Student and Supervisor Guidelines – Ethics clearance(s) for research in the context of a joint doctoral degree under a partnership agreement with an international institution.

1. Introduction

Stellenbosch University (SU) has several partnership agreements with international institutions in different countries that make provision for SU researchers to jointly supervise PhD students who enrol at both partner institutions. The purpose of this document is to describe some of the considerations around ethics clearance that such students and supervisors should keep in mind when embarking on a joint degree research process and to refer to resources that should be consulted, if uncertainty arises.

2. Joint doctoral degrees at Stellenbosch University

SU's partnership agreements with international institutions make provision for the joint enrolment of students for degree programmes where they are jointly supervised (by a supervisor from each partner institution). The students work on a single topic and produce a single thesis, which is examined by a joint examination committee and upon successful defence of the thesis, the candidate is awarded a joint degree from SU and the partner institution.

A joint degree typically requires observation of the procedures of application, admission, and enrolment by the candidate at both partner institutions. The student is subject to the rules and regulations of both institutions and must fulfil the requirements for obtaining the degree at both institutions. At present, many of the academic administrative requirements and some legal aspects that govern a candidate's joint degree are covered in an individual candidate agreement. The individual candidate agreement is usually informed by a framework agreement concluded between the partners.

Under a joint degree agreement, it is often useful to distinguish between the partner institutions for practical purposes and to try to avoid unnecessary duplication. The main or home University is usually designated in the individual candidate agreement and is generally determined based on one or more of the following criteria:

- Funding: the institution that funds (majority of) the doctoral research or the institution to which the supervisor belongs under whose authority the application for funding occurred;
- Presence: the institution where most of the doctoral research takes place, where the PhD researcher will spend most of his/her research time (usually based on access to research infrastructural considerations);
- Origin: the institution where the doctoral research was initiated, where the PhD candidate first registered.

If the above criteria are not sufficient to distinguish between the two institutions, the main institution will normally be decided by mutual agreement. The second institution where the student is jointly enrolled for the PhD is thus designated the Partner University.

Whilst it is undesirable to require students to duplicate all processes and procedures at both institutions, this may be necessary for the conclusion of certain matters, particularly where institutions may have different requirements and especially where there may be conflicting requirements. Ethics clearance for the student's research is a requirement that may pose such

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challenges, as requirements may be different between countries. For example, in South Africa, all research activities that anticipate interaction with human participants, the use of human data/information or biological specimens must be reviewed and approved by an accredited research ethics committee, prior to the start of research. In addition, unlike some countries, including the USA, even if data is anonymised, Research Ethics Committee (REC) review is still required in South Africa.

All animal research, teaching and testing activities in South Africa are subject to prior ethics review and approval by an accredited REC – with animals as primary focus. The South African National Standard for the care and use of animals for scientific purposes 10386:2008 is a guideline document that sets the minimum standards for research involving animals. It defines an animal as follows: "*live, non-human vertebrate, including fertilized eggs, foetuses and embryos, i.e., fish, amphibians, reptiles, birds and mammals, and encompassing domestic animals, feral animals, purpose-bred animals, farm animals, wildlife and higher invertebrates, such as the advanced members from the Cephalopoda and Decapoda (for example, octopus, squid, cuttlefish)*". This definition should thus be used to confirm the need for ethics review and approval of a project.

Research, teaching and testing activities in South Africa utilizing recombinant DNA, biohazardous materials, genetically modified organisms (GMOs) and engineered nanomaterials that have the potential to negatively impact the physical, biological, or spatial environment must also undergo an ethics review and approval process by a REC – with biosafety as primary focus.

3. Some considerations for ethics clearance(s) for joint degree projects

The following is a non-exhaustive list of factors, which should be taken into consideration by any student and their supervisor(s) when contemplating or embarking on a joint PhD degree at SU and a partner university abroad.

- a. Ethics clearance must be secured before any data collection commences. Therefore, the student and the supervisors must factor the time required to secure ethics clearance into their planning. At SU, it takes at least 2-3 months from an application being made to the REC before a researcher gets the final decision on their clearance, at which point they can commence with their data collection.
- b. Early on, the student and the supervisors must acquaint themselves with the ethics clearance requirements and procedures of both institutions as well as specific in-country requirements that may impact ethics review for protocol approvals and subsequent data collection. It would be advisable for consultation with the relevant research ethics committee/institutional review board at both institutions to take place for proactive clarification of requirements and the time required to obtain ethics clearance to be met by the candidate.
- c. Due consideration must be given to the research topic and the subject of the intended investigation that may have different cultural meanings in different settings. For example, the use of socially constructed categories, such as race, ethnicity and gender may be highly sensitive in one context but less sensitive in another.
- d. Local conditions, definitions and adherence to national regulatory requirements may make it mandatory to obtain ethics clearance in both countries.
- e. The site of data collection generally guides where ethics clearance must be sought but it would not necessarily exempt a candidate from the ethics approval requirements of the

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partner institution. In cases where REC/IRB review and approval is required in both countries, the site of data collection can also be used to determine which REC/IRB would have the primary mandate or final decision-making authority. For example, if the research is conducted in South Africa, the SA REC should have the final decision-making on what requirements ought to be met for approval.

- f. Where data will be collected in two or more sites in different countries, then the ethics clearance requirements of both countries (including local and national regulations, permit requirements and any other required permissions from external bodies, where applicable) must be respected and complied with.
- g. Ethics clearance submissions and ethics approvals for joint degrees where Stellenbosch University is involved would need to be available in English.
- h. Depending on the requirements of each, it may be possible, under certain circumstances for one of the institutions to grant an exemption from ethics clearance depending on the nature of the study design of the candidate's project (for example, the use of secondary data or meta-analyses). Alternatively, it may be possible for one institution to conduct a reciprocal review on the strength of ethics clearance obtained at the partner institution. This would require communication with the relevant research ethics committees, in advance, to ensure the requirements for reciprocal review are met. Finally, in the candidate's interest and if the partner institutions' policies allow for it, it may be possible to undertake joint review. Such arrangements would need to be agreed upon in advance between the institutional partners with clarification of the scope of such a joint review.

4. Contact details for further information

To obtain advice on the above considerations and assistance with selecting the most suitable SU REC(s) for your study, please find the contacts details of the different SU RECs below:

SU Research Ethics Committee	REC Co-ordinator	Email address
Social Science, Behavioural & Education Research (REC: SBER)	Mrs Clarissa Robertson	<u>cgraham@sun.ac.za</u>
Biological & Environmental Safety (REC: BES)	Mr Winston Beukes	wabeukes@sun.ac.za
Animal Care and Use (REC: ACU)	Mr Winston Beukes	wabeukes@sun.ac.za
Health Research Ethics Committee 1 (HREC1)	Ms Melody Shana	<u>melodys@sun.ac.za</u>
Health Research Ethics Committee 2 (HREC2)	Ms Brightness Nxumalo	brightness@sun.ac.za

Useful links:

Integrity and Ethics

Navigating the SU Ethics Approval Process

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