Opt-Out and Consent-to-Contact Guidelines

WHI ancillary studies (AS) recruiting WHI participants will need to subcontract with the WHI Clinical Coordinating Center (CCC) or relevant Regional Center(s) (RC) as the first level of permitted contact with AS eligible participants. The CCC or RC(s) send an introductory packet to the AS eligible participants briefly explaining the ancillary study and requesting transfer of participant contact information to the AS study team for further contact and study consenting. If recruiting from only one or a few RCs, a subcontract may be arranged with the particular RC(s). If the AS PI is an investigator with the CCC or relevant RC, budget arrangements may be internally discussed.

There are two types of introductory packets, opt-out or consent-to-contact, that support permitted transfer of participant contact information to the AS study team. Opt-out and consent-to-contact mechanisms differ in approach, type of permission from participants and implementation.

- The opt-out mechanism is a passive consenting process that allows contact information to be transferred to the AS study team if participants do not request opting out of having their contact information transferred to the AS team within an estimated 30 days of receiving the introductory packet. Operationally, for clarity, the CCC does not use the word consent when the process being used is opt-out.
- The consent-to-contact mechanism is an active consenting process that requires participants return a signed and dated interest form within an estimated 30 days of receiving the introductory packet that gives their permission (consent) to having their contact information transferred to the AS study team for further contact by the AS study team.

The standard participant contact data elements to transfer must be specified in the introductory packet. These data elements include the participant name, mailing address(s) and telephone number(s). Where in the introductory packet the data elements are specified depends on the type of introductory packet.

- For an opt-out packet, the data elements are specified in the cover letter.
- For a consent-to-contact packet, the data elements are specified in both the cover letter and the consent form.
- If additional demographic data, such as race/ethnicity, education level at WHI baseline or age, etc., are needed, then rationale for the expanded data element request needs to be provided and WHI-approved during the AS application process and IRB-approved before mailings occur. Although information in addition to contact information may be thought to be helpful, requesting this type of additional information may result in higher opt-out or lower consent-to-contact rates due to participant concern for privacy at this pre-study-consent stage. It may also insert bias by recruiters when contacting participants unless they are blinded to all but the contact information.

There are pros and cons to selecting the opt-out or consent-to-contact mechanism.

	Pros	**Cons**
Opt-out	• A possibly higher number of enrollments than by consent-to-contact as the AS study team has opportunity to talk with a greater number of potential study participants. • Less expensive than consent-to-contact.	• A possibly lower return on effort by the AS study team than by consent-to-contact. The AS study team may spend more time and expense with more participant interaction before study consent that yields a relatively lower consent rate, though generally still higher than with consent-to-contact.
Consent-to-contact	• A possibly higher number of more seriously interested participants.	• Likely to return a more limited recruitment list. • More expensive than opt-out.

Experience has shown that the most cost-effective contact approach, whether opt-out or consent-to-contact, involves a single mailing, i.e., no non-responder re-mails, and no non-responder reminder calls. Customized plans or requests can be considered, e.g., allowing participant calls to respond to consent-to-contact mailings.