

Explanation of Informed Consent Section – on HSRP Form

* A signed Informed Consent Form is usually required from study participants.

Attach the Informed Consent as a separate document, when you submit the Protocol.

Explanation of Informed Consent section of the Protocol Form: (Page 5 of 8, of blank protocol)

A. Waiver of Informed Consent; Waiver of Signed Informed Consent; Informed Consent Process

B. Informed Consent Process:

If “NO” to both A1 and A2, describe below (in C) how informed consent will be obtained.

C. Waiver of Informed Consent; Waiver of Signed Informed Consent; Informed Consent Process

If NO to either A1 or A(2), describe below step by step how informed consent will be obtained.