

Information Sheet for NIH Employees Participating in Intramural Research Protocols

As an NIH employee, contractor, IRTA or other associate, you may participate in Intramural research studies. You may be motivated by altruism, a commitment to research in your own or related fields, or want access to clinical trials of potential direct therapeutic benefit. When deciding, you should make an *informed* decision about participation. This information sheet offers some points to consider for employees who are considering research participation at NIH.

First, similar to any individual who is considering research participation, you should seek adequate information about the study purpose, what is required of you in terms of procedures, interventions and time, and what the potential risks and benefits are expected to be. For more information, see <http://www.cc.nih.gov/participate/studies.shtml>

Whether you are thinking about participation in a research study that is being conducted by your supervisor, or others who you work closely within your laboratory, branch, or unit, or research that is being conducted in an area for which you have no affiliation, you should consider some additional factors:

1. **Possible bias.** Are you confident that you can be unbiased about reporting answers, side effects, or other information that could influence the study outcome or risk to you?
2. **Confidentiality.** Are you comfortable sharing your medical history (including, for example, mental health history or sexually transmitted diseases) and your social history (e.g. substance use) with study investigators who may or may not be your coworkers, or with the possibility of them discovering something about your health during the study?
3. **Pressure.** Do you perceive any pressure or expectations from either the study team or your supervisor or colleagues regarding participation? If so, does that pressure influence your decision or make it difficult for you to choose whether or not to participate? Remember it is your choice whether or not to participate. If you have concerns about enrolling in a study, the Department of Bioethics and the Office of Human Subjects Research Protections (OHSRP) are both available to help.
4. **Time.** Can you take time off from work to complete the study requirements or participate solely during non-duty hours? See the NIH Policy Manual 2300-630-3 "Leave policy for NIH employees participating in NIH medical research studies"

According to NIH guidance, anticipated inclusion of employees in research studies must be approved by the IRB, and when the individual obtaining consent is a supervisor or co-worker of a prospective participant, an independent person (e.g. through the Clinical Center Department of Bioethics, National Institute of Mental Health Human Subjects Protection Unit, or other entity as approved by the Institutional Review Board (IRB)) should monitor the consent process, unless waived by the IRB.

If you have any questions or concerns, please contact the Department of Bioethics at (301) 496-2429 or the OHSRP at 301-402-3444.