St George's Research Ethics Committee

Annual Report 2016 – 2017

Contents

St. George's Research Ethics Committee

Background

St. George's Research Ethics Committee (SGREC) was formed in 2015 to review research projects that did not require review by a National Health Service Research Ethics Committee (NHS REC). Research being undertaken by, or that intends to use as participants, St. George's students or staff, should undergo ethical scrutiny by SGREC.

SGREC will also scrutinise research being undertaken in St. George's University Hospitals NHS Foundation Trust, where the participants are NHS staff recruited by virtue of their role, the research does not include treatments or taking of blood and where the research does not require scrutiny by an NHS REC.

The Terms of Reference and *Modus Operandi* for SGREC were modified from versions supplied (with kind permission) by Imperial College London and were agreed upon and accepted by the SGREC during the meeting on 10th January 2016. The current versions of the Terms of Reference and *Modus Operandi* can be found in appendices 1 and 2 respectively.

Reporting Period

The reporting period covered in this document is the academic year 2016-2017, which includes from 1st September 2016 to 31st August 2017. Previous SGREC annual reports have covered calendar years, but the decision was made to move the reports to academic years, in line with other reporting within the University. It is hoped that this will enable comparison of the amount and type of research coming through SGREC with other activity within the university.

Types of membership

At the beginning of the reporting period, the SGREC had 9 members (September 2016); by the end of the reporting period, there were 12 members (August 2017). The average number of members across the 12 months was 10. Members were made up of the Chair, representatives from each SGUL institute (Institute of Infection and Immunity; Molecular and Clinical Sciences Research Institute; Population Health Research Institute; and the Institute for Medical and Biomedical Education) student representatives and external members. Other members included representatives from the library and data management services, and representation from the Joint Research and Enterprise Office.

In March of the reporting period, the Chair of the Committee at the time, Dr Rachel Allen, announced her intention to step down as Chair of the Committee. Advertising for the position began in May and in July, Sandra Ashton from the Molecular and Clinical Sciences Institute was appointed as the Chair of the Ethics Committee. Dr Allen continued to represent the Institute of Infection and Immunity on the Committee and act as Deputy Chair.

List of meetings scheduled

Below is a list of the meetings of the SGREC scheduled during the reporting period. Meetings were scheduled to be held on the second Wednesday of every other month, although this was deviated from in November as no applications needed to be discussed. The meeting scheduled for 11th January was held electronically.

2016-2017
14th September 2016
11th January 2017 [electronic]
8th March 2017
10th May 2017
19th July 2017

SGREC process

Several changes to the SGREC process were implemented during the reporting period. There was a change to the application approvals pathway between the Research Ethics Officer and the Institute Director. In the previous system, the researcher would approach the Institute Directors for application sign off in the first instance. The application would then proceed with required documentation to the Ethics officer. See appendix 3.

This process gave rise to some issues. Upon closer scrutiny by the ethics officer, the application / documentation submitted was found to be of variable quality and with errors in places. This resulted in the application and Institute Director sign off needing to be revisited. An example of this would be Institute Directors signing an application where the researchers use SurveyMonkey rather than LimeSurvey when collecting data.

