

OHS Information Sheet Guidelines for Sharing of Protocols

The request comes up from an outside party, possibly a committee for a recent NCI project or maybe even a patient's insurer – "We need a copy of the Protocol of your clinical research studies for business purposes." – ***what should you do?***

When questions arise about releasing a Protocol to someone other than the study team and/or DFHCC study sites (a "third party"), ***seek advice from the DFCI Clinical Research Agreements Office*** ("CRAO"). Mary Melloni, RN, JD, MBA is the Director of the CRAO. She can provide you with guidance and recommendations for DFCI, DFPCC and DFHCC clinical research agreement issues such as third party Protocol release requests. If such requests come to Beth Israel Deaconess Medical Center (BIDMC), consult with Denise Graham, RN, JD, Manager of the BIDMC Clinical Trials Office under BIDMC Research and Academic Affairs.

In general, Clinical Trials Protocols that have industry sponsorship or support ***should never be shared*** with an entity outside of the DFHCC – or even with DFHCC employees who are not directly involved with the functions of the trial itself. Sharing this information could violate confidentiality restrictions in the Clinical Trial Agreement negotiated by the CRAO. Disclosures that are not permitted under the Clinical Trials Agreement potentially expose the Institution to a legal suit by the industry sponsor or funder for breach of confidentiality obligations.

Permission to share confidential Protocols must be requested from the sponsor or funder. The Finance Department makes requests for payment and insurance-related issues; the Study Team requests permission for a project or publication-related disclosures.

If a sponsor or funder agrees to share the Protocol with a third party, a Confidentiality Agreement (CDA) should be put in place to define who has access to the Protocol, the purposes of sharing the information and any other restrictions on its use. The CRAO will negotiate the CDA prior to release of the Protocol.

For questions about sharing Protocols with third parties or other clinical research agreement issues, please contact Mary Melloni. When in doubt – feel free to ask!

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