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Health Research Ethics Committee (HREC)

Guidance: Student projects linked to a larger study

When to submit an HREC application for a new protocol and when to submit an HREC amendment application

The requirements for HREC submissions are based on the regulatory requirements for research protocol review in South Africa, and they centre around the review and approval of a *particular research protocol* and the objectives and data collection attached to that protocol that are required to answer the particular research question.

In general the rule of thumb for HREC submissions (including for PhDs and Masters) is as follows:

1. If the student is pursuing a **new research question**, then they must submit an **HREC application for a new protocol** (this includes the conduct of a sub-study linked to a parent study, or a sister-study using the data from the original study);
2. If the student is merely **pursuing one of the existing, already-approved objectives of a protocol already approved by HREC**, then **no new HREC submission** for the research project would be required (unless the Stellenbosch University policy for that particular environment requires that the student submit and receive their own HREC approval). The student should be listed as part of the research team and if not already on the team, should be added through an **HREC amendment application for a new investigator**;
3. If the student is **adding a new objective to a protocol already approved by HREC**, then a **standard HREC amendment application** is required to add the objective. The student should be listed as part of the research team and if not already on the team, should be added through an **HREC amendment application for a new investigator**;

This is often not as simple as it seems as the line between a new research question and a new objective within an existing research question can be hazy. The onus therefore rests with the student and/or supervisor to adequately explain/detail the nature of their proposed research in their HREC submission or in their justification for why they believe there should be no HREC submission.