

**SWEDISHRESEARCHCENTERSTAFF
PARTICIPATIONINRESEARCH**

| ClinicalResearchPolicy/Procedure | |
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| Approved: October2008 | NextReview: October2011 |

Purpose

To protect the confidentiality and rights of Swedish Research Center (SRC) staff from disclosure or abuse. To protect the investigator and SRC staff from perceived or actual threats to employment status and other potential forms of coercion to participate in research. To protect the investigator, SRC staff and research data from a perceived or actual conflict of interest or research misconduct. To provide a mechanism of access for SRC staff and investigator to protocols for which they may clinically benefit.

Responsible Persons

Swedish Research Center Director, Research Managers, Investigators, and Swedish Medical Center Ethics Consult Team.

Definitions

Swedish Research Center Staff (SRC Staff) includes any employee of Swedish Medical Center who is responsible for conducting research or the support thereof under the supervision or auspices of the Swedish Research Center.

Institution-sponsored Research is any research protocol overseen by a SMC designated Institutional Review Board (IRB) and conducted using SMC resources or patients.

| Policy |
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Swedish Medical Center (SMC) takes seriously its ethical responsibility and obligation to assure that all research activities undertaken at SMC are performed in accordance with the highest standards of human subject protection, scientific recordation and interpretation. For physician-investigators, concurrently maintaining the roles of research investigator, treating physician, and/or co-worker may create conflicts, ethical dilemmas and tension.

In the interest of minimizing the possibility of coercion or undue influence with regard to participation in research, this policy provides guidelines and specifies the conditions under which SMC employees and/or SRC Staff may participate in research.

All other institutional policies regarding the privacy and confidentiality of Protected Health Information or other sensitive information shall apply.

Guidelines

1. SMC employees not affiliated with the SRC may participate in Institution-sponsored Research as long as the individual in question does not report directly to the investigator in the course of his/her employment with SMC.
2. SMC employees may not be specifically targeted or solicited to participate in research studies through the use of organizational media that is designed for the sole purpose of employee communication. Areas and media of SMC that are used for public communication however may be used to solicit research participants.
3. SRC Staff may not enroll in non-treatment related research protocols such as preventative, qualitative or behavioral research, a subject. Neither a case or control research
4. SRC Staff may not participate in research activities for data, methodology, or equipment validation purposes.
5. Participation in a research study may be an important treatment option for some SRC Staff. Certain research studies may provide the only access to a new medication or treatment, which may provide good or better options than standard treatment. If possible, enrollment of SRC Staff in a research protocol should be initiated in a protocol covered under the auspices of another institution. If a member of the SRC Staff wishes to participate in Institution-sponsored Research, and alternative options are unavailable, the Staff member must seek the review and approval of the Swedish Medical Center Ethics Consult Team before participating in the study.

 - A member of the SRC Staff who wishes to participate in Institution-sponsored research must obtain an ethics consultation prior to participating in the research. The SRC Staff member, physician or investigator may be asked to provide information and/or feedback based upon the SRC Staff member's ethics consultation. Ethics consultations can be obtained 24 hours a day as needed by calling the hospital operator and asking for an ethics consult. Documentation of ethics approval must be placed in the participant's study file.
 - ➔ **NOTE:** The failure of an Investigator or staff to obtain here required approvals can result in disciplinary action up to and including discontinuation of SRC or IRB approval for conducting research at SMC, and/or termination of employment.
6. All other institutional policies regarding the privacy and confidentiality of Protected Health Information or other sensitive information shall apply.

Forms

N/A

Supplemental Information

- ClinicalResearchPolicy/Procedure: RESEARCHMISCONDUCT

ExpertConsultants

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RegulatoryRequirement

N/A

References

N/A

Addendum

N/A

pk:SwedishResearchCenterStaffParticipationinResearch–v.2.0.doc(10/13/08)