TITLE: Confidentiality of Research Information		
SOP #: RCO-103 *(formerly PM-412)*	**Page:** 1 of 3	**Effective Date:** 1/14/16

1. POLICY STATEMENT:

Research information, including data, will not be released to parties outside DF/HCC without permission of the Sponsor. Within DF/HCC, research information will be released only to those DF/HCC personnel involved in the study or who otherwise have a need to access it for purposes of the study.

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, data, and all other research information.

5. PROCEDURE:

5.1. Research information is considered confidential and proprietary and is owned by the Sponsor. As such, it 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. Within DF/HCC, research information may be released only to those DF/HCC personnel involved in the study or who otherwise have a need to access it for purposes of the study. Release to any other DF/HCC personnel requires permission of the Sponsor.

5.3. Research information, including data and protocols, may not be used for other research projects without the permission of the Sponsor and the approval of the DFCI IRB. Sponsor approval must be submitted to the IRB with the new project application.

5.4. Permission for release of research information must be documented in writing by the sponsor as follows:

5.4.1. Protocols that are Industry sponsored or supported may require a Confidentiality Agreement (CDA). The Clinical Research Agreements Office must be contacted for guidance.

5.4.2. Email or other written documentation is acceptable for non-Industry sponsors.

5.5. The correspondence documenting approval for the release of the research information must be filed at the Lead Site in the essential regulatory documents.

5.6. Any breach of confidentiality or violation of this policy is considered serious non-compliance and must be reported to the Institutional Review Board (IRB).

5.7. This policy does not apply to the informed consent document, which can be shared with outside parties and with DF/HCC personnel not involved with the study without permission.

5.8. 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.

5.9. 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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