

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

TITLE: Confidentiality of Research Information		
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1. POLICY STATEMENT:

Research Information, including Research Data, will not be released to parties outside of Dana-Farber/Harvard Cancer Center (DF/HCC) without permission of the Sponsor. 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.

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, 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.

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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.

Research Information may be released only to those DF/HCC personnel who agree to the terms and conditions of use required in order to access Research Information.

5.2. 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 DFCI Institutional Review Board (IRB). Such Sponsor approval must be submitted to the IRB with a new project application.

5.3. Permission for release of Research Information must be documented in writing by the Sponsor as follows:

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

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

5.4. The correspondence documenting approval for the release of the Research Information must be filed at the Lead Site in the essential regulatory documents.

5.5. For all Principal Investigator (PI)-initiated trials:

5.5.1. Prior to any transfer of Research Data to parties outside of DF/HCC, the Sponsor-Investigator must submit a formal data request to the Office of Data Quality.

5.5.2. 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

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

- 5.5.3. 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.
- 5.5.4. Research Data to be transferred should be de-identified.
- 5.5.5. 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.
- 5.6. Any breach of confidentiality or violation of this policy is considered serious non-compliance and must be reported to the DFCI IRB.
- 5.7. This policy does not apply to the informed consent document, which can be shared with parties outside of DF/HCC.
- 5.8. 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.
- 5.9. 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

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7. RELATED REFERENCES:

International Conference on Harmonisation – E6

8. RELATED RESOURCES:

None

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