**Terms of Reference: School (of Medicine) Student Project Ethics Committee (S-SPEC)**

***Membership:***

Undergraduate Student Rep years 1-2 *Mr Stephan Abdullah,*

*Mr Simran Parmar*

Undergraduate Student Rep years 3-5 *Miss Emma Hockey*

Postgraduate Student Rep *Miss Yolanda Gómez Gálvez*

Cross Faculty Rep *Mr Glenn Hussey*

Lay Rep *Mr David Clamp*

Academic Undergraduate Staff Rep *Dr Sarah Hart, Dr Russell Crawford, Mr Steven Buddle*

Academic Postgraduate Staff Rep *Dr Heidi Fuller, Dr Clive Gibson*

Clinical Academic Rep *Dr Janet Lefroy, Dr Maggie Bartlett*

Chair *Dr Karen Adams*

***Scope:***

Ethical review of all student projects involving human participants and cadaveric material, including interview, questionnaire and experimental studies. The ethics review process provides safeguards for staff, students, and project participants. For the purposes of these guidelines, a ‘project involving human participants’ contains one or more of the following elements:

1. Experimentation on human beings and cadaveric material
2. The observation of human beings for the purposes of a student project
3. The recording, storage, or use of personal data for use in a student project; personal data for these purposes include all information (excluding that already in the public domain) about existing individual people or about those who have died within living memory

Any project that falls into one of the categories above and does not require NRES (National Research Ethics Service) approval must be reviewed by S-SPEC. For research involving cadaveric material conducted solely within the Medical School building, Keele School of Medicine Anatomy facility has global ethics approval but each project will need to be individually reviewed by S-SPEC. Any other projects proposing to use human tissues should contact the Human Tissues Officer and apply to the University Ethics Review Panel (ERP).

The processes outlined here apply only to projects undertaken by undergraduate students (UG) and students on a postgraduate taught course (PGT). If UG or PGT students are doing work which forms part of a research project led by Keele staff or a Keele PGR student then the entire project should be treated as staff/PGR research and applications should be made to the University ERP.

The S-SPEC chair along with senior management will also be responsible for regulating access to medical students as research participants from both internal (School of Medicine) and external (Keele and other University) applicants. This is to protect students from external surveys that have not received ethical approval from a relevant body and avoid over-burdening them with participation requests. Any external requests approved by senior management will be forwarded to the S-SPEC chair who will maintain a register of ***all*** current projects involving medical students, regardless of which committee has granted approval, to enable a full overview of research activity. The chair will also collaborate with the relevant year/programme leads to organise access arrangements. Approved external research projects will be posted on the KLE and an alert sent to the relevant student group. Any requests for research involving access to Medical School data, staff or students will also require approval by senior management before ethical review can go ahead.

***Terms of Reference***

To be responsible for, and report to the University Research Ethics Committee (UREC) and the School of Medicine (Learning and Teaching Committee) on the following:

1. Identifying, reviewing, approving and monitoring the ethical considerations which form part of student research projects undertaken as part of a taught course within the school
2. Providing guidance to individual enquiries and referrals to the appropriate ethical committee for research review
3. Protecting the interests of Keele medical students by ensuring research participation requests have received appropriate ethical approval from a relevant body
4. Maintaining contact with relevant year leads/course director to negotiate access to Keele medical students by the researcher and monitor the number of research projects being conducted
5. Ensuring that S-SPEC provides annual reports to UREC on:
	* Numbers and types of student projects reviewed and approved
	* A summary of the specific ethical issues that have been raised
	* Policy areas that need to be addressed
6. Ensuring that the annual report is sent to all academic members of the School of Medicine
7. Maintaining a research request repository

***Constitution***

*Quorum requirements*

A quorum shall consist of four members (to include the Chair) for meetings.

Where ethical review of projects is undertaken through email correspondence, written responses from at least five members will be required, and approval will only be granted where responses are unanimous\* If a unanimous decision cannot be reached when reviewing a project, a face to face meeting of S-SPEC meeting will be called.

*Frequency and Timing of Meetings*

One face to face meeting a year will be held and minutes will be recorded.

*Timetable for Review of Terms of Reference*

Annually, in line with the timescale of the Annual Report to UREC.

*\*Project Review Procedures*

The project is submitted to the Committee Chair via the Administrator. Submitted details will include the study protocol, participant consent and information procedures, a completed ethics application pro-forma and a copy of the peer review that has been undertaken for the project.

The chair will scrutinise the proposal to ensure complete documentation is provided, and any project that should be reviewed by an alternative ethics review committee will be returned to the applicant for submission to the correct body.

The study details and ethics application will be circulated by email to all committee members with a request for feedback and completion of the ethics approval pro-forma within ten working days. There is an expectation that members should return a review for a minimum of 50% of applications that are received within one academic year.

The Chair collates members’ responses and communicates the outcome of the ethical review to the student by means of a formal letter.

Any issues of concern or generic issues will be picked up and discussed at the next ethics committee meeting.

*Ethics Offences*

An ethics offence takes place if the student’s project requires but has no prior School ethics approval ­or if the project deviates substantially from what was approved by the S-SPEC (or equivalent). The S-SPEC chair in consultation with colleagues will determine whether any alleged offence warrants a penalty or no offence has taken place so no further action is required. All identified offences will be deemed as serious by the Medical School and depending on the severity of the offence, students will be required to have a formal meeting with the relevant year lead or course director with the possibility of referral to Health and Conduct Committee (or the post-graduate equivalent) or in exceptional circumstances, Fitness to Practice. Any offences classed as major by the University regulations (Regulation 8, Section 11) or repeated minor offences will be referred to the Student Conduct Manager.

*Appeals Procedure*

In the event that an application is rejected, an appeal may be made to Nicola Leighton, Research Governance Officer, Keele University.

**FLOW CHART OUTLINING THE PROCESS FOR INVESTIGATING ALLEGED ETHICS OFFENCES WITH *ACADEMIC* AND *PROFESSIONAL* IMPLICATIONS**

Alleged offence is referred to the S-SPEC Chair

Chair of S-SPEC in consultation with colleagues determines

1. If alleged offence warrants further action or the alleged offence is mistaken and can be dismissed
2. If the offence warrants further action and needs to be considered as a breach of professionalism or academic misconduct

No offence

Minor Offence

No further action required

Major Offence

Chair of S-SPEC shall:

1. inform the student that an offence has been committed
2. refer the student to the relevant year leads/ programme lead for a formal meeting. This may result in referral to Health and Conduct Committee (or the post-graduate equivalent) or Fitness to Practice

Refer to Lynn Knight, Student Conduct Manager who, if satisfied that there is a case for investigation, shall inform the student of the nature of the allegation and of the arrangements by the Academic Misconduct Panel constituted under regulation 8.12.3. Following the outcome of this, the S-SPEC Chair will also follow the procedure outlined for minor offences to address professionalism issues