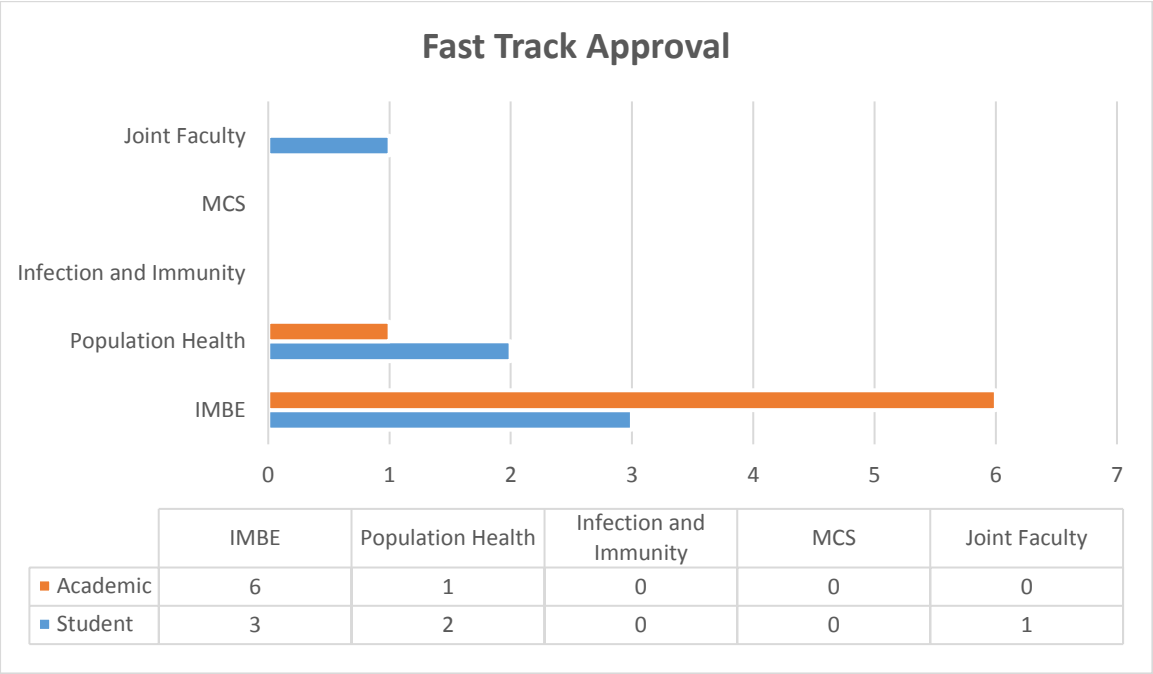
A new application process was proposed by the SGREC Chair and Research Ethics Officer. Project applications would be submitted to the Research Ethics Officer in the first instance, for initial scrutiny and validation of submitted documentation. Only at this stage would the application be forwarded to the institute directors for final scrutiny and sign off – reversing the old process. See appendix 4.

By adapting the approach to ethics approval submission, Institute Directors have the confidence that they are reviewing the correct documents, and the ones that will be used in the study. Further this approach would reduce the workload for the Institute Directors as they would only see a project once.

Introduction of this system also ensures that the Research Ethics Officer (JRES) should act as the first point of contact and submission for all ethical reviews conducted at St Georges University.

Breakdown of projects reviewed in the reporting period (including summaries)

The total number of studies for the academic year of 2016- 2017 was 26. The charts below give an insight into the types of approval process, and from which research institute.



	IMBE	Population Health	Infection and Immunity	MCS	Joint Faculty
Academic	6	1	0	0	0
Student	3	2	0	0	1

Institute	Student	Academic Staff	Institute Total
IMBE	3	6	9
Population Health	2	1	3
Infection and Immunity	0	0	0
MCS	0	0	0
Joint Faculty	1	0	1
			13

The Institute of Medical and Biomedical Education (IMBE) and Population Health Institute (PH) are the two institutes that predominantly utilized the fast track process over the reporting period. For IMBE, the majority of those were academic staff applications over student applications. That trend was reversed for the PH institute.

Project summaries:

IMBE

Full title of project:	Reference no:	SGREC16.0013
Characteristics of Physician Associate programs across the United Kingdom		
Project summary:		
Physician Associate education in the United Kingdom is rapidly expanding. In 2013 there were two programmes in Britain. By September 2016, there were 16 programmes. By September 2017 nearly 30 programmes will be open. Many more programmes are being planned. We would like to survey the leadership of each existing programme regarding number of students, academic schedule, predominant modes of instruction, and composition of faculty to describe the landscape of Physician Associate education. We anticipate publishing the work in a Physician Associate education peer-reviewed journal.		

Full title of project:	Reference no:	SGREC16.0014
Investigation of stress and coping among Final Year students studying Medicine and 3rd Year Biomedical Sciences as St George's University of London		
Project summary:		
Informing students of coping strategies that are effective in managing stress may help to them to reduce the negative impact of stress on their own lives, improve their quality of life and enjoyment of their university experience. A study carried out by the National Union of Students on 2013 reported that 80% of participants felt stressed, 55% felt anxious, and 40% had feelings of worthlessness and hopelessness (Helen Kerr 2013). Dyrbye et al (2008) reported that 11% of students said they had experienced suicidal ideation within the previous year. There is no doubt that some undergraduates experience problems with stress. There are multiple potential causes; living away from home, managing financial resources independently, peer pressures, relationship problems and the pressure of getting good grades. Burnout is described as emotional exhaustion resulting in an unfeeling and impersonal response to patients and reduced sense of personal achievement (Maslach, 1982). Current research has shown a significant increase in levels of burnout as students progress through their medical training from 21% in Year one to 31% in Year four (Dyrbye et al. 2006;Santen, Holt, Kemp, & Hemphill 2010). Higher levels of personal accomplishment may be protective (Thomas et al. 2007). It may be that personal accomplishment increases as students become more proficient in clinical skills. Santen et al (2010) reported that students who had a greater perception		

of control over their lives experienced significantly lower burnout. Resilience is a psychological characteristic that enables individuals to continue to thrive even after exposure to a stressful event. Dunn et al (2008) suggest a conceptual model whereby increased resilience may help prevent the development of burnout and elements of resilience may be learned (Dunn et al. 2008).

