VERBAL HIPAA AUTHORIZATION TEMPLATE

TEMPLATE INSTRUCTIONS:

* Instructions and comments are indicated in blue boxes, and [yellow highlighting].
* Delete the instructions and comments after reading and following.

In seeking HIPAA authorization, 8 elements and statements are required by HIPAA regulations to be provided to subjects in order to obtain valid authorization. VCU researchers can ensure all of the HIPAA authorization requirements are being met by utilizing this template language as directed.

**In order to use this template for expedited and full board studies, you must request a Partial Waiver of Authorization in the IRB submission. Request to waive the following 2 elements:**

**1) the authorization signature and**

**2) the requirement to provide the subject with a copy of the signed authorization.**

**In addition, if you choose not to include all of the required elements in your script, you must request a Partial Waiver of some elements of authorization and list the elements that you want to waive**.

Researchers also have the option to draft their own authorization language. If drafting your own language, your script should either: include all 8 elements in order for the authorization to be valid, or a Partial Waiver should be requested for the missing elements/statements.

For more information about HIPAA, see <https://research.vcu.edu/media/office-of-research-and-innovation/humanresearch/understanding_hipaa_and_research_for_investigators9.28.2020_accessible.pdf>

As part of this research study, we will ask you to permit us to access existing information from your healthcare records. [Insert if applicable: New health information will also be added to your healthcare records from study-related tests, procedures, visits, and/or questionnaires.] This type of information is considered “Protected Health Information” that is protected by federal law.

To conduct of this research we may use *[describe the type of health information to be used, including all that apply:* Your complete health record, Diagnosis & treatment codes, Discharge summary, History and physical exam, Consultation reports, Progress notes, Laboratory test results, Medical imaging reports, Imaging films/scans/pictures, Photographs or videotapes, Your complete billing record, Your itemized billing information, Information about drug or alcohol abuse, Information about Hepatitis B or C tests, Information about psychiatric care, Information about sexually transmitted diseases*, or specify others as applicable]*.

By agreeing to this study, you authorize [VCU and VCU Health / VCU and VCU Dental Care] to use and/or share your health information for this research. The health information just described may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research: the Principal Investigator and Research Staff, the Study Sponsor [delete if none], Research Collaborators [delete if none], Data Coordinators [delete if none], Data Safety Monitoring Boards [delete if none], Health Care Providers at [VCU Health / VCU and VCU Dental Care], Institutional Review Boards, Government/Health Agencies, and Others as Required by Law. Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

EXPIRATION OF AUTHORIZATION information: **Insert ONE of the following options:**

[Option 1:] This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

[Option 2:] This research study involves a Data Registry or Sample Repository and the authorization will expire [specify other expiration time point].

[Option 3:] This authorization will expire when [specify other expiration time point].

You may change your mind and take back the right to use your protected health information at any time. However, even if you take back your Authorization, the researchers may still use or release any health information that they have already collected about you for the study. If you take back this Authorization, you may no longer be allowed to participate in the research study. To take back this Authorization, you must write to [insert the Principal Investigator’s name and mailing address].

Do you have any questions about how your health information will be used and released in this study?

AUTHORIZATION STATEMENT: **Insert either Option 1 OR 2 as appropriate**

[Option 1: If authorization is given by the adult research participant:]

Do you agree that health information that identifies you may be used and disclosed for this research as we previously described?

\_\_\_\_\_\_\_\_\_\_ YES \_\_\_\_\_\_\_\_ NO

[Option 2: If authorization is given by the research participant’s personal representative (LAR for an adult participant or parent/ legal guardian for a child participant):]

Do you agree that health information that identifies **[use the research participant or individual’s name]** may be used and disclosed for this research as we previously described?

\_\_\_\_\_\_\_\_\_\_ YES \_\_\_\_\_\_\_\_ NO

Please describe your authority to act for the participant: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_