NELSON MANDELA UNIVERSITY

Standard Operating Procedures
Research Ethics Committee (Human) (REC-H)

- **Study suspension and termination**

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1 STUDY SUSPENSION AND TERMINATION

1.1 POLICY

1. According to the Department of Health, where a research ethics committee is satisfied that such circumstances have arisen that a research project is not being conducted in accordance with the approved protocol and that, as a result, the rights and welfare of participants are not or will not be protected, the research ethics committee may withdraw approval. The research ethics committee shall also inform the researcher and the institution of its action and shall recommend that the research project be discontinued or suspended. Where ethical approval has been withdrawn, a researcher must discontinue the research and comply with any special conditions required by the research ethics committee.

1.2 PURPOSE

1. The purpose of this policy is to outline the procedures for suspending or terminating research.

1.3 PROCEDURES

1. The REC-H may suspend or terminate a study based on a report or allegation of:
    a. Unanticipated problems involving risks to participants or others.
    b. Serious or continuing non-compliance.
    c. Findings in the continuing review or monitoring process.

1.4 SUSPENSION

1. A suspension occurs when the REC-H Committee or Chair places a temporary hold on research that has been previously approved so that no new participants may be accrued, no research interventions may occur unless necessary for currently enrolled participants' safety and welfare, and no follow-up may be conducted unless it is in the best interest of participants and approved by the Committee.
2. Note: The word 'suspension' in this section refers to suspensions as a result of the REC-H decision but can also refer to suspensions that occur automatically due to a lapse of Committee approval. *A suspension due to lapse of Committee approval will be referred to as an 'administrative closure' which will automatically occur when the Committee approval period expires.*
3. The REC-H Chair will notify the PI of the suspension or termination in writing, providing reasons. The Chair will inform the PI of steps to be taken as a result of the suspension or termination of the research study.

1.5 TERMINATION

1. Termination of a previously approved protocol occurs when the REC-H withdraws approval and stops all research activity permanently. No new participants may be enrolled, and no further research interventions can occur. Where indicated, follow-up visits may be conducted with Committee approval to monitor participants' safety and welfare.
2. The REC-H Chair will notify the PI of the suspension or termination in writing, providing reasons. The Chair will inform the PI of steps to be taken as a result of the suspension or termination of the research study.

1.6 STEPS TO BE TAKEN

1. Steps could include:
    a. Drafting a plan to withdraw participants which protects their safety and wellbeing.

b. Notifying current participants, by phone, email or in person, that the study has been suspended or terminated and providing reasons for the action.
c. Notifying participants of any follow-up procedures, assessments or referrals which are necessary and permitted by the REC-H for their safety. This may require a gradual withdrawal, if an abrupt discontinuation is likely to put participants at risk.
d. Temporary or permanent transfer of responsibility for the study to another PI.
e. Reporting any adverse events or outcomes to the REC-H and sponsor which happened during follow-up.

2. All written communication from the investigator to the participants requires REC-H approval prior to distribution.
3. The PI may appeal against the decision to suspend or terminate a study within seven calendar days of receiving written notification. The written appeal to the REC-H needs to include a plan for ensuring that the rights and welfare of currently enrolled participants are protected and a plan to ensure that future participants will be protected if the study receives Committee approval.

1.7 Investigator-Initiated Voluntary Suspension or Termination (Discontinuation)

1. An investigator may choose to voluntarily suspend or terminate some or all activities of an approved protocol.
2. The investigator must notify the REC-H Chair and provide reasons for the suspension or termination.
3. The committee may request any additional information in order to make an independent determination.
4. Researchers (staff and/or students) of currently active studies who determine that the discontinuation of study is imminent for whatever reasons, are required to complete and submit a notification for the discontinuation/closure of the study.
5. For the discontinuation of a study and therefore the data collection for which ethics approval was granted, the discontinuation/closure report should be submitted no later than 1 month after reaching such a conclusion.

1.8 Records

1. The date that the research is suspended, terminated, or voluntarily suspended or terminated must be noted in the protocol file and the database.
2. All correspondence relating to these actions will be filed with the protocol.

1.9 Administrative Closure of a Protocol or Suspension due to Lapse of Ethics Committee Approval

1. If a continuing review of an active study is not approved prior to the expiry date, the REC-H approval will automatically end, and the study will be suspended. It is the responsibility of the PI to monitor approval periods and to ensure that continuing review reports are filed in time to allow expedited of full committee review.
2. Whilst the committee will try to send our letters informing PIs of a suspension for lapse of approval, PIs remain responsible for suspending all research activities.
3. For the imminent closure of a study, a closure report may be submitted on conclusion of data collection activities as long as it is known that no further interaction with participants will be conducted. An updated progress report must be submitted with the closure report. A suspension due to lapse of Committee approval will be referred to as an 'administrative closure' which will automatically occur when the Committee approval period expires.

4. For a study where ethics approval has lapsed.
    a. A new ethics application is required, which will undergo the full review process for new applications. If a low-risk study, the applicant submits their project through the Department/Faculty committee, and it will subsequently be ratified at the REC-H. If a medium/high risk study, it must serve at a convened meeting of the REC-H. A new ethics reference number will be allocated. Information on previous ethics clearances obtained for the previous (lapsed) study should be included in the new application.
5. Researchers are advised to familiarise themselves with the Closure/Discontinuation of a Study guidelines and instructions prior to completing and submitting a relevant request for study termination/suspension. Failure to do so might result in a delay in the review and approval of the request.
6. Researchers (staff and/or students) of currently active studies who determine that the closure of study is imminent for whatever reasons, are required to complete and submit a notification for the discontinuation/closure of the study.