This study aims to investigate perceptions of stress, burnout, resilience and the types of coping strategies used to manage stress among undergraduate students studying medicine and Biomedical Sciences at St George's University of London.

Full title of project:	Reference no:	SGREC16.0015

Investigating moral distress among doctors and nurses working in adult general intensive care

Project summary:

Ethical and moral dilemmas are inherent in medical practice and healthcare. Moral distress was first described in 1984 as occurring "when one knows the right thing to do, but institutional constraints make it nearly impossible to pursue the right course of action" (Jameton, 1984). Previous research indicates a wide range of situations and factors may cause moral distress to healthcare professionals. These include being required to provide aggressive medical treatments which individual healthcare professionals believe may not be in the patient's best interest and/or which prolong the dying process, lack of fully informed consent, disregard for patient's wishes, personal lack of assertiveness and feelings of powerlessness which may limit individuals ability to speak up in challenging situations, inadequate staffing, compromising patient care due to pressures to reduce costs etc (7). Healthcare professionals who are repeatedly exposed to situations in which they feel they are unable to carry out what they believe to be ethically and morally appropriate action are at risk of burnout, withdrawal from the moral dimensions of patient care, and of leaving the profession (2;4;7-9). Consequently, this may impact on the quality of care, patient satisfaction and patient safety.
Moral distress is characterised by frustration, anger, guilt, physical symptoms, and/or anxiety due to the threat to the moral integrity of the individual (10;11). Epstein and Hamric (2009) suggest that it is the perceived requirement to compromise personal core values or professional obligations distinguishes moral distress from other types of emotional distress such as compassion fatigue and posttraumatic stress disorder(4). Staff who have been qualified longer report greater levels of moral distress and it has been suggested that repeated exposures to moral distress may cause a crescendo effect (4). Previous studies have shown that doctors report lower levels of moral distress than nurses, possibly due to the power hierarchy between these two groups and relative independence from constant close proximity to morally distressing situations (2;12).
Moral distress has been shown to be an important factor among critical care staff in terms of job dissatisfaction, burnout and staff retention (5;7;13).
This study will use a confidential survey of all nurses and doctors employed on a fulltime or part-time contract to work in the adult Intensive Care Unit (ICU) at Epsom & St Helier University Hospital NHS Trust seeking to determine how often staff have experienced moral distress and the degree of distress caused. Providing information to staff and managers of how significant this issue is within their particular clinical area will help to

them to identify risk areas, develop and maintain strategies to support staff, reduce any resulting negative impact of this particular type of stress on professional satisfaction, improve the quality of patient care and staff retention.

Five hypotheses based on previous research will be tested:

1) Nurses will report experiencing greater levels of moral distress than doctors.
2) Staff with more years of experience will report greater levels of moral distress.
3) Females will report greater levels of moral distress than males.
4) Staff reporting greater levels of moral distress will be more likely to be considering quitting their job.
5) Staff experiencing greater frequency of moral distress and/or degree of distress will report greater anxiety and/or depression.

As technology in acute medicine becomes more sophisticated, healthcare in intensive care units adapts to optimize patient care and prolong life. This often requires high levels of skill, staffing and complex decision making. The findings of this survey will be summarized and fed back to both managers and staff. The aim is to provide information on whether moral distress is problematic in this unit, and to encourage discussion of which issues are important and how staff can be effectively supported.

The surveys have been discussed with senior ICU staff and approved by the Consultant Nurse, Matron and Research Consultant.

Full title of project:	Reference no:	SGREC16.0016

Pilot study for the evaluation of the SHINE programme

Project summary:

The SHINE evaluation will explore the extent to which the SHINE programme is meeting its aims and to identify any areas for future improvement. The evaluation will adopt a mixed methods approach, combining a survey which all SHINE participants will complete at the end of their learning journey which aims to provide an overview of the success of the programme from an institutional perspective. Qualitative data will be gathered through a series of semi-structured interview with SHINE participants and mentors to explore their learning journey in relation to their personal and professional development. Data will be thematically analysed to provide a framework with which to assess both the individual and institutional impact of the SHINE programme.

