

INSTRUCTIONS FOR UNSIGNED (VS. SIGNED) PERMISSION AND ASSENT FORMS

1) **PERMISSION:** If you wish to obtain *verbal* or *online* unsigned permission instead of signed (written/ documented) permission:

a. **For Verbal Permission:**

-In the protocol, you must apply for waiver of signed permission. Go to the **Child Assent & Parent/ Guardian Permission** section; under the **Documents & Waivers** tab, in the pop-up box for **Assent/Permission Description**, click on Assent or Permission Type field and select “*Unsigned Parent/Guardian Permission Form*” (or “*Altered and Unsigned Parent/Guardian Permission Form*” if appropriate). Select Criterion A or B for waiver justification and answer questions asked in the box.

(*Note:* Most studies do not qualify under Criterion A, which requires that there are absolutely NO other data besides the signed consent/permission/assent form that could link the subject and the research. Thus, it is usually preferable to select *Criterion B*, providing justification that the research presents no more than minimal risk of harm to participants, and involves no procedures for which written consent is normally required outside of the research context [assuming the latter is accurate].)

-In the permission form discussion of **confidentiality** measures, include mention that parents/ guardians will be asked for oral rather than signed permission.

-In the **Permission** section at the end of the form, remove signature and date lines and replace with appropriate wording, e.g.:

PERMISSION:

If you wish to allow your child to be in this study, please say so. If your child also agrees, we will give you a copy of this form to keep for future reference.

[Optional]

Signature of Investigator/Person Obtaining Permission

Date

b. **For Online Permission:**

-Apply for waiver of signed permission in the protocol as above. Select Waiver Criterion B (if accurate that study involves no more than minimal risk, etc.) and explain that waiver is requested because permission will be obtained online.

-In the Permission section at the end of the form, remove signature and date lines and replace with appropriate wording, e.g.:

PERMISSION:

If you wish to allow your child to be in this study and your child also agrees, please *[give instructions, e.g., “print a copy of this page to keep for future reference, then click on the ‘Accept’ button below.”]*

2) **ASSENT**: If you wish to obtain **verbal** or **online** unsigned assent instead of signed (written/ documented) assent:

a. **For Verbal Assent.**

In the protocol, go to the **Child Assent & Parent/Guardian Permission** section; under the **Documents & Waivers** tab, in the pop-up box for **Assent/ Permission Description**, click on **Assent or Permission Type** field, and select “*Assent Document.*” You do not need to request a waiver of signed/written assent, as this is not required under the regulations. But as part of the description of the assent procedures, you do need to explain that you wish to obtain verbal instead of signed assent and why (e.g., children who are your target subjects are too young to sign; signing the form would not be culturally appropriate for your subject population; or whatever is accurate).

In the Assent form, remove signature and date lines at the end of the form and replace with appropriate wording, e.g.:

ASSENT of Adolescent (13-17 years old [or whatever your subject group’s age range is]):

If you wish to participate in this study, please say so. If your parents also agree, we will give you a copy of this form to keep. That way you can look at it later if you want to.

Signature of Investigator/Person Obtaining Permission

Date

b. **For Online Assent.**

As above, select “*Assent Document*” as **Assent or Permission Type**. You do not need to request a waiver of signed assent, but as part of the description of the assent procedures, you do need to note that you are requesting unsigned assent because assent will be obtained online. (Include explanation of how you intend to assure informed, voluntary assent and protect the rights of the minor subject without personal interaction between the researcher and the prospective participant.)

In the Assent form, remove signature and date lines at the end of the form and replace with appropriate wording, e.g.:

ASSENT of Adolescent (13-17 years old [or whatever your subject group’s age range is]):

If you wish to participate in this study and your parents also agree, *[give instructions, e.g., “print a copy of this page to keep for future reference, then click on the ‘Accept’ button below.”]*