Office of Regulatory Research Compliance

Institutional Review Board

**Form “K1”: Assent-Research Involving Children**



**FORM “K1”: ASSENT**

**CHILDREN: ASSENT FORMS**

|  |  |
| --- | --- |
| **Principal Investigator**: Click here to enter text. | **Date**: Click here to enter text. |
|  |  |
| **Email**: Click here to enter text. | **Phone**: Click here to enter text. |
|  |  |
| **School/College and/or Department:** Click here to enter text. |  |
|  |  |
| **Title of Project**: Click here to enter text. |  |
|  |  |

**Important Note:**



Parents, legal guardians or a legally authorized representative must sign parental consent forms permitting minors to participate in research projects. An Informed Assent Documentation for young adults (13-17 years of age), minors (12 and under) or waiver of assent for children age less than 12 years must be prepared. Language must be simplified as appropriate for the age of the participants. For children unable to read and sign the written assent form, a verbal script should be used in lieu of the written Informed Assent Form.



**There are 3 sections on this form. The Child should complete only the applicable section based on age**

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**Form “K1”: HU Assent Form: For Young Adults Ages 13 -17 years**

**SECTION 1:**

**Invitation:** You are invited to be in a research study being done by*{name}*from theHowardUniversity. Research studies are done when researchers want to find new ways of treating patients or solve a human or society problem. You are invited because {*condition which* *renders the individual eligible}.*

**Purpose of the Research:** Describe purpose of the research

**Procedures:** This study is being conducted by the person(s) listed above. You will be asked to:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Time Commitment:** It will require(minutes/hours)to complete. The(questionnaire/test/procedures) will be administered at location)\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Benefit**: The benefit to you for participating in this study is that Click here to enter text.\_\_\_\_\_\_\_\_\_. We anticipateminimal psychological risks, and personal time inconvenience. You will be given (gift card/remuneration). The results of this research will be useful to \_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_.

**Payment**:Describe whether there is payment for participation, and if so, who will receive payment(the child or the parent).

**Voluntary Withdrawal:** You may withdraw from this study at any time withoutjeopardizing your status in your class/school/etc., or your relationship with Howard University and/or Howard University Hospital.

**Needs Additional Information:** If you would like any further information about this study,you may contact Dr(s). (PI/FA) at Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_. You may also call the Howard University Institutional Review Board at (202) 865-8597, from 8:30 a.m. to 5:00 p.m., Monday through Friday, if you would like to discuss this study with someone other than the investigators.

**Sign your name if you agree to take part in this study**:

Click here to enter text. Click here to enter text.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of the CHILD Date of Assent

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**Form “K1”: HU Assent Form for Children Age less than 12 Years**

**SECTION 2:**

**Information Giving:** I have been told that my mother/Father/or the person who takescare of me, has said that it is okay for me to take part in this study about :\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

\_\_Click here to enter text.\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Who Explained What:** The people in charge have explained to me what the study isabout and what will happen.

**Why Do You Agree to Participate**: I am taking part because I want to. No one willget angry with me if I say no. I have been told that I can stop at any time that I want to and nothing will happen to me if I want to stop.

Sign your name if you agree to take part in this study.

Click here to enter text. Click here to enter text.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

Sign Your Name on This Line Date

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**Form “K1”: HU Waiver of Assent for Children Age less than 12 Years**

**SECTION 3:**

I have determined that this child does not have the capacity to give assent because of the following:



|  |  |
| --- | --- |
| Maturity |  Psychological state of the child |
|  |  |  |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | \_\_\_\_\_\_ / \_\_\_\_\_ / \_\_\_\_\_ |
| **Signature of Investigator** | **Typed or Printed Name** | **MM / DD / YY** |

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