Full title of project:	Reference no:	SGREC16.0018

Student perceptions of cheating in higher education

Project summary:

The project aims to explore how cheating (academic dishonesty) is understood by students and how extensive it is thought to be. The students undertaking the project will carry out a thorough literature search and will survey other students to assess:

1. Whether or not there are gender differences in responses to academic dishonesty
2. What factors might be likely to contribute to students engaging in academic dishonesty

The survey will be analysed to identify patterns and correlations between academic dishonesty, gender and contributing factors. Survey participants will be asked if they would like to take part in an interview or focus group to share their understandings of academic dishonesty and factors affecting it.

The focus group will be audio-recorded and transcribed. The data will be thematically analysed. The findings of the study will inform how students are educated on what constitutes academic dishonesty and how to avoid it.

Full title of project:	Reference no:	SGREC16.0019

1) A cross sectional survey exploring medical students' ethical views regarding Health Incentives and the possible stigma surrounding obesity in the UK
2) A cross sectional survey to explore the views of healthcare students about the migration of healthcare workers
3) Tuberculosis, ethics and responsibility: a cross-sectional survey of healthcare students
4) The impact of Zika on ethical and legal arguments about abortion: a cross sectional survey

Project summary:

These research projects are designed to enable students to conduct a philosophical (ethical) analysis of a particular topics in global health. However, in order to provide some context to the philosophical discussion students are also required to collect data using attitudinal surveys. Qualitative data will be gathered from SGUL students to explore their understanding of particular global health issues and their opinions on these issues. Data will be thematically analysed to provide a framework and context for the philosophical analysis.

Full title of project:	Reference no:	SGREC16.0020

1) Investigation of Final Year students attitudes towards a career in general practice.
2) Investigation into the knowledge and skills of Final Year medical students regarding paediatric asthma

Project summary:

1) There is a shortage of general practitioners in the UK. There has been little research into why a minority of students choose to be general practitioners. This study will investigate the facilitators and deterrents of choosing general practice as a career. The study requires no identifying information from students, but requires them only to fill in a questionnaire about potential factors important to them when making career choices. The outcomes of the research will inform actions taken by SGUL to encourage medical students to choose primary care, and will contribute to the National Debate.
2) Paediatric asthma is a major cause of paediatric morbidity and mortality. Poor adherence to treatment is an important cause of morbidity and mortality. Low confidence in managing asthma, when it is symptomatic, is also potentially an important cause of under treatment. This study will investigate the knowledge, skills and attitudes of Final Year medical students regarding paediatric asthma. The study requires no identifying information from students, but requires them to complete a semi structured questionnaire containing knowledge questions about clinical management. There is no identifying data kept linked to the answers. The answers and outcomes will inform the teaching of paediatric asthma through planned dissemination to academic staff and student representatives.

Full title of project:	Reference no:	SGREC17.0018

Longitudinal study investigating the self-reported wellbeing of a group of 3rd year students studying Biomedical Sciences or intercalating medical students at St. George's, University of London

Project summary:

Primary aim: To investigate self- reported wellbeing in a group of undergraduate students throughout the third year of their degree course and examine any fluctuations across the year.
Secondly: To examine whether students who report a larger social support network have greater levels of wellbeing.
Thirdly: To observe whether undertaking a 12 week module in Behavioural Medicine involving cognitive behavioural tasks designed to increase wellbeing influences these students' perceptions of wellbeing in comparison to students who are not undertaking this module.

Full title of project:	Reference no:	SGREC17.0019

Investigation of stress and coping among Final Year students studying Medicine and 3rd Year Biomedical Sciences as St George's University of London

Project summary:

Informing students of coping strategies that are effective in managing stress may help to them to reduce the negative impact of stress on their own lives, improve their quality of life and enjoyment of their university experience.

A study carried out by the National Union of Students on 2013 reported that 80% of participants felt stressed, 55% felt anxious, and 40% had feelings of worthlessness and hopelessness (Helen Kerr 2013). Dyrbye et al (2008) reported that 11% of students said they had experienced suicidal ideation within the previous year. There is no doubt that some undergraduates experience problems with stress. Current research has shown a significant increase in levels of burnout as students' progress through their medical training from 21% in Year one to 31% in Year four (Dyrbye et al. 2006;Santen, Holt, Kemp, & Hemphill 2010).

