**Directions for use of this template:**

1. This template contains language for Waiver of Documentation of Consent. Written HIPAA Authorization may be required and directions are included for this process.
2. Save this template to your computer.
3. Insert information specific for your study where the form says to “insert.”
4. Delete all parentheses, and text that does not apply to your study.
5. Delete these directions
6. Submit the ad text to IRB-HSR for approval.

* ***This email would be used only for Expedited studies enrolling adults, infants, or children less than 7 years of age .*** *A survey /questionnaire or link to a questionnaire would be attached to this email.* 
  + *If the survey contains NO PHI and only a random study ID (created independently of potential subject’s identifiers), and the survey study (or this initial part of the study) is being conducted SOLELY by email then this template is the right one for your study. The subject would not be coming in for study visits or will come in for study visits later.*
  + *IF the survey contains identifiers or Health Information, do not ask that the information be returned in an email. Instead you may provide a link which subjects are directed to use to answer survey questions through a secure, HIPAA compliant tool such as Question Pro. Please consult with Information Security and also be sure your protocol and Data Security Plan reflects this process accurately.*
* *If the survey contains identifiers and Health Information, a Stand Alone HIPAA Authorization will be required as well.*
* *If the study involves children age 7- 17 years, then conducting the study in this manner of data collection will not work because you have no means of obtaining assent. Consider performing this survey over the telephone.*
* *If the survey involves those with cognitive impairment then this manner of data collection will not work because you have no way of verifying understanding of the study/ ability to provide consent (even if documented). Consider doing this study by telephone.*

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Dear x,

The UVA Health System Department of (*insert*) is conducting a research study about *(insert*).

*Insert how you obtained contact information:*

* You are receiving this email because you/your infant/your young 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 are receiving this email because you/your infant/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.

**USE THIS STATEMENT ONLY IF YOU HAVE OBTAINED PERMISSION FROM THE POTENTIAL SUBJECT’S UVA PHYSICIAN:** Your doctor, Dr. ***insert name*** wanted you to be aware of this research study and gave us permission to contact you.

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

If you agree to participate/agree to allow your infant/your child to participate, this study will involve completing the survey (*add as necessary)* and the attached Stand Alone HIPAA Authorization *(if the survey collects HIPAA identifiers and PHI*).

Insert risks and benefits

You do not have to be in this study/allow your infant/your child to be in this study if you do not want to participate/allow your infant or child to participate. Your decision to be in any study/allow your infant or child to be in this study is totally voluntary. Your care/Your infant’s care/Your child’s care at UVA will not be altered by your decision to participate or not participate/by your decision to allow your infant/child to participate or not participate.

If you feel you understand the study and would like to participate, please: *Select one:*

* complete the attached survey and email back to me (only appropriate if no PHI is being collected
* complete and return by email the attached Stand Alone HIPAA Authorization (*if the survey attached collects HIPAA identifiers and PHI*). Then log into this website to complete the survey:

The completion and return of these documents will indicate your consent to be in this study.

If you have questions prior to participating, please contact:

* (*insert contact information*)

Your information will not be shared outside of this study team except to those groups 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

Thank you for your time,

*Signature of sender*

*(insert name of sender)*

*(title of sender)*

Principal Investigator: *Insert name*

Study Title: (*insert title)*

IRB-HSR *# : (insert)*