**Title of research study:** [insert title of research study here with protocol number, if applicable]

We are contacting you because you ***[are participating/have participated]*** in this research study. When you agreed to participate, we told you we would share any new information about the study that might affect your willingness to continue to participate, and we have new information to share with you.

***What has changed about this study?***

* ***Describe any new information and/or procedures.***
* ***Describe any new risks, potential risks, or increased frequency or severity of previously known risks that could result from continued participation in the study and/or participating in the new procedures.***
* ***Describe any new information that doesn’t fit into one of the two sections above (e.g. a new Conflict of Interest)***

***What are my rights if I decide to continue to take part in this study?***

Continuing to take part in this study is your choice. You can choose to continue to participate in this study or to withdraw. If you would like to explore your options for withdrawal or alternatives to participating in research, please contact the research team as described below. Whatever decision you make, there will be no penalty to you and you will not lose any of your regular benefits.

***Who can I contact if I have questions about continuing in this study?***

**The Research Team:**

You may contact the following researchers with any questions or concerns about the new information in this consent or your continued participation in this study: ***[Insert the name(s) and phone number(s) of the appropriate investigators.]*** You can also call the UC Davis Page Operator at (916-734-2011) to reach ***[insert name(s)]*** 24 hours a day, 7 days week.

**UC Davis Institutional Review Board:**

If you have questions about your rights while taking part in this study, or you have concerns or suggestions and you want to talk to someone other than the researchers about the study, you may contact the UC Davis IRB at (916) 703-9158, hs-irbeducation@ucdavis.edu, or 2921 Stockton Blvd, Suite 1400, Room 1429, Sacramento, CA 95817

***How do I indicate my agreement to continue to participate?***

If you want to continue to participate in this research study, you should ***[let the study team know/sign and date below]***. You will be given a copy of this consent form addendum to keep.

**Signature Block for Capable Adult**

|  |
| --- |
| Your signature documents your permission to take part in this research. |
|  |  |  |
| Signature of subject |  | Date |
|  |  |
| Printed name of subject |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Adult Unable to Consent**

|  |
| --- |
| Your signature documents your permission for the named subject to take part in this research. |
|  |  |  |
| Printed name of subject |  |  |
|  |  |  |
| Signature of legally authorized representative |  | Date |
|  |  |
| Printed name of legally authorized representative |
|  |  |  |
| Signature of person obtaining consent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

***[Add the following block if you will document assent of the subject.]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the subject is so limited that the subject cannot reasonably be consulted.
 |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |

**Signature Block for Children**

|  |
| --- |
| Your signature documents your permission for the named child to take part in this research. |
|  |  |
| Printed name of child |
|  |  |  |
| Signature of parent or individual legally authorized to consent to the child’s general medical care |  | Date |
|  | * Parent
* Individual legally authorized to consent to the child’s general medical care (See note below)
 |
| Printed name of parent or individual legally authorized to consent to the child’s general medical care |
| **Note:** Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s general medical care. Contact legal counsel if any questions arise. |
|  |  |  |
| Signature of parent |  | Date |
|  |  |
| Printed name of parent |
| If signature of second parent not obtained, indicate why: (select one) |
| * The IRB determined that the permission of one parent is sufficient. ***[Delete if the IRB did not make this determination]***
* Second parent is deceased
* Second parent is unknown
 | * Second parent is incompetent
* Second parent is not reasonably available
* Only one parent has legal responsibility for the care and custody of the child
 |

***[Add the following block if you will document assent of children]***

|  |  |
| --- | --- |
| Assent | * Obtained
* Not obtained because the capability of the child is so limited that the child cannot reasonably be consulted.
* Waived by the IRB because the intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
 |

 ***[Add the following block to all consents]***

|  |  |  |
| --- | --- | --- |
|  |  |  |
| Signature of person obtaining consent and assent |  | Date |
|  |  |  |
| Printed name of person obtaining consent |  |  |

 ***[Add the following block if a witness will observe the consent process. E.g., short form of consent documentation or illiterate subjects.]***

|  |
| --- |
| My signature below documents that the information in the consent document and any other written information was accurately explained to, and apparently understood by, the subject, and that consent was freely given by the subject. |
|  |  |  |
| Signature of witness to consent process |  | Date |
|  |  |
| Printed name of person witnessing consent process |