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**Institutional Review Board**

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# Inclusion of Students and Employees in Research

The purpose of this guidance is to indicate when and how [employees and students of NYU Langone Health may be included as research subjects in research conducted at or under the auspices of NYU Langone Health](https://med.nyu.edu/research/office-science-research/clinical-research/resources-researchers-study-teams/institutional-review-board-operations/irb-policies-structure-accreditation).

Students and employees recruited as research subjects are more vulnerable to coercion or undue influence. Researchers must put measures in place to tackle these issues when they intend to enroll either population. Keep in mind these reasons why these populations may be vulnerable to coercion or undue influence:

**Students** may feel their participation in research is necessary as part of their academic requirements, or that failing to participate will negatively impact their relationship and academic/professional opportunities with the instructor/investigator or NYU Langone Health.

**Employees** may feel unable to exercise free choice in their decision to participate, due to belief that their decision may affect (favorably or unfavorably) their performance evaluations, advancement opportunities, or other employment-related decisions.

## IRB Submission Requirements, Recruitment Methods, Ancillary Review

### Considerations When Enrolling Employees or Students

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| Employees should: | Students should |
| 1. be informed in consent process/form the extent medical information and/or research data may be accessible to supervisors or others 2. never be required to enroll/continue in research as a condition of employment, or other employment-related decision 3. not have their Occupational Health records reviewed by investigators for research without IRB approval, unless the employee has given their authorization 4. only participate in research conducted outside their  work areas and hours | 1. be informed in the consent process/form that neither academic status nor grades will be affected by participation 2. be informed of the extent to which medical information/research data may be accessible to instructors or others 3. participate outside of classroom or laboratory hours to minimize potential risks in breach of confidentiality 4. only participate in research conducted in a classroom/laboratory (i.e., surveys) when it is at the end of the period, to allow non-participating students the option of leaving to alleviate pressure |

**When submitting to the IRB your study protocol will need to:**

1. **Provide justification or sound rationale** for the inclusion of employees and/or students in the research must be included in the protocol and inclusion/exclusion criteria. Justification must indicate that the reason for inclusion and methods of recruitment of either group are not based on convenience when they would not otherwise be appropriate for inclusion.

**Note:** The IRB may grant an exception to a subset of employees/students if the research relates to employees in a particular department, or to students in a particular course. If allowed, the recruitment plan must include additional strategies to ensure voluntariness and minimize potential influence of the investigator to recruit when subjects may include employees/students directly supervised or enrolled by the investigator.

***For example:*** *research that examines teaching methods in a particular course taught by the investigator*

1. **Explain how the privacy and confidentiality** of employees/students included in research will be protected. The protocol should include procedures that will mitigate the potential risk of compromised confidentiality and privacy of either group, and where applicable, the researcher should consider including a Certificate of Confidentiality (“CoC”) when the research includes sensitive topics, including but not limited to:

* *Mental health*
* *Drug/alcohol abuse*
* *Sexual behavior*

1. **The appearance of coercion and undue influence** of employees/students must be minimized in recruitment methods, including the informed consent process, form, and other procedures. The informed consent process and form must state that the subject’s decision to participate will not impact the status of employment, academic status, and/or grades respective to the target subject population. This must be outlined in the protocol as well.
2. **Outline Recruitment methods:** Methodsthat require the employee/student to reach out regarding participation are known as *passive recruitment* *methods* and are preferred. Such methods include, but are not limited to: an unassociated, non-supervisory recruiter, flyers approved by the IRB and RED+F, or NYU Langone Health-wide e-mails to specific groups that encourage those interested to reach out for information.

**Please note that ancillary review** will be required in addition to IRB approval for studies in which employees/students will be the focus of subject recruitment efforts, studies that require *direct recruitment* of employees and/or students, or studies that may otherwise be of concern to the institution. Departments requiring such review include:

* NYU Langone Health’s Department of Human Resources (HR)
* Department of Graduate Medical Education (GME)
* Vilcek Institute of Graduate Biomedical Sciences (Vilcek)
* Associate Dean for Biomedical Sciences (for PhD students)