

Hollings Cancer Center

At the Medical University of South Carolina

Policy Number: DM-03

Policy: Subject Eligibility and Protocol Waiver Process

Policy Manual: Research Administration

Supersedes:

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Purpose: To ensure subject eligibility, patient safety and scientific validity for all human studies activated at the Hollings Cancer Center.

Policy Statements: Eligibility criteria are established to ensure patient safety and prove efficacy of the test article in question. While no eligibility waivers should ever be sought for an NCI study, seeking eligibility waivers for non-NCI funded studies is strongly discouraged. There may be instances where a waiver may be sought, but it is the policy of the Hollings Cancer Center that no waivers based on a lower performance status be allowed, as a subject's performance status is a crucial marker of physiologic function shown to predict outcome of treatment. When a waiver is granted for a lower performance status, it can increase the risks for the subject considered for enrollment and impacts the scientific validity of the study. Moreover, any request for such a waiver suggests that the principal investigator does not believe that the enrollment criteria are relevant to the study objectives. In any case, the principal investigator must be prepared to submit a request to the sponsor to amend the criteria, and inform the IRB of such a request in a timely fashion.

Procedures:

1. Upon screening a potential patient, if the subject does not meet the eligibility criteria as specified in the IRB approved protocol, that subject will not be enrolled into the clinical trial. If the principal investigator believes the unmet criteria is/are not clinically relevant, they

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may request a waiver from the sponsor, provided that eligibility criteria in question are not based on performance status.

2. When a waiver is sought, it suggests that the principal investigator believes the eligibility criteria in question are not relevant to the objectives of the study. Therefore, the principal investigator must submit a document to the sponsor requesting that they modify the criteria in question along with the clinically relevant reasons supporting this opinion. If the protocol is in the process of being amended to address the concern, a copy of the revised protocol eligibility may be submitted in lieu of the letter to the sponsor. If the protocol is investigator-initiated, a copy of the revised protocol must be submitted. The amendment must follow the usual IRB approval process.
3. If the sponsor has approved the waiver, the protocol deviation needs to be reported to the IRB immediately via the IRB protocol deviation reporting form. A copy of the letter to the sponsor mentioned above or, in the case of an investigator-initiated trial, the revised protocol must accompany the protocol deviation reporting form.
4. The PMC will review all eligibility waivers to determine the impact they have on the patient's safety and on the scientific validity of the study in question. In the event that a waiver is not approved the investigator will be notified.

Approved by: Protocol Monitoring Committee