THE MOUNT SINAI HOSPITAL, NEW YORK STANDARD: POLICY AND PROCEDURE	SUBJECT NO. HIM-MI-6.2C
DEPARTMENT: Health information Management SUBJECT: Uses and Disclosures of PHI : Phone Consents for Minimal Risk Studies	

CROSS – REFERENCE:
Consents (GPP-312)

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Reviewed:	12/12	03/03/2014	3/2/2015	2/8/2016			
Revised:	MM/YY						

POLICY:

1. Phone consents may be used in circumstances consistent with the relevant rules and regulations where the IRB has granted the researcher such permission and the principal investigator is planning to obtain protected health information (PHI).
2. Generally, e-mail and fax may be used to return a signed consent in addition to regular mail, except where the IRB believes that there is sufficient risk to privacy that they impose limitations on the method to be used.

TOOLS: consent form, data collection tool

PROCEDURE:

I. Send the approved phone consent authorization to the prospective research subject for review.

II. Arrange for a conversation between the participant and the authorized members of the research team to allow for full discussion of the combined consent /authorization. If verbal consent is obtained, collect identifiable data as applicable.

III. If there is an adult witness ("a second staff member " as defined in Consent Policy A3-113) on the phone at the time of the initial verbal consent, there is no need to have the documents returned and the data collected can be used.

IV. If there is no adult witness to the phone consent/authorization, arrange to have the written document returned in a manner approved by the IRB, which may include regular mail,

fax, emailed scanned document, etc. If after two weeks, the signed document is not returned, the research team must either :

A. Destroy the collected data and not use them in the research, or

B. Strip all identifiers and links such that the de-identified data are permanently anonymized, at which point the data can be used.

References: 45 CFR 46.117c