TITLE: Enrolling Subjects onto Secondary Studies Evaluating Research		
POLICY #: CON-103	**Page:** 1 of 3	**Effective Date:** 1/14/16

1. POLICY STATEMENT:

Overall Principal Investigators proposing secondary studies on the research process will take steps to ensure that the interests of study sponsors and others responsible for primary research studies are protected.

2. BACKGROUND:

Individuals may from time to time propose research studies designed to evaluate or improve the research process itself. For example, an individual might wish to study how well subjects understand their research studies, or to evaluate an intervention designed to improve understanding among subjects. Such secondary studies generally involve individuals who are considering participating in, are currently enrolled in, or have declined participation in a primary research study.

Recognizing the importance of understanding and improving the research process, Dana-Farber/Harvard Cancer Center (DF/HCC) supports the conduct of such secondary studies. At the same time, such studies must be performed in a way that respects the interests of sponsors and subjects.

3. RESPONSIBLE PERSONNEL:

3.1. Overall Principal Investigator (PI)

4. DEFINITIONS:

4.1. **Certificate of Confidentiality:** A document issued by the National Institutes of Health (NIH) that protects identifiable research information collected during the course of a study from forced disclosure. It allows individuals who have access to research records to refuse to disclosure personal identifying information in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

4.2. **Primary Research Studies:** Studies of anticancer or other disease-focused interventions in which individuals at DF/HCC institutions are participating.

4.3. **Secondary Studies Evaluating Research:** Research studies that evaluate the research process itself and recruit individuals considering, taking part in or declining participation in research.

5. POLICY:

5.1. Overall PIs proposing secondary studies will follow methods to protect the confidentiality of study data and determine whether or not permission must be requested from sponsors of primary research studies prior to instituting secondary studies.

5.2. Overall PIs will obtain confirmation from the contracts and/or legal offices to ensure that conduct of secondary studies do not violate non-disclosure or confidentiality agreements placed on primary research studies.

5.3. Methods to enhance data confidentiality may include but not be limited to:

5.3.1. De-identifying the data at the completion of the study so that the data cannot be linked to individuals, protocols or sponsors

5.3.2. Obtaining a Certificate of Confidentiality

5.4. When secondary studies evaluating research involve subjects drawn from a large number of primary research studies (i.e., five or more trials), Overall PIs are not required to obtain permission in advance from study sponsors.

5.5. When secondary studies recruit subjects from a small number of primary research studies (i.e., fewer than five), Overall PIs are required to obtain permission in advance from study sponsors.

6. APPLICABLE REGULATIONS & GUIDELINES:

21 CFR 50 – Protection of Human Research Subjects
21 CFR 54 – Financial Disclosure by Clinical Investigators
21 CFR 56 – Institutional Review Boards
21 CFR 312 - Investigational New Drugs – Drugs for Human Use
21 CFR 812 - Investigational Device Exemptions
45 CFR 46 – Protection of Human Subjects
FDA Industry Guidelines and Information Sheets
FDA Compliance Policy Guidance Programs: 7348.809, 7348.810, and 7348.811

7. RELATED REFERENCES:

International Conference on Harmonisation – E6
OHRS Information Sheet: Instructions for Obtaining and Documenting Informed Consent of Non-English-Speaking Participants

OHRS Information Sheet: Legally Authorized Representatives

8. RELATED FORMS & TOOLS:

OHRS Short Form Consent Document
OHRS Short Form Addendum Document
Oncology Protocol System (OncPro)