

<b>SOP: GA 102</b> <b>Version No:</b> <b>Effective Date: 01/01/07</b>	<b>TRAINING AND EDUCATION</b>	<b>Supersedes Document Dated:</b>
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## 1. POLICY

Training of IRB staff and members is critical if the IRB is to fulfill its mandate to protect the rights and welfare of research subjects in a consistent manner throughout Sparrow Health System's research community.

IRB members, staff and others charged with responsibility for reviewing, approving, and overseeing human subject research should receive detailed training in the regulations, guidelines, ethics and policies applicable to human subjects research.

All IRB members and staff will be apprised of Sparrow Health System's organizational structure with emphasis on the independent nature of the relationship between IRB and Sparrow Health System. The actions of the Board and the administrative staff relating to their responsibilities to protect human subjects of research will not be measured or evaluated in terms of institutional or financial goals.

### Specific Policies

#### 1.1 Training

- 1.1.1 Management level staff and members of any IRB who are overseeing research on human subjects, as defined in 45 CFR 46.102 (f) and/or 21 CFR 56.102(e), that is managed, funded, or taking place in an entity under the jurisdiction of the Trustees of Sparrow Health System will receive initial and ongoing training regarding the responsible review and oversight of research and these policies and accompanying procedures.
- 1.1.2 IRB Administrator establishes the educational and training requirements for IRB members and staff who review biomedical and behavioral research involving human subjects at this institution and who perform related administrative duties. Initial and ongoing training is provided and documented by this institution through the OROC.
- 1.1.3 Members of the IRB will participate in initial and continuing training in areas germane to their responsibilities.
- 1.1.4 Chairpersons will receive additional training in areas germane to their additional responsibilities.
- 1.1.5 Principal Investigators, IRB staff and others involved in the Sparrow Health System's research community will receive initial and continuing training in the areas germane to their responsibilities, including all Standard Operating Policies and Procedures (SOP).
- 1.1.6 IRB members, OROC staff, and others involved in the Sparrow Health System's research community will be encouraged to attend workshops and other educational opportunities focused on IRB functions. The Sparrow Health System will support such activities to the extent possible and as appropriate to the responsibilities of members and staff.
- 1.1.7 For ongoing educational requirements, as of 1/3/06 all active investigators, research staff, IRB members, and associated staff shall provide documentation of successful completion of an appropriate web-based

Human Subjects Training Tutorial on a semi-annual basis. Documentation must be sent to the OROC Office.

### **1.2 Documentation**

Evidence of training and continuing education will be on file in the OROC.

## **2. SCOPE**

These policies and procedures apply to all IRB members, Investigators, and all involved in the Sparrow Health System's research community.

## **3. RESPONSIBILITY**

IRB Administrator is responsible for establishing, conducting and/or supervising all relevant training programs for IRB members and staff.

IRB Chairperson (or designee) is responsible for guiding the development of IRB member training programs, in collaboration with the IRB Administrator.

## **4. APPLICABLE REGULATIONS AND GUIDELINES**

21 CFR 56.107

45 CFR 46.107

OHRP IRB Guidebook

NIH NOTICE: OD-00-039 Required Education in the Protection of Human Research Participants

## **5. REFERENCES TO OTHER APPLICABLE SOPs**

This SOP affects all other SOPs.

## **6. ATTACHMENTS**

GA 102-A Training Checklist and Documentation – IRB Member

GA 102-B Acknowledgement Form – IRB Staff

GA 103-C Acknowledgement Form – Investigator/Research Staff

## **7. PROCESS OVERVIEW**

Each Investigator, research staff, IRB member and other related staff members are required to complete the following training:

- All persons shall read the "Belmont Report." In addition, those individuals shall review the IRB Standard Operating Procedure Manual (SOP) as related to their function in research.
- IRB Members and OROC staff are required to complete the Institution's HIPAA Training annually.
- All persons are required to document (bi-annually) the completion of one of the following Human Subjects Training tutorials:

Department of Health and Human Services, Office of Human Research Protections web-based human subjects training tutorial and supply the OROC with a completion certificate. <http://www.hhs.gov/ohrp/education/index.html#materials>

Michigan State University's Training Tutorial (CITI).  
[http://www.humanresearch.msu.edu/training/training\\_index.htm](http://www.humanresearch.msu.edu/training/training_index.htm)

National Institutes of Health, National Cancer Institute.  
<http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp>

## 8. PROCEDURES EMPLOYED TO IMPLEMENT THIS POLICY

Who	Task	Tool
<i>IRB Administrator</i>	Establish training and educational requirements and content for IRB members and staff. Set annual budget.	
<i>IRB Administrator</i>	Based on requirements and budget, determine training & education schedule. Schedule speakers, acquire outside publications, schedule attendance at NAIM and seminars as budget allows.	IRB Staff IRB Members
<i>IRB Administrator, IRB Coordinator</i>	Notify IRB members as to available training materials & schedule. Send reminders as needed.	
<i>IRB Coordinator</i>	Maintain documentation of all training and education completed.	Training Checklist and Documentation – IRB Staff/Members, Investigators/ Research Staff