

NIH Intramural Research Program		
Office of Human Research Subjects Protections	Effective Date: 09/14/2020	
Research Involving NIH Staff as Subjects	Policy 404	Version: 1.0

NIH Frequently Asked Questions (FAQs) for NIH Staff Who are Considering Participation in NIH Research (Version Date)

These FAQs are designed to help NIH staff make an informed decision when considering research participation at NIH.

1. Can NIH staff and immediate family members of the study team participate in NIH research?

Yes, generally NIH staff and immediate family members of the study team, are permitted to participate in human subjects research conducted by the NIH. This includes the enrollment of a study team member, or their immediate family members, in the study.

There are NIH policy requirements when NIH staff or immediate family members of the study team participate in the research. For the protection of NIH staff, and to protect the validity of the science, certain safeguards may need to be put in place. For more information about policy requirements related to staff participation in NIH research, see *Policy 404 Research Involving NIH Staff as Subjects*.

NIH staff who participate in NIH intramural research must comply with NIH policy including, but not limited to:

- a. Any prohibitions or restrictions on participation in NIH research by the NIH staff member's Institute or Center;
- b. NIH compensation requirements; and
- c. NIH leave requirements. (See [NIH Manual Chapter: 2300-630-3 - Leave Policy for NIH Employees Participating in NIH Medical Research Studies](#))

2. Can NIH staff and immediate family members of the study team participate in NIH research, regardless of whether the research offers prospect of direct benefit or not?

Yes, NIH staff and immediate family member of the study team can participate in NIH research whether or not the research offers the prospect of direct benefit. However, when the research offers no prospect of direct benefit, there are certain safeguards that must be put in place by NIH policy, that offer additional protections for NIH staff or immediate family members of the study team.

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3. Why does OHSRP have policy and offer additional protections for NIH staff and immediate family members of the study team participating in NIH research?

- When NIH staff have a subordinate relationship to an investigator on the study team, is part of the work unit where the research is taking place, or when immediate family members of the study team are recruited or enrolled on NIH research, there is the potential for undue pressure on these parties to participate in the research. For example, children of an investigator are minors, and do not have independent decisional authority to decline to participate in their parent’s research. Similarly, staff who are in a subordinate position to the investigator recruiting them to participate in the research, (e.g., more junior staff, or trainees) may not feel free to decline participation in the research of their superior.
- In addition, there are other risks of participation by NIH staff on the research because there are limitations on confidentiality protections for staff participating in research at the NIH. This is explained more in [FAQ #6](#).
- There are NIH policies that prohibit NIH employees from receiving compensation for research participation during work hours. This is explained more in [FAQ #11](#).
- There are NIH policies that require supervisory approval for NIH staff to participate in research during work hours. This is explained more in [FAQ #9](#).
- If a member of the study team participates as a subject in their own research, or if a research subject is also in subordinate relationship with an investigator on the research team, or if a research subject is also part of the work unit where the research is taking place, there are concerns about potential adverse impacts to the study or to safety for that subject. For example, if a subject is not fully accurate about their health information because of their status as NIH staff, then this might impact the scientific integrity of the research or lead to potential harm to the subject themselves. Or a study team member who is a study subject may have trouble recognizing and reporting adverse events. This is explained more in [FAQ #14](#).
- Lastly, this is not an exhaustive list of concerns but there are resources you can turn to for more information or if you have other questions described in [FAQ#19](#).

4. When can I be excluded from participation in research?

A staff member may not participate in research if: 1) participation is prohibited by Institute/Center (IC) policy, or 2) the staff member is excluded by the criteria of the protocol in which they want to enroll.

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5. Can a Special Volunteer, NIH trainee, or Guest Researcher participate in NIH Research?

Yes, a Special Volunteer or NIH trainee, may participate in intramural research studies unless: 1) participation is prohibited by Institute/Center (IC) policy, or 2) they are excluded by the criteria of the protocol in which they want to enroll.

Guest Researchers may participate in NIH research similar to other members of the general public.

6. Are there any privacy or confidentiality considerations I should be aware of?

Other NIH staff (possibly including your co-workers or superiors) could have permissible access to your health or research record. These records will likely include private information collected about you during the course of the research (e.g., in medical records, or hospital systems). You should also keep in mind, as with any other record system, there is the potential for a privacy breach, or staff might not comply with NIH privacy and confidentiality requirements. You should ask yourself:

- Are you comfortable accurately sharing your medical history (including, for example, mental health history or STDs) and your social history (e.g. substance use) with study investigators, some of whom may be your coworkers?
- Are you comfortable with the possibility of your coworker or supervisor discovering something about your health during the study (e.g. pregnancy status or a new diagnosis)?

If you don't feel comfortable sharing this type of information with NIH study investigators, you may want to assess whether or not you want to participate in the NIH research.

7. Do I have to tell the study team private personal information?

Each protocol includes eligibility criteria to recruit the desired population of subjects. These criteria are designed based on scientific needs and participant safety. If you are not truthful, or you omit information about your health history or social history, your participation in the research could result in harm to you or adversely impact the results of the research.

8. What does NIH do to ensure that my private personal information is protected and access to it is restricted?

NIH is a federal agency; therefore, it is bound to certain privacy and confidentiality standards by federal law, regulation, and policy. For example, NIH must take certain

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actions to protect your information, keep it confidential, and establish authorized users. However, these protections will not prevent your private information from becoming available in medical records or research data systems, which can be accessed by authorized users both inside and outside of the study team. This means that study team members, which may include your co-workers or your superiors, who are authorized users of these systems, may appropriately access your records and the information contained therein.

