**Mail-out Correction Letter Template**

**For studies that interact with subjects by mail, this letter template is intended for use when consent documents, questionnaires, or other study materials must be returned to the subject for corrections.**

* **If the consent process for the study will be conducted by mail, use of this letter must be described, as applicable, in Sections VII.D.29 and VII.D.30 of the HawkIRB application.**
* **If questionnaires or sample collection kits will be mailed to subjects as part of study procedures, and the research team needs to return these items to the subject for corrections, if received incomplete or in error, the use of this letter must be described in Section VII.E.6.**
* **In addition, if a questionnaire/survey is returned with unanswered question(s) or incomplete response(s), Section VII.E.6 should describe any follow up. Specifically, describe if the research team will contact the subject by phone or will use this letter to notify the subject of the incomplete response(s) and allow the subject to complete the response(s) or verify that s/he intended to leave the incomplete response(s). However, because subjects are free to skip any question(s)/item(s) they prefer not to answer, it is not appropriate to send this letter in reference to unanswered question(s) more than once.**
* **A plan describing the use of this letter, any additional materials that will be sent, or phone calls that will be made to subjects must be included in HawkIRB. See the Guide for Human Subjects Research and the Help Icons in Sections VII.D.29, VII.D.30 and VII.E.6 of the HawkIRB application for further details.**

**Edit this document to address the specifics of the research study, including all potential scenarios that may require corrections and submit for IRB review and approval:**

* **Choose the applicable sections of this letter and options contained in brackets as they apply the study and revise as appropriate. (For instance, if the study is NOT collecting biological specimens, delete all references to biological specimen/sample collection.)**
* **Delete all other options that do not apply.**
* **A generic section to correct errors that may not have been anticipated or addressed in other sections is included. If this section is retained, it should be completed by the research team at the time the letter is sent.**
* **Remove all text in blue.**
* **Upload the letter to the Attachments Tab in the HawkIRB application under the Miscellaneous category.**
* **Do not include the IRB approval stamp place holder on this letter template**

Dear [**Subject or Parent Name**]:

Thank you for participating in our research project **[include the title of the project or descriptor of the study]**. We appreciate your time.

We recently received [**your/your child’s**] [**Informed Consent Document/questionnaire/survey/sample collection kit**] in the mail. Upon review, we noticed [**a problem/a few problems**] with the [**consent form/questionnaire/survey/sample**].

**Select the appropriate statement(s) from the following and delete those that do not apply.**

To ensure the Informed Consent Document is correct and accurately represents your choices, we ask you to review the sections of the original consent that are outlined below.

The IRB approved a newer version of the Informed Consent Document after you signed and returned the consent document we initially mailed you. Therefore, please review the new version we have enclosed with this letter. If you are still interested in participating, please complete the new consent, sign and date with today’s date*.*

The questionnaire/survey/sample is [**describe the deficiency**].

* **If a questionnaire/survey is returned with unanswered question(s)/incomplete response(s), the research team may use this letter to inform the subject of this and allow the subject to respond to these item(s) or verify the subject intended to leave the incomplete response(s). However, because subjects are free to skip any question(s)/item(s) they prefer not to answer, it is not appropriate to send this letter in reference to unanswered questions/incomplete response(s) more than once.**

**Select the** **description of area(s) in the Informed Consent Document needing revision from the following and delete those that do not apply.**

* **If the consent document instructs subjects to initial the optional agreements, leave the first statement and choose *[initials]* in the next two statements.**
* **If the consent document does not specify initialing the boxes, delete the 1st statement in each section and choose the [*‘an X’ option*] in the next 2 statements:**

**In the optional agreement for [applicable section *(e.g.,* Video Recording, Tissue for Future Use, Future Contact)] on page(s) \_\_\_\_:**

You placed an “x” or another mark to indicate your choice(s) instead of your initials; please initial next to your mark.

If your intention is to participate in **[applicable section],** please place [**an X/your initials**] in the space provided next to the “Yes” option.

If you do not want to participate in [**applicable section**], please place [**an X/your initials]** in the space provided next to the “No” option.

**For studies involving genetic testing select the appropriate section(s) and delete those that do not apply:**

**In the genetic testing section explained on page(s) \_\_\_\_\_:**

**The following statements pertain to participating in genetic testing:**

You placed an “x” or another mark to indicate your choice(s) instead of your initials; please initial next to your mark.

