

**DANA-FARBER / HARVARD CANCER CENTER
STANDARD OPERATING PROCEDURES FOR HUMAN SUBJECT RESEARCH**

TITLE: Confidentiality of Research Information		
SOP #: RCO-103 (<i>formerly PM-412</i>)	Page: 1 of 2	Effective Date: 9/17/12

1. POLICY STATEMENT:

Research information will not be released to parties outside DF/HCC without permission of the Sponsor.

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

- 3.1. Overall Principal Investigator (PI)
- 3.2. Site Responsible Investigator
- 3.3. Subinvestigator
- 3.4. Research Nurse
- 3.5. Study Coordinator

4. DEFINITIONS:

- 4.1. **Research Information:** Documents that include the protocol, investigational drug brochure, clinical research forms, regulatory files, and all other research information.

5. PROCEDURE:

- 5.1. Research information is considered confidential and cannot be released to any individual or party outside of DF/HCC without permission of the sponsor. Examples of parties considered outside of DF/HCC include subjects (potential or enrolled), the subject's family members or friends, third party payers; other healthcare facilities or investigators employed at outside institutions, or media.
- 5.2. A request for release of research information requires approval in writing by the sponsor.
 - 5.2.1. Protocols that are Industry sponsored or supported may require a Confidentiality Agreement (CDA). The Clinical Research Agreements Office should be contacted for guidance.
 - 5.2.2. Email or other written documentation is acceptable for non-Industry sponsors.
- 5.3. The correspondence documenting approval for the release of the research information must be filed at the Lead Site in the essential regulatory documents.

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- 5.4. Any breach of confidentiality is considered an unanticipated problem and must be reported to the Institutional Review Board (IRB).
- 5.5. This policy does not apply to the informed consent document or protocol summaries and study worksheets created by the research team, which can be shared with outside parties without permission.
- 5.6. This policy does not apply to federal and state agencies such as the Department of Health and Human Services (DHHS), the Food and Drug Administration (FDA), the National Institutes of Health (NIH) including the National Cancer Institute (NCI), the Office for Human Research Protections (OHRP) or other domestic or foreign government bodies if release of protected information is required by law and/or is necessary for oversight purposes and quality assurance.
- 5.7. This policy does not apply to the NCI requirement for the release of protocol documents for PI-initiated protocols without industry support.

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

8. RELATED FORMS & TOOLS:

None

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