Before deciding to enroll in an NIH study, you are encouraged to discuss the specific information that may be collected in the study and raise any concerns that you may have with the PI.

You can also find out more information about research record privacy and confidentiality protections from your IC Privacy Coordinator or medical record standards by contacting the Clinical Center Privacy Coordinator. (See <https://oma.od.nih.gov/DMS/Pages/Privacy-Program-Privacy-Coordinators.aspx>.)

9. Can I participate in research during work hours?

Yes, you may participate in research if it is during work hours. However,

- You must have supervisory approval prior to enrolling in the research.
- You should review the [NIH Policy Manual 2300-630-3 Leave Policy for NIH Employees Participating in NIH Medical Research Studies](#) for information about types of leave that are available for research participation during work hours.

10. Can I participate in research if it is not during work hours?

Yes, you may participate in research if it is not during work hours. However, if you think that your participation might impact your work hours or duties, you should review the [NIH Policy Manual 2300-630-3 Leave Policy for NIH Employees Participating in NIH Medical Research Studies](#) for additional information.

11. Can I be compensated for research participation?

You should review the [NIH Policy Manual 2300-630-3 Leave Policy for NIH Employees Participating in NIH Medical Research Studies](#) for information about whether you can receive compensation, including compensation for participation in research during work hours.

12. Can I refuse compensation if I participate in research?

Yes, any subject participating in NIH research can refuse to be compensated and still participate in the research, it is your choice. However, you should review the [NIH Policy](#)

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[Manual 2300-630-3 Leave Policy for NIH Employees Participating in NIH Medical Research Studies](#) for information about leave requirements if you are participating during work hours.

13. My supervisor is the PI on the research. Can they waive the requirement for taking leave?

No. If you are participating in research during work hours, you must be in a leave status (annual leave, LWOP, or sick leave). See [NIH Policy Manual 2300-630-3 Leave Policy for NIH Employees Participating in NIH Medical Research Studies](#) for information about types of leave that are available for research participation during work hours.

14. What should I consider if I am a research participant on research in my own lab or branch?

As a research participant, you must be able to report honestly information about side effects or other private information, or about research activities, (e.g., following the instructions on the protocol as written) that could influence the outcome of the research. You should consider if you are comfortable providing this information to your co-worker or supervisor if they are members of the study team. If you are not honest, or omit this information due to your close relationship with your co-workers or study team members, there is the potential that you could adversely impact the results of the research, or even worse, harm yourself, your reputation, or your job.

15. I don't want to participate in the research, but my supervisor, co-worker, or PI has asked me. Do I have to?

No. Participation in NIH research by NIH Staff is strictly voluntary. It is your choice whether or not to participate in research and your decision about participation will not have an effect, either beneficial or adverse, on your position at NIH.

If you feel your supervisor or colleague expects you to participate or is pressuring you, and that pressure is making it difficult for you to decide freely, you can seek assistance from other parties at the NIH (e.g., the Office of Human Subjects Research Protections, the Clinical Center (CC) Bioethics Consult Service, the CC Patient Representative, the NIH ombudsman, or the OD civil program).

16. If I participate, will I get any additional employment benefits?

No. NIH HRPP *Policy 404 Research Involving NIH Staff as Subjects* specifically requires the PI to provide you with a “description of protections to ensure that neither participation nor refusal to participate as a research subject will have an effect, either beneficial or adverse, on the staff’s employment, training, or position at the NIH.”

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17. If I am interested in participating who will provide me with information about the study?

For most clinical studies, in which there is the prospect of direct benefit to the participant, you could find out about studies from any number of sources (e.g., a friend, co-worker, your primary care provider, a flyer, or advertisement). However, by NIH policy, studies that do not offer the prospect of direct benefit, but do permit the enrollment of NIH staff, may only recruit staff via flyers and recruiting materials displayed in the workplace where public announcements are permitted to be posted. In addition, solicitation by supervisors of subordinates should not be direct, either orally or through individual mailings or email distribution.

18. Who will conduct the consent process with me if I am a part of the work unit where the research is taking place or am participating on research where I am in a subordinate relationship with an investigator on the research team?

Whenever possible, consent should be obtained by an investigator who is not in a supervisory relationship to you. When consent is conducted, a third party must be present to observe the consent process. This process is used to minimize the risk of undue pressure on you. This can be achieved by one of the following methods:

- At the NIH CC, a consent monitor is available through the CC Department of Bioethics Consultation Service or by a Clinical Research Advocate from the NIMH Human Subjects Protection Unit (HSPU); or
- A consent monitor may also be another party independent of the study team (e.g., an IC monitor); or
- Lastly, if a consent monitor is not available, the consent process may be observed by another qualified investigator on the study who is independent of the NIH staff member’s work unit and not a supervisor to the NIH staff member. If no such person exists, consent observation may be performed by any qualified investigator on the study.

19. Who can I contact for more information?

If you are thinking of enrolling as a subject at the NIH Clinical Center or other NIH research site and you have any questions or concerns, you can contact the Office of Institutional Review Board (IRB) Operations or the Office of Human Subjects Research Protections (OHSRP) at 301-402-3713. If you want to participate in research at the NIH Clinical Center, you can contact the Patient Representative at 301-496-2626. If you are at an NIH research site other than the Clinical Center, you can also contact local site leadership or the overseeing IC’s leadership.