All Final Year students in Year 3 of their Biomedical Sciences degree and Final year medical students will be contacted using their University email addresses and sent information about the survey, an invitation to participate and an electronic URL link to the online survey. Participation will be voluntary and anonymous. This will be an on-line survey conducted using LimeSurvey. Students will be asked to complete a questionnaire seeking to determine their perception of the stress, level of anxiety, depression and burnout, measure personality characteristics and investigate the coping strategies they use to manage stress. Consent will be assumed if participants complete the survey. Data will be collected by two undergraduate students who will analyse and write up the findings as part of their BSc research project.

This study aims to investigate perceptions of stress, anxiety, depression, and burnout in two groups of undergraduate students studying medicine and Biomedical Sciences at a UK medical school. It will also examine personality factors and the types of coping strategies they use to manage their stress. The study also aims to inform both students and the institution about the experience of stress among undergraduate students, to increase awareness of effective stress management strategies to help avoid its onset of burnout and manage stress more effectively, and to provide evidence to support and maintain the development of student support services. Informing students of coping strategies that are effective in managing stress may help to them to reduce the negative impact of stress on their own lives, improve their quality of life and enjoyment of their university experience.

PH

Full title of project:	Reference no:	SGREC16.0017
Attitudes towards older adults among medical students		

Project summary:

Old age is often perceived as a time of illness and loneliness, and younger individuals often hold negative attitudes towards older adults (Kite, Stockdale, Whitley, & Johnson, 2005; Löckenhoff et al., 2009; Lyons, 2009). Negative attitudes and the perpetuation of negative stereotypes are harmful as older adults may embody these views, which in turn may shape their health, cognition and even longevity (Levy, 2009).

With an ageing population, it is important to have a workforce that is willing and able to adequately care for elderly patients. In the UK, geriatric medicine is one of the specialities with most posts that remain unfilled (Federation of the Royal College of Physicians of the UK, 2016). Attitudes affect behaviour (Conner & Norman, 2015). Positive attitudes towards older adults are related to an increased interest in geriatric medicine (Fitzgerald, Wray, Halter, Williams, & Supiano, 2003; Wilderom et al., 1990). However, previous studies have shown that medical students may hold negative or simply neutral views towards older adults (Deary, Smith, Mitchell, & Maclennan, 1993; Reuben, Fullerton, Tschann, & Croughan-Minihane, 1995; Stewart, Eleazer, Boland, & Wieland, 2007). While some studies show that medical students who are further along their course may have more positive views on older adults when compared with those at the start of their course (Hughes et al., 2008), others find that the reverse is true (Kishimoto, Nagoshi, Williams, Masaki, & Blanchette, 2005). In many cases it is thought that increased knowledge about ageing and greater contact with older adults help to improve attitudes. However, studies assessing the extent to which contact with older adults affects attitudes have mixed findings (Fitzgerald et al., 2003; Steer & Arbor, 2010; Wilderom et al., 1990).

Research assessing attitudes towards older adults among medical students in the UK is limited and this study aims to address this gap in the literature. This study will assess whether attitudes towards older adults differ across the different years of the course and by frequency of contact with older adults outside of the clinical context. The study will also assess if attitudes towards older adults differ by gender, ethnic group, and country of origin (home/EU versus international students).

Full title of project:	Reference no:	SGREC16.0022

1) Evaluating the effect of cosmetic lenses on global eye health
2) 2.The policy approaches to the Prevention and Management of Diabetes through Reductions in a Variety of Country Settings
3) 3.What policies are promoted to combat the increase in non-communicable diseases in low and middle income countries using the USA as a high-income exemplar
4) Global Policy Directions for Emerging and Re-emerging Diseases

5) To what extend will the upcoming sugar tax have an effect on the prevention of childhood obesity in South West London
6) To what extent are current Japanese policies adequately equipped at handling the social pressure caused by Alzheimer's Disease in their population, in comparison with that of the British

Project summary:

These research projects are designed to enable students to conduct an analytical review of particular topics in global health. However, in order to provide some context discussions will be required with health managers and professionals and representatives of civil society. Qualitative data will be gathered from to explore understanding of particular global health issues and their opinions on these issues.

In the case of one student (project 1) contacts would also include companies selling contact lenses, hospital ophthalmic staff and patients.

In the case of one student (project 2) contacts would include SGUL students and members of the public.

Full title of project:	Reference no:	SGREC16.0023

A critical review of global initiatives for neglected tropical diseases.

