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 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 mechanism for enrolling a subject on an active multicenter protocol who does not meet the stated eligibility criteria and enrollment of the subject will not affect the final analysis or interpretation of the study.

POLICY STATEMENT

It is the policy of the OPSM to ensure that all participants to be enrolled in multicenter research protocols are eligible.

PROCEDURE

- For a PI override to occur the protocol must state that eligibility exemptions are allowed.
- MD Anderson Principal Investigator (PI) and participating site PI must agree that the inclusion of the subject will not affect the final analysis or interpretation of the study.
- The participating site PI must obtain approval from his/her IRB for the eligibility exemption before submitting the request to the MD Anderson PI.
- The MD Anderson PI will provide documentation of his/her appropriate rationale for allowing the exemption by completing the PI Override Request Form and submitting it to the MD Anderson Institutional Review Board (IRB).
- Any project specific guidelines must also be followed.
• In the event that this request is denied, the subject cannot be registered. Both the MD Anderson PI and the participating site PI will be notified.

For subjects from MD Anderson:
The local MD Anderson department shall follow the institutional policy regarding PI overrides.

REFERENCES

M.D. Anderson Cancer Center Office of Protocol Research departmental page under section PI Override Request Form and Procedure

DOCUMENT HISTORY

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