**Directions for use of this template:**

1. **Save this template to your computer.**
2. **Insert information specific for your study where the form says to “insert.”**
3. **Delete all parenthesis, italics and text that does not apply to your study.**
4. **Delete these instructions once your script is complete**

REMEMBER IF YOU ARE RECRUITNG CHILDREN, PARENTS MUST BE CONTACTED AND

GIVE PERMISSION FOR THEIR CHILD TO BR APPROACHED PRIOR TO CONTACT WITH THE CHILD

VERIFY YOUR IRB PROTOCOL OR APPLICATION ALLOWS FOR VERBAL CONSENT

Hello,

Am is speaking to (*potential subject or parent’s name/guardian’s name if a child is being recruited*)?

*If YES, then continue:*

*Choose one of the below*

***If you are cold contacting: :***

My name is x***.***  I am a (*Clinical Research Coordinator, Physician, etc.)*at the University of Virginia. The Department/Division of x is doing a study about x. I am contacting you because (*choose one of the answers below*):

* You/your child were/was seen in our department for (insert). It is a goal in our department to keep our patients informed of research in which they may be interested while carefully protecting your confidentiality. To do both we follow federal regulation called HIPAA.
* you/your child were/was seen at the UVA Health System for x. UVa feels it is important to inform patients of research projects in which they may be interested while protecting their privacy. For this reason we follow federal regulations called HIPAA which allow the UVa Health System to release your information to researchers at UVa, so that we may contact you regarding studies you may be interested in participating. We want to assure you that we will keep your information confidential.
* your doctor, Dr. ***insert name*** wanted you to be aware of this research study and gave us permission to contact you. ***DO NOT USE THIS RESPONSE UNLESS YOU HAVE OBTAINED PERMISSION FROM THEIR UVa PHYSICIAN:***

May I have your permission to talk to you about this new study?

* *If no, say Thank you for your time and end the call.*
* *If yes, continue as below.*

The purpose of this research study is to (*insert a description in lay language*.

If you/your child agree to participate, this study will involve (i*nser*t)

Insert risks and benefits

Insert compensation

You/your child do not have to be in this study if you do not want to participate. Your decision to be in any study is totally voluntary. Your/your child’s care at UVa will not be altered by your decision about being in this study. Your/your child’s relationship with your doctor will not be affected by your decision to participate/allow your child to participate or not.

Do you have any questions? (*Answer any questions the adult or parent may have*)

Well let’s see how good of a teacher I was – I am going to ask you a few questions about the study:

* What is the purpose of the study
* What do you have to do to be in the study
* What are the risks?
* What are the benefits

*Correct any answers that are not correct.*

* *If the potential subject is not able to answer questions accurately and if there is any question regarding subject ability to understand say: “*It looks like you will not be eligible for this study. Thank you so much for your time and I hope you have a nice rest of your day.
* *If the potential subject is able to answer the questions say:*OK very good. Do you think you/your child would be interested in being in this study?
* *If no, say Thank you for your time and end the call.*
* *If yes continue below*:

***IF A CHILD 7 years or older IS BEING ENROLLED YOU MUST ALSO SPEAK WITH THE CHILD AND OBTAIN VEBAL ASSENT –Keep this section. If only adults are being enrolled, delete this section:***

Do I have your permission to speak with your child about this study? I also need to make sure they are interested in the study.

* *If no, say Thank you for your time and end the call or set up another time to talk to child.*
* *If yes continue below*:

Hi, My name is x. I work at the University of Virginia and we are doing a study about x.

The purpose of this research study is to (*insert a description in lay language*.

If you agree to participate, this study will involve (i*nser*t)

Insert risks and benefits

Insert compensation

You do not have to be in this study if you do not want to participate. Your decision to be in any study is totally voluntary. Your care at UVa will not be altered by your decision about being in this study. Your relationship with your doctor will not be affected by your decision to participate/allow your child to participate or not.

Do you have any questions? (*Answer any questions the child may have*)

Well let’s see how good of a teacher I was – I am going to ask you a few questions about the study:

* What is the purpose of the study
* What do you have to do to be in the study
* What are the risks?
* What are the benefits

*Correct any answers that are not correct.*

Say :OK very good. Do you think you would be interested?

* *If no, say Thank you for your time and end the call.*
* *If yes continue below*:

**\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\*\***

**If YOU NEED TO DO PRESCREENING FOR ELIGIBILITY, PLEASE ADD THIS SECTION. IF NOT DELETE**

**Prescreening Permissions**

*Choose one of choices below depending on the nature of your study:*

* *If the child is not able to answer prescreening questions or it is preferred that a parent/guardian answer prescreening questions say:* I will need to speak with your mom/dad/guardian again to ask some questions to see if you qualify for the study. Do I have your permission to ask your mom/dad/guardian some questions about you to see if you are eligible to be in the study?

*Once parent is on the phone say:* So (your child) is interested in the study. I need to ask some questions about his/her health to see if they qualify.

* If the child is able to answer the prescreening questions say “I need to ask you some questions to see if you qualify for the t study

I want you to know that I am going to write down your answers. I promise to keep the information you provide confidential and will only share the information with the study team. The only people outside the study that will see this information, are those people inside and outside of UVA who are responsible for making sure studies are conducted correctly and ethically. If you decide to participate in this study now, but decide later to stop, you need to know that the information already collected will continue to be used.

May I continue with the questions?

* *If no, say Thank you for your time and end the call.*
* *If yes continue with prescreening if applicable.* :

**PRESCREENING QUESTIONNAIRE**:

***NOTE ONLY QUESTIONS RELATED TO INCULSION/EXCLUSION CRITERIA MAY BE ASKED***

**Inclusion Criteria**

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | Inclusion criteria (add rows as necessary) | Comment |
|  |  |  |  |
|  |  |  |  |

*All questions above must be YES in order to qualify*

**Exclusion Criteria**

|  |  |  |  |
| --- | --- | --- | --- |
| YES | NO | Exclusion criteria (add rows as necessary) | Comment |
|  |  |  |  |
|  |  |  |  |

*All questions above must be NO in order to qualify*

|  |
| --- |
| **If they do not pre-qualify:**Thank you for your time: It looks as if you/he/she does not qualify for this study, but we hope to have more trials opening in the future. The information you have provided during this telephone call will be stored with the study records in a way that does not identify you /your child personally.  |

|  |
| --- |
| **If they pre-qualify: MOVE ON TO OBTAIN VERBAL CONSENT FOR STUDY**From the information you provided, it looks like you pre-qualify for the study. As I said before this study /this part of the study will be done over the telephone. I am going to ask you some questions that will take x amount of time.May be continue with the study questions? |

NOTE YOU WILL BE REQUIRED TO OBTAIN WRITTEN HIPAA AUTHORIZATION USING THE STAND ALONE HIPAA AUTHORIZATION FORM IF IDENTIFIERS WILL BE DOCUMENTED DURING THIS RESEARCH.

*Continue with study.*