**AAH RSPP GUIDANCE**

**Recruitment of Employees as Research Subjects**

**PURPOSE**
The purpose of this guidance document is to assist investigators /study coordinators regarding research submissions that include the recruitment of employees as subjects.

Definitions of *Italicized words* can be found in the [AAH RSPP Glossary](#).

**GUIDANCE**

**Can employees be targeted as subjects of a research study?**
Yes, in some cases. Even if not intended, pressure to appear to supervisors and/or colleagues as cooperative and supportive of their department’s work makes AAH employee subjects a vulnerable population in these circumstances. Such pressure may manifest itself with respect to both the initial decision to participate and any subsequent decisions to continue or discontinue participation. Participation in research conducted by one’s department may also pose unique confidentiality considerations. Therefore employees may require greater protections when targeted as subjects of a research study. The IRB has the latitude to place additional restrictions/protects on the inclusion of employees due to their classification as ‘vulnerable’.

In the application to the IRB, the investigator must justify the need for inclusion of employees in the research study. He/she must also document how the identification and recruitment of the employees will be done so as to protect their privacy and be free of undue influence. The application must specifically describe plans to protect the privacy of the employees and how recruitment will occur.

In the informed consent, the employee must be offered the option of not participating, and be allowed to make this choice without repercussion from the investigator or AAH. The AAH RSPP informed consent template includes language that must be included when employees are targeted as subjects of the research.

**Can employees of the investigator be recruited as research subjects?**
Recruitment of an investigator’s staff is, in most cases, considered coercive and not allowed or done so with extra precautions in place.

Steps must be taken to minimize any undue influence or the appearance of undue influence or coercion. These plans must be included in the IRB application. The investigator must also take steps to recruit other individuals from within the hospital or clinic who are not his/her direct reports.
What factors will be considered by the AAH IRB in research targeting employees as subjects?

1. In most cases the research must be no greater than minimal risk to employee. Research studies where there may be a therapeutic benefit to the employee, but is greater than minimal risk, may also be considered.
2. Participation in the research represents a potential educational opportunity for the employee.
3. The recruitment of these employees as subjects involves only indirect methods (i.e., potential subjects are not recruited on a personal basis). These subjects are recruited through the posting of IRB-approved flyers/ads or through IRB-approved communications sent out to a larger group (e.g., mass mailings through email or letters).
4. The consent process will not be conducted by someone with whom the employee has a status relationship (i.e. supervisor, manager).

The IRB will assess whether the inclusion is warranted by the protocol, and whether the recruitment and consent processes are free from undue influence, and the confidentiality of these subjects will be protected adequately.

Is administrative authorization needed when employees are to be targeted as subjects of the research study?
Yes. Administrative authorization via the AARI RAP process is required. A copy of the administrative authorization must be included with the submission application.

REQUIREMENTS
- OHRP Guidance: see OHRP FAQs on informed consent- coercion and undue influence-