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| Experimental Research and Investigational Studies | **Last Revision:** | November 2015 |
| **Last Reviewed:** | November 2017 |
| **Applies to the THA Group of Companies:** | * Island Health Care * Island Hospice * Independent Life at Home * RightHealth® |
| **Included in the following THA Manual:** | Administrative Policies & Procedures  Ethics, Rights, & Responsibilities |

#### POLICY

The organization supports and accommodates, as appropriate, patient participation in research or investigational medication and treatment studies. The patient has the right to refuse to participate in any such study without compromising his/her access to care, treatment, and services.

**PURPOSE**

To protect the safety of patients participating in experimental research or investigational studies.

# PROCEDURE

1. Involvement with experimental research or investigational studies must be approved by THA Group senior management prior to initiation.
2. The physician ordering investigational medication or treatment is expected to be a registered investigator for the specific drug or treatment.
3. The physician’s orders for such procedures, treatment, and medications are accompanied by a consent form that includes the patient’s signature for participation in the investigational study. If the study involves investigational medication, a complete drug protocol that outlines drug characteristics, actions, admixture, administration procedures, side effects, and special precautions is provided.
4. Staff who receive the research information verify that the copy of the informed consent for investigational medication use or treatment includes the name of the person initiating the consent form and the date the form was signed. In addition, the form includes acknowledgement that the patient has received a complete and written explanation of the treatment and procedures to be followed, possible side effects and complications, and addresses the patient’s right to privacy, confidentiality, and safety. Acknowledgement that the patient has received information on alternative services that could prove advantageous is also included.
5. The senior management reviews, at the least, the following:
6. Investigational protocol in relation to the organization’s mission and ability to provide the necessary care and services.
7. The safety and practicality of home administration and/or treatment.
8. A method to conduct reviews and identify who will be involved.
9. The relative risks and benefits to the patient.
10. The process used to obtain the patient’s informed consent, and the need for the organization to consent to participate in the research.Qualified personnel may administer investigational medication or provide treatment per specific physician orders and applicable practice standards, monitor the patient’s response to the medication or treatment, and communicate as required to the physician and/or authority supervising the study.
11. The copy of the informed consent form as well as all other written information received from the referring physician is filed in the patient’s medical record.
12. If a research related injury occurs (physical, psychological, social, financial, or other), the staff member noting the injury informs the physician/clinical supervisor immediately. A research related injury is treated as an occurrence (see Adverse Events Policy).

**EVALUATION**

New knowledge from internal and external research is integrated into practice as applicable.