Tip Sheet: Enrollment of NIH Staff

Definitions

- NIH Staff-An employee defined by 5 USC §2105, an NIH contractor, a Special Volunteer, a Guest Researcher, or a trainee.
- Immediate Family Members-Generally, a group of relatives that includes parents, siblings, spouse, and children.

Policy

- NIH staff and immediate family members of the research team are generally permitted to participate in human subjects research conducted by the NIH, whether or not the research offers the prospect of direct benefit.
- When the **research offers prospect of direct benefit to the subject** (e.g., a study with potential therapeutic intervention for a condition from which the subject suffers), it is not a requirement of the PI to obtain IRB approval for enrollment of NIH staff or an immediate family member of the study team on the research.
- For **research that does not offer the prospect of direct benefit to the subject**, such as studies on healthy volunteers or natural history studies, the protocol should clearly describe safeguards that will be implemented if the recruitment and/or enrollment of NIH staff or immediate family members of the study team, is anticipated. If the enrollment of NIH staff or immediate family members of the study team is not anticipated at time of Initial Review, and the PI plans to include NIH staff as subjects, a modification indicating safeguards must be approved by the NIH IRB in advance of enrollment.

Consent Process When Enrolling NIH Staff as Participants

- The consent process for enrollment of NIH staff must be clearly described in the protocol.
- Regardless of whether the research offers the prospect of direct benefit, if the potential subject is an NIH staff member who is in a subordinate relationship with an investigator on the research team or is part of the work unit where the research is taking place, whenever possible, consent should be obtained by an individual in a non-supervisory relationship with the subject. A consent monitor or other qualified investigator must be present to observe the informed consent process.

IRB Member Considerations When Research is Conducted with NIH Staff as Participants

- It is the responsibility of the NIH IRB to determine whether the protocol's proposed safeguards for research including anticipated enrollment of NIH staff or immediate family members of the study team are adequate.
- Confirm that the protocol contains a section describing the participation of NIH staff or family members of the study team as well as a section that clearly describes the consent considerations and process for this population.
- Verify that the protocol describes the following:
    - Whether staff or family members will be included in the research.
    - The safeguards for this subject population (e.g., recruitment methods, consent monitoring or having another investigator confirm eligibility of the subject.)
    - Recruitment plan:
        - Solicitation of subordinates should not be direct, either orally or through individual mailings or email distribution.
        - Recruitment materials may be displayed only where public announcements are permitted.
    - Prior to enrolling NIH staff members, investigators must provide and request that these potential subjects review the following:
        - FAQs for Staff who are Considering Participation in NIH Research
        - Leave Policy for NIH Employees Participating in NIH Medical Research Studies

Where Can Additional Information/Related Resources About Enrollment of NIH Staff as Participants?

- For additional information about enrollment of NIH Staff as subjects, see *Policy 404, Research Involving NIH Staff as Subjects*.