**Research Participant Consent and HIPAA Authorization: Verbal Script**

**Title of study**

{Headings for organization purposes only, will not be read to the participant}

**{INTRODUCTION}**

You are being invited to take part in a research study because you are (a healthy volunteer, have been diagnosed with a condition, etc.). This study is about…

(Describe the general research aim(s), say who you are, and who is supervising the research, any collaboration with other institutions, the medical center or university affiliation and that the project has been reviewed and approved by the Tufts Health Sciences IRB.)

Your participation in this research study is entirely voluntary. You may decide to stop being a part of the research study at any time. Your decision to participate in this study will not affect your receipt of medical care at Tufts Medical Center/Tuft University).

We plan to enroll [number] subjects in this study [at Tufts Medical Center/Tufts University].

**{PROCEDURES}**

In this study, you will be asked to…

(Provide a complete explanation of the procedures; this explanation must be sufficiently detailed to ensure that participants can provide “informed” consent, including time commitment and tasks/procedures/visits and what information will be included in the data set. Please keep in mind that procedures listed in this section should not be standard of care but the procedures specific to this study.)

**{BENEFITS}**

There are no direct benefits to you participating in this study. The results of this study (may contribute to a better understanding of X / lead to better care for patients diagnosed with X; customize for your study).

**{RISKS}**

Although there exists a risk of loss of confidentiality, this risk is minimized by (not collecting any identifiable data OR coding the identifiable data collected [name, medical record number, birth date, etc.] and keeping it separate from other study data). If you are not comfortable with any question you are free not to answer and can withdraw from the study at any time (and your data will not be included in the study/however your data collected to that point will be included in the study).

**{PRIVACY AND CONFIDENTIALITY}**

The data we collect does not contain any personal information about you except (describe as applicable. Note that any recordings made will be destroyed once transcribed, if applicable. ) Any identifying information collected will be coded and access to the code key is limited to the PI (PI name here) (or research team.)

**{ALTERNATIVES}**

The alternative is to not participate in this (survey/interview) and not have your data included in the study.

**{RESEARCH RELATED INJURY}**

There are no expected physical risks to participation in this study therefore research related injury is not expected.

**{COST AND PAYMENT}**

Participation in this study is at no cost to you. You will receive X in return for your participation (include payment type, and/or reimbursement information as applicable).

**{HIPAA AUTHORIZATION}**

As part of this study, I am asking you to give authorization to release some of your private health information (PHI). We will be collecting information from your medical record related to the diagnosis and management of your [condition or diagnosis subject to the research such as “cancer”], as well as any new information obtained as part of this study. This information may be shared with Dr. *X* and the research staff at [Tufts Medical Center or Tufts University Health Sciences] as well as other individuals at [Tufts Medical Center or Tufts University Health Sciences] who may need access to the information to do their jobs. They will take special care to maintain confidentiality and privacy about you and your PHI. These parties may further disclose your health information to [insert names of organizations/individuals] for their use in connection with the research study. [Tufts Medical Center or Tufts University Health Sciences].Those individuals who receive your health information may not be required by Federal privacy laws to protect it and may share your information with others without your permission.

This authorization does not expire but you may, at any time, change your mind and revoke (take back) this authorization. Even if you revoke this authorization, this site’s clinical, administrative and research staff may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you no longer want your health information used or shared you must make this request in writing and submit it to [(for Tufts Medical Center) HIPAA Privacy Officer for Research, 800 Washington Street, Box 5100, Boston, MA 02111 (for Tufts Dental School) HIPAA Privacy Officer for Research at One Kneeland Street, Room 334, Boston, MA 02111]. If you revoke this authorization, you may no longer be allowed to participate in the research described to you.

Do you have any questions?

Do you agree to authorize [Tufts Medical Center or Tufts University Health Sciences] to use and/or disclose your health information for this research?

[ ] Yes

[ ] No

**{FOR FURTHER INFORMATION}**

I/PI’s name will be glad to answer your questions about this study at any time. You may contact him/her at (provide at least two ways to contact the PI, e.g., email, phone, physical address). Would you like me to repeat that contact information so you can write it down?

**BY COMPLETING THE (SURVEY/INTERVIEW) YOU ARE CONFIRMING THAT YOU AGREE TO PARTICIPATE IN THIS STUDY AS IT HAS BEEN DESCRIBED TO YOU.**

I have fully explained to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the nature and purpose of the above-described study and the risks that are involved in its performance.  I have answered all questions to the best of my ability. I’ve obtained from the subject verbal consent to participate and authorization to use or disclose identifiable health information for the purposes of this research.

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Date                                                                      Principal Investigator or Representative’s Signature