SCOPE

This policy applies to any multicenter research protocol for which MD Anderson Cancer Center (MD ACC) is the lead institution and under the oversight of the 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

Provide a standard policy regarding the registration of subjects involved in multicenter research protocols that are coordinated by the OPSM.

POLICY STATEMENT

The OPSM will follow the centralized subject registration procedures defined by this policy when the coordinating center of a multicenter research protocol has the responsibility to provide for the centralized registration of subjects.

PROCEDURE

Protocol Language

The procedures for centralized registrations must be stated in the protocol.

Informed Consent

Subjects must sign and date an Institutional Review Board (IRB) approved consent form prior to protocol registration and initiation of treatment.
Release of Protected Personal Health Information

In accordance with the OPSM’s Multicenter Subject Confidentiality Policy, the OPSM will attempt to limit the use of protected health information in its trials. However, portions of a subject’s protected health information may be collected. In order for the OPSM to collect this information on any subject enrolled, the subject must have signed an authorization for the release of their protected personal health information to MD Anderson Cancer Center.

Centralized Registrations

A centralized registration procedure will be used. Subjects who are considered candidates for the study will be evaluated for eligibility by the participating investigator. There will be a 2-part registration procedure:

1) Participating Institution Registration

Subjects at participating institutions should be registered with their institutional central registration following each institution’s established policies.

2) OPSM Registration

Participating institutions must register subjects with the OPSM in accordance with project specific procedures. All participating institution subjects must be registered with the OPSM before protocol treatment/intervention is initiated. Late registrations will not be accepted.

Registrations performed by the OPSM (if applicable) will be completed within 1 business day after the date the registration is received from the participating site or as defined in the protocol and DQMP.

Subject ID Number

At the time of registration the participating institution’s subject will be assigned a OPSM subject number. This number is unique to the subject and written on all data and correspondence for that subject prior to submission to the OPSM.

MD Anderson subjects will be registered using their MD Anderson medical record number.

Registration Verification Letter

For registrations performed by the OPSM a Registration Verification Letter will be e-mailed to the participating institution after the registration is completed.

Initiation of Therapy/Study Interventions
Subjects must be registered with MDACC before receiving study treatment/interventions. Treatment/Interventions may not be initiated until the participating institution receives the subject’s Registration Verification Letter.

Confidentiality

All documents, investigative reports, or information relating to the subject are strictly confidential. Any subject specific data or reports (i.e. Pathology Reports, MRI Reports, Operative Reports, etc.) that the site submits to the OPSM will adhere to the OPSM’s Multicenter Subject Confidentiality Policy.

REFERENCES

ICH GCP 5.1 Quality Assurance and Quality Control
ICH GCP 5.5 Trial Management, Data Handling, and Record Keeping
ICH GCP 5.23 Multicenter Trials


DOCUMENT HISTORY

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