TITLE: Confidentiality of Research Protocols	
SOP #: PM-412	**Page:** 1 of 2

Applicable Regulations & Guidelines:

Other References: Refer to applicable agreements including clinical trial agreements (CTA), material transfer agreements (MTA) or cooperative research and development agreements (CRADA)
OHRS Information Sheet: "Guidelines for Sharing of Protocols"

Responsible Personnel: All research study personnel including investigators and study staff

Policy Statement: Research protocols will not be released to parties outside DF/HCC without permission of the Sponsor**.**

Definitions:

Research protocols - These documents include the protocol document, investigational drug brochures, clinical research forms and other protocol related documents excluding the informed consent document.
Sponsor – This may be a pharmaceutical company, a sponsor-investigator, or a DF/HCC institution.

Procedure:

1) Research protocol documents are 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 research subjects (potential or enrolled), patient's family members or friends, third party payers; other healthcare facilities or investigators employed at outside institutions, or media.

2) A request for release of research protocol documents requires approval in writing by the sponsor. A Note-to-File signed by the Overall P.I. is acceptable documentation for DF/HCC PI-Initiated protocols. Protocols that are Industry sponsored or supported may require a Confidentiality Agreement (CDA). The DFCI Clinical Research Agreements Office should be contacted for guidance. The correspondence documenting approval for the release of the research protocol documents must be filed in the DF/HCC Lead Site Regulatory Binder.

3) This policy does not apply to the informed consent document or protocol summaries and study worksheets created by the study team, which can be shared with outside parties without permission.

4) 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), 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) This policy does not apply to the National Cancer Institute (NCI) requirement for the release of the protocol documents for DF/HCC PI-initiated protocols without industry support.