

**CONSENT FOR PARTICIPATION IN A RESEARCH PROJECT
YALE UNIVERSITY SCHOOL OF MEDICINE – YALE-NEW HAVEN HOSPITAL**

Study Title: *[Insert title of the study.]*
Principal Investigator: *[Insert name.]*
Funding Source: *[Insert name of company or agency.]*

[If the study involves different consent forms for different populations, duplicate this form and identify each population group as the subtitle of the study.]

ADDENDUM

This consent addendum gives new information about the research study in which you agreed to participate. Your study doctor will discuss this new information with you. The [risks and/or new procedures, etc.] noted below are in addition to those which you were informed about in the previous consent form. You should know enough about this study's risks and benefits to make an informed judgment about whether or not you wish to continue to take part in the research. Once you understand the new information, you will be asked to sign this form. This process is known as informed consent. You will receive a copy of this signed form for your records.

Brief Description of the Project

[This should be limited to 2-3 sentences, and serve as a reminder for the subject of the overall purpose and design of the study.]

New Risks, Additional Information

- *Include only newly identified risks related to previously explained or newly added study interventions or procedures, or additional information uncovered during the course of the study should be stated.*
- *Identify all reasonably foreseeable risks, discomforts or inconveniences associated with participation in the study, and describe how they will be managed.*
- *Risks should be listed in hierarchical order, from most likely to least likely to occur.*
- *Where such information is available, the consent form should state the likelihood of risks occurring. For example, "most subjects in a similar study had headaches and felt nauseous," or "10 out of 100 people who took drug X felt dizzy."*

New Procedure(s) *[If applicable]*

If you agree to continue your participation in this study, you will be asked to *[describe the new study interventions or procedures clearly, in roughly chronological order, and how the new procedures relate to previously described procedures, if appropriate].*

Principal Investigator:
Funding Source:

HIC #
version:

[If subject is being given a choice about participating in the new procedure in the consent addendum, the following can be used:]

- I willingly consent to participate in the study-specific *[procedure]*.

Initials: _____ Date: _____

- I do not wish to participate in the study-specific tissue *[procedure]*.

Initials: _____ Date: _____

Principal Investigator:
Funding Source:

HIC #
version:

Authorization

I have read (or someone has read to me) this form and have decided to continue to participate in the project described above. Its general purposes, the particulars of involvement and possible hazards and inconveniences have been explained to my satisfaction. My signature also indicates that I have received a copy of this consent addendum form.

Name of Subject: _____

Signature: _____

Date: _____

Signature of Principal Investigator

Date

or

Signature of Person Obtaining Consent

Date

If you have further questions about this project or if you have a research-related problem, you may contact the Principal Investigator [include name and full telephone number]. If you would like to talk with someone other than the researchers to discuss problems, concerns, and questions, offer input, discuss situations in the event that a member of the research team is not available, or if you have any questions concerning your rights as a research subject, you may contact the Human Investigation Committee at (203) 785-4688.

*THIS FORM IS NOT VALID UNLESS THE FOLLOWING BOX
HAS BEEN COMPLETED IN THE HIC OFFICE*

THIS FORM IS VALID ONLY THROUGH: _____ HIC PROTOCOL #: _____ INITIALED: _____
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