a result of allowing their information to be used as data in this research include: <insert the direct benefits>.

OR

There are no direct benefits to your child for allowing their information to be used as data in the research. The indirect benefits are <insert the indirect benefits>.

Risks to your child participating in this research
There is minimal risk associated with allowing your child's information to be used as data in this research.

OR

The risks to your child as a result of allowing their information to be used as data in this research, include <insert risks identified in the IRB application>. These risks are mitigated through <insert details as to how the risks to participants are mitigated>

Researcher obligations
Due to <identify why you are a mandatory reporter (e.g., your professional role as XXX, local/state/federal reporting requirements, etc.>, I have an obligation to report <select or

insert what applies (e.g., child neglect and abuse, sexual abuse of an adult ages 28 years old or younger, elder neglect and abuse, sexual discrimination and harassment of students, etc.)>. This means that if in reviewing the information <I or we> notice <insert in lay terms topics that would lead to reporting>, <I am or we are> obligated to report that to the appropriate authorities. The risks associated with reporting this information include <insert possible risks to reporting>.

What are the risks associated with the information accessed about my child?
The risks to your child as a result of allowing their information to be used as research data include <insert relevant risks>. These risks will be mitigated through implementing data protections in accordance with NC State University data protection standards.

Who can access my child's data and how will their data be shared and used in the future?
For administrative purposes, <I or we> may share your child's name with <insert funder, NC State University Accounting/HR, etc.>. The information <I or we> share with them <will/will not> be associated with your child's individual identifiable data.

Because this study is funded by the NIH, data about your child including <insert data such as whole genome, genomic data such as ___, or other data points> will be shared with the larger research community. Your child's data will not be directly identifiable but <I or we> cannot guarantee anonymity now or in the future.

Your child's data, with direct identifiers removed, will be stored, used, and shared with others for future research studies without additional consent from you or your child. This may include sharing your child's individual de-identified data with other researchers, journals, data repositories, and/or funding sources.

OR
Your child's data will not be used or shared for future research studies. <I or We> will delete your data after <insert time period or range, e.g., the regulations indicate at least 3 years>.

OR
<I or We> would like to keep, use, and share your child's individually identifiable data with others for future unspecified research. In order to do this, <I or we> need your additional consent, which can be found after this document. If you do not provide additional consent, then any of your child's data that we store, use, and share with others for future research will not be identifiable.

How will data about my child be reported to the public? Are there risks associated with that?
Your child will be easily recognized by the way <I or we> report the results from our study in publications, presentations, etc. This is because <insert why they are easily recognizable>. As a result of how <I or we> share information about your child, the

possible risks to your child, you, or others you know include <insert risks of being associated with the study or having their data directly identifiable>.

OR

Even though <I or we> will not directly identify your child when <I or we> share the results of the study, it's still possible someone could figure out who your child is from the information <I or we> will include. This is because <I or we> will report the data like <state how you will report the data such as N size or specific demographics and stories>. Because of that, someone may be able to re-identify your child from the project because of <state how they could be re-identified in publications>. As a result of possible re-identification, the risks to your child, you, or others you know include <insert risks of being associated with the study or having their data possibly re-identifiable>.

OR

<I or We> will not include your child's individual responses, such as quotes or specific answers, when <I or we> share the results of the study. Instead, the data will be aggregated or reported as summary statistics. As a result, there are minimal risks to your child as a result of how we report the data.

OR

<I or We> may quote your child or share specific responses from your child in the study publications and presentations but <I or we> will not include your child's name or any other information that could easily identify your child. As a result, there are minimal risks to your child as a result of how we report the data.

If your child is physically in the European Economic Area (EEA)

The GDPR is a European law that details conditions under which it is lawful to collect, use, disclose or process personal data. For this research project, the information being <accessed/processed> is <explain the personal and pseudonymized data you're using for research purposes]. [Insert name of researcher> is collecting this data and you can find their contact information at the top of this form.

This information is <accessed/processed> by <insert method>. The reason this is being <accessed/processed> is <explain why you need the data to answer your research question>. One lawful basis for doing so is your consent. The information will be used for <insert time frame> and will be used for research purposes. The data will be stored for <insert time frame> and the data will be shared with <insert information about with whom data will be shared>. The information will <not> be shared with someone in another country under the lawful basis of your consent and the legitimate interest of research. If the data is shared, it will be shared in <select one: an identifiable format, a format where it's possible to guess who your child is, or a completely de-identified format>.

The effect of the <access/processing> of this data to your child is <explain the possible effect(s) for participants>. The use of your child's information is unlikely to cause harm to them. If you would like to request access to the information from this project about your child, rectify the information about your child, or remove all of your child's information from this research project, you may do so by contacting the researcher named above unless it is impossible to identify your child's information amongst the other data. The EEA representative that you may contact is <insert individual's name, professional email, and office phone number>.

Right to withdraw your child's participation

Your child's participation is voluntary. Even if you agree initially, consent is an ongoing process. Your child can stop participating at any time for any reason. To do so, <talk about the immediate ways they can withdraw their permission to use their child's information as data>.

If you withdraw your child from the study, <I or we> will remove your child's information from the dataset. <I or We> will not be able to delete your child's data if <I or we> cannot identify which responses are your child's or if the data has already been published.

Compensation

There is no compensation for allowing your child's information to be used as data in this study.

OR

For allowing your child's information to be used as data in this study, your child will receive <insert compensation>. If your child withdraws from the study before it ends, your child will <describe whether they will receive any compensation if they withdraw early>.

What if your child is a student?

Allowing your child's information to be used as data in this research is not a class requirement. Your child's participation or lack thereof will not affect their class standing, grades, or relationship with their instructors or advisors.

What if you are an employee?

Allowing your child's information to be used as data in this research is not a requirement of your employment. Your child's participation or lack thereof will not affect your job.

Research collaborations

This research project is a cooperative effort <select one: between or among> the following entities: <insert names of all participating entities such as universities and organizations>.

Sponsorship and funding
This research is funded by <insert name of funder/sponsor>. This means that the sponsor is paying the research team for completing the research. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study. If you would like more information, please ask the researcher(s) listed at the top of this form about the funding and sponsorship.

What if you have questions about this study?
If you have questions at any time about the study itself or the procedures implemented in this study, you may contact the <student> researcher, <insert name>, at <insert NC State email address> and <insert phone number>. You can also contact the faculty advisor for this research, <insert name>, at <insert NC State email address> and <insert office phone number>.

What if you have questions about your child's rights as a research participant?
If you feel your child has not been treated according to the descriptions in this form, or your child's rights as a participant in research have been violated during the course of this project, you may contact the NC State University IRB (Institutional Review Board) office. An IRB office helps participants if they have any issues regarding research activities. You can contact the NC State IRB office at IRB-Director@ncsu.edu, 919-515-8754, or fill out a confidential form online at https://research.ncsu.edu/administration/participant-concern-and-complaint-form/

Consent for your child to participate
By signing this consent form, I am affirming that I have read the above information. All of the questions that I had about this research study have been answered. If I consent for my child to participate, I understand that I can stop my child's participation at any time without penalty or loss of benefits to which my child is otherwise entitled. I am aware that I may revoke my consent for my child to participate in this research study at any time.

☐ **Yes, I give permission for my child to be in this research study.**

Name:_____
Today's Date: _____
Child's Name: _____

☐ **No, I do not want my child to be in this research study.**
Thank you for your consideration.