If your intention is to participate in genetic testing by providing a saliva sample, please place **[an X/your initials]** in the space provided next to the “Yes” option.

If you do not want to participate in genetic testing, please place **[an X/your initials]** in the space provided next to the “No” option.

**The following statements pertain to storing genetic samples for future gene research:**

You placed an “x” or another mark to indicate your choice(s) instead of your initials; please initial next to your mark.

If you would like to participate in genetic testing and allow us to store your sample for future gene research after our use, please place **[an X/your initials]** in the space next to “Yes”.

If you would like to participate in genetic testing but would like your sample destroyed after it is used for this study, please **[an X/your initials]** in the space next to “No”.

**The following statements pertain to storing genetic samples for future research in another area specified in the consent document:**

You placed an “x” or another mark to indicate your choice(s) instead of your initials; please initial next to your mark.

If you would like to participate in genetic testing and allow us to store your sample for possible future [**specify the type]** research, please place [**an X/your initials**] in the space next to “Yes”.

If you would like to participate in genetic testing but would not like your sample used for future [**specify the type**] research, please place [**an X/your initials]** in the space next to “No”.

**The following statements pertain to storing genetic samples for future medical research in general:**

You placed an “x” or another mark to indicate your choice(s) instead of your initials; please initial next to your mark.

If you would like to participate in genetic testing and allow us to store your sample for future medical research in general, please place [**an X/your initials]** in the space next to “Yes”.

If you would like to participate in genetic testing but would not like your sample used for future medical research, please place [**an X/your initials**] in the space next to “No”.

**In the signature section on page(s) \_\_\_\_\_ :**

**Select the appropriate statement(s) and delete those that do not apply.**

**The following statements pertain when the subject is an adult.**

Because you are providing us with [**information/a sample]**, you are considered a subject in our study. For this reason, please print your name on the ‘Subject’s Name (printed)’ line.

Please sign your name on the ‘Signature of Subject’ line and enter today’s date on the ‘Date’ line.

**The following statements pertain when the subject is a minor.**

Because [**individual to be enrolled]** is a minor, the subject signature blocks must be completed by both [**individual to be enrolled]** and the parent/legal guardian of **[individual to be enrolled].**

Therefore, please have [select one or both of the following as applicable]

[**individual to be enrolled]**

* print [**his/her]** name on the ‘Subject’s Name (printed)’ line and
* sign [**his/her]** name on the ‘Signature of Subject’ line and
* enter today’s date on the ‘Date’ line

**[and]**

[**one/both parent(s)]**

* print [**his/her/their]** name and
* sign [**his/her/their]** name and
* enter today’s date in the parent signature block section.

**The following statements pertain when the subject is cognitively impaired and a legally authorized representative has provided consent.**

Because [**individual to be enrolled]** is cognitively impaired, the subject signature blocks must be completed by the legally authorized representative (LAR) of **[individual to be enrolled]**

Therefore, please have the **[LAR]**

* print the subject’s name on the ‘Subject’s Name (printed)’ line and
* print **[the LAR]** name and
* sign [**the LAR]** name and
* enter today’s date in the LAR signature block section

**This following section may be included to address unforeseen scenarios and should be completed by a member of the research team at the time of use.**

**Other:** **In the** [**indicate the section and page of Informed Consent Document/questionnaire/survey and/or describe the problem noted with the sample/collection kit. (in bold)]**

If your changes mean you need to cross something out, please draw a single line through it, place your initials, and today’s date next to the line.

If you should have any questions about this letter, the [**consent form/questionnaire/survey/sample**] or the items we have asked you to review, please contact [**research team contact name and number]***.* We would be pleased to speak with you to make sure that **[your choices are accurately represented on the consent form/your responses on the [questionnaire/survey] are complete and accurate/your sample is adequate**].

When you are finished and are satisfied with the changes you have made, please return the [**consent document/questionnaire/survey/sample]** in the enclosed pre-addressed, stamped envelope.

Again, thank you for your contribution to our study. The time and effort you have taken to volunteer are greatly appreciated.

Sincerely,

**Research team contact name and phone number**