

**Checklist for attachments for a sub-study under a larger study research ethics approval applications to the HREC:**

Document		Tick if attached	Comment
1	Have the data/biological samples already been gathered, or are these in a process of longitudinal gathering, or part of an intervention?	If yes:  If no:	Continue  Make sure the larger study truly qualifies as a larger study by completing the <b>attached evaluation form</b> .
2	Is the study clearly stated as an objective in the larger study?	If yes:  If no:	Continue  Make sure the larger study truly qualifies as a larger study by completing the <b>attached evaluation form</b> .
3	Cover letter that indicates: <ul style="list-style-type: none"> <li>• Title of the larger study</li> <li>• Title of the sub-study</li> <li>• Student information</li> <li>• Supervisor(s)</li> <li>• What the sub-study is about and how it fits into the larger study; the objective(s) it intends to fulfil from the original study</li> <li>• What documents are attached</li> <li>• Detailed description of any outstanding issues of the larger study identified during the evaluation of the larger project (see evaluation form below) done by the project leader and how it will be addressed. <i>(Note: This should be handled as a separate amendment to the larger study if it involves changes that will still take place in future and should be done before the sub-study is submitted for ethics approval.)</i></li> </ul>		
4	Executive summary of the sub-study (150 words only)		
5	Original proposal of the larger study		
6	Original informed consent documentation of the larger study		
7	Copy of the ethics approval certificate of the larger study		
8	Letter from the project leader clearly indicating <i>which objective(s) will be covered</i> as a sub-study under the larger project, as well as clearly specifying <i>what part of the previously collected data/biological samples can be used and for what</i>		
9	Approval letter of the sub-study by the scientific/proposal committee		
10	New proposal of the sub-study		
11	2-page narrative CVs of all the researchers in the sub-study		
12	Proof of ethics training over the past three years for all the researchers involved in the sub-study		
13	Signed NWU code of conduct for researchers for each team member		
14	Signed statistical consultation form		
15	<b>Submitted as hard or scanned copies:</b> Printed and signed pages of the ethics application form for the declarations by the project leader, statistical consultation services, director of the research entity		
16	Checklist of attachments		

<b>If applicable:</b>			
17	Confidentiality agreement		
18	Indemnity form		
19	Form A for delegated ministerial consent in the case of greater than minimal risk research in children with no prospect of direct benefit to them		
21	Permission letter of the chairs of the HREC and HHREC if the study is an affiliated study or sub-study under a larger study on another campus than where the student is registered		
22	Evaluation form to see if the larger study qualifies as a larger study, completed by the project leader		