Multicenter Subject Confidentiality

SCOPE

This policy applies to any multicenter research protocol for which MD Anderson Cancer Center (MDACC) is the lead institution and under the oversight of Office of Protocol Support & Management (OPSM). It is the policy of the OPSM to ensure that participating sites conduct the trial in compliance with the currently approved protocol/amendment(s), Good Clinical Practice (GCP) Guidelines, Standard Operating Procedures (SOPs) and Federal and State Regulations.

PURPOSE

Define the processes that the OPSM will follow in order to ensure multicenter subject confidentiality in accordance with the Health Insurance Portability and Accountability Act (HIPAA) and ICH GCP Guidelines.

POLICY STATEMENT

The OPSM will attempt to limit its use of personal protected health information. However, portions of a subject’s protected health information may be collected. The following quality assurance process will be applied to multicenter clinical research studies that are under the oversight of the OPSM and that require the submission of a subject’s protected health information.

PROCEDURE

Authorization for the Release of Protected Health Information

In order for the OPSM to collect protected health information on any subject enrolled in a study, the subject must have signed an informed consent document, which includes an authorization for the release of protected personal health information (IC/A). The consent and the authorization documents may be included in a single document or in separate documents dependent upon the local policies of the participating institution.
The authorization that each institution obtains to use and disclose protected health information must include MD Anderson as an entity with whom they will share data. Each institution should also list the sponsor in their authorization form. This consent and authorization (IC/A) document authorizes the OPSM to collect and retain documents, reports, and/or information which would relate to the subject’s participation on the protocol into which the subject is being enrolled. This document also authorizes the OPSM to send aggregate and/or composite data for the entire study to participating institutions.

Subjects that have not signed a consent and release of their personal protected health information may not be enrolled in the study.

**De-identification of Subject Data**

All documents, investigative reports, or information submitted to the OPSM and relating to the subject are strictly confidential. Any subject specific data or reports (i.e. Pathology Reports, MRI Reports, Operative Reports, etc.) submitted to the OPSM should include the assigned OPSM subject ID number and protocol number and must have the subject’s full name & social security number de-identified. Subject initials may be included or retained for cross verification of identification.

The de-identification process can be waived only when the following criteria are met:

1) The participating institution provides the OPSM a written IRB policy or statement that the identification process is not required on documents submitted to the OPSM.

2) The study participants give their authorization to MD Anderson for the use and disclosure of their protected health information.

**REFERENCES**

- The Health Insurance Portability and Accountability Act (HIPAA) of 1996
- 45 CFR Part 164: The HIPAA Privacy Rule on Security and Privacy
- ICH GCP 2.1, 2.3, 2.9 & 2.11 The Principles of ICH GCP
- ICH GCP 5.1 Quality Assurance and Quality Control
- ICH GCP 5.23 Multicenter Trials
## DOCUMENT HISTORY

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