DANA-FARBER / HARVARD CANCER CENTER
POLICIES FOR HUMAN SUBJECT RESEARCH

TITLE: Confidentiality and Secondary Use of Research Information		
POLICY #: RCO-103	**Page:** 1 of 5	**Effective Date:** 1/31/~~19~~2020

1. POLICY STATEMENT:

Commented [SC1]: Updated throughout to remove old terminology and clarify requirements for PI at each participating site.

Research information, including research data, is considered confidential and proprietary and is owned by the Sponsor. The release of research information to entities outside of and within DF/HCC is controlled and must meet the requirements in this policy.

~~Overall~~ Principal Investigators proposing secondary studies designed to evaluate or improve the research process must take steps to ensure that the interests of study sponsors and others responsible for primary research studies, as well as the subjects, are protected.

2. BACKGROUND:

None

3. RESPONSIBLE PERSONNEL:

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

4. DEFINITIONS:

4.1. **Research Information**: Documents that include the protocol, investigational drug brochure, clinical research forms, regulatory files, collected study data, and all other information associated with the foregoing.

4.2. **Research Data**: Clinical and other pertinent data collected during the conduct of a research protocol (e.g., safety indicators, results). Research data may exist in multiple locations, including medical records, source documentation, case report forms, and research databases. For the purposes of this policy, research information includes research data.

4.3. **Sponsor**: A person who takes responsibility for and initiates a clinical investigation. The sponsor may be an individual or pharmaceutical company, governmental agency, academic institution, private organization, or other organization.

4.4. **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.

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

4.6. **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. Research information is considered confidential and proprietary and is owned by the Sponsor. As such, it cannot be released to any party outside of DF/HCC without permission of the Sponsor. Examples of parties considered outside of DF/HCC include, but are not limited to, study subjects (potential or enrolled), the subject's family members or friends, third party payers, non-DF/HCC healthcare facilities, investigators employed at non-DF/HCC institutions, or media in all formats.

5.2. Within DF/HCC, research information will be released only to those DF/HCC personnel who:

- agree to the terms and conditions of use within this policy, which are required in order to access research information, and
- are involved in the relevant research study, or
- need to access research information for purposes of participation in or support of the relevant study.

5.3. This policy does not apply to the informed consent document, which can be shared with parties outside of DF/HCC.

5.4. This policy does not apply to federal and state agencies such as, by way of example, the Department of Health and Human Services, the Food and Drug Administration (FDA), the National Institutes of Health including the National Cancer Institute (NCI), the Office for Human Research Protections, 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.

5.5. This policy does not apply to the NCI requirement for the release of protocol documents for investigator-sponsored protocols without industry support.

5.6. Any breach of confidentiality or violation of this policy is considered serious non-compliance and must be reported to the IRB of Record.

5.7. **Use or Release of Research Information**

5.7.1. Research information, including research data, may not be used for research projects that are not specified in the protocol and signed informed consent without permission of the Sponsor and approval of the IRB of Record. Such Sponsor approval must be submitted to the IRB with a new project application.

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

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

5.7.2.2. Electronic and hard copy documentation are acceptable forms of written permission from non-industry Sponsors.

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

5.7.4. For all DF/HCC investigator-sponsored trials:

5.7.4.1. Prior to any transfer of research data to parties outside of DF/HCC, the Sponsor-Investigator (or designee) must submit a formal data request to the Office of Data Quality.

5.7.4.2. There must be a non-disclosure agreement (CDA) in place prior to any transfer of research information (in particular a research protocol) or a data transfer agreement in place prior to any transfer of any research

data to parties outside of DF/HCC, unless such transfer of research data is specifically permitted by the study protocol and signed informed consent.

5.7.4.3. Any research data may be transferred only after all required monitoring and data cleanup activities have been completed and verified by the study monitor and the Office of Data Quality.

5.7.4.4. Research data to be transferred should be de-identified.

5.7.4.5. If research data to be transferred contains any Protected Health Information (PHI) as defined by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), all uses of such Data must be authorized by the signed HIPAA authorization.

5.8. **Secondary Studies Evaluating Research**

5.8.1. ~~Overall~~ PIs proposing secondary studies evaluating research must implement methods to protect the confidentiality of study data. This must minimally include, but may not be limited to:

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

5.8.1.2. Obtaining a Certificate of Confidentiality

5.8.2. ~~Overall~~ PIs proposing these secondary studies must determine whether or not permission must be requested from sponsors of the primary research studies prior to initiating secondary research.

5.8.2.1. 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.

5.8.2.2. 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.

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

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 RESOURCES:

None