1) A critical review of global health initiatives for neglected tropical diseases – leprosy in low and middle-income countries.
2) A Critical Review of Global Health Initiatives for Onchocerciasis
3) Why has Guinea Worm Disease still not been eradicated in all countries?
4) What are the issues surrounding Neurocysticercosis, a neglected tropical disease found in the USA
5) A critical review of global initiatives for trachoma

Project summary:

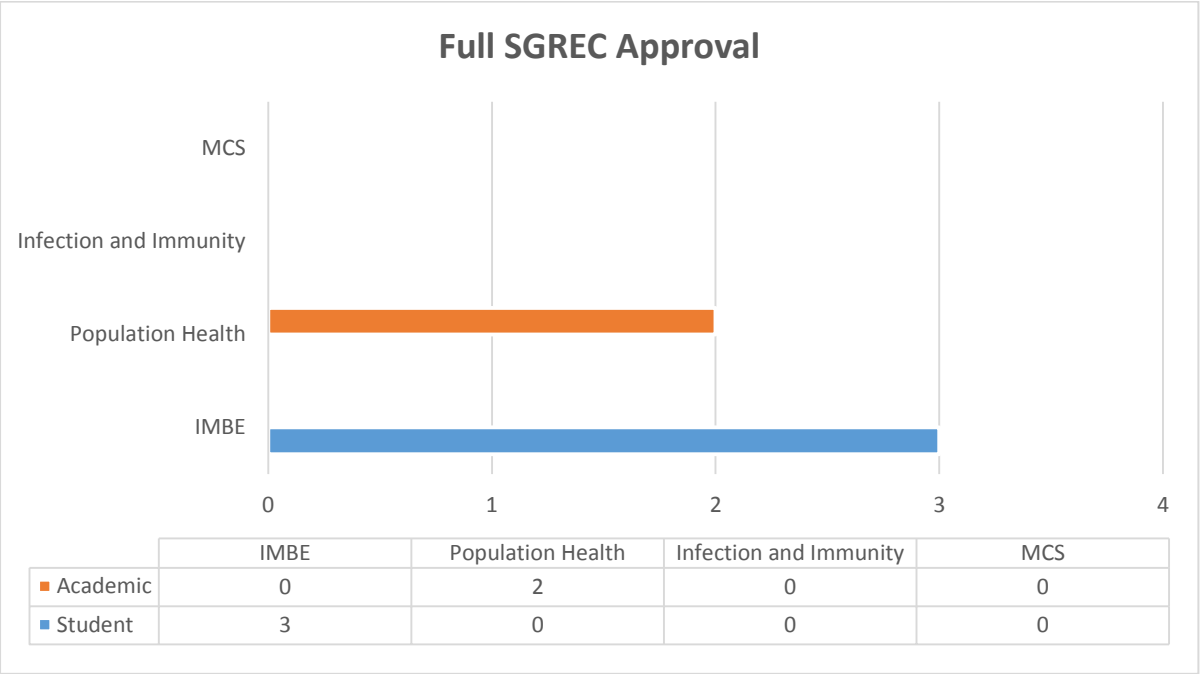
These research projects are designed to enable students to conduct an analytical review of global health initiatives for neglected tropical diseases, a key priority for the Sustainable Development Goals. The projects will largely involve desk-based research. In addition, the students will arrange discussions with professionals and representatives of relevant organisations working in their field of study. This will provide the students with the opportunity to gain a deeper understanding of their chosen topic. Qualitative data will be gathered from these discussions to explore key issues in global health initiatives for particular neglected tropical diseases.

JF

Full title of project:	Reference no:	SGREC17.0011
Intensive care nurses' perception and awareness of critical care follow-up clinics – a qualitative study		

Project summary:

Prolonged stay in the intensive care unit may impact patients' physical, psychological and cognitive function. Intensive care follow-up clinics have been set up across the UK to provide support for those patients and their relatives (in accordance with the Department of Health (2000) comprehensive review and the NICE guidelines (2009) 'Rehabilitation after critical illness in adults'). The positive impact of these clinics has been reported in the literature from their users' points of view. However, there is very limited data provided on the ICU nurses' awareness and perception of such service. This project aims to explore this issue in a large teaching hospital in London. The secondary objective is to investigate how feedback gained from ICU follow-up clinic could impact on nurses' practice. The primary use of focus groups will be data-gathering to test the feasibility and strategy for more extensive study.



Institute	Student	Academic Staff	Institute Total
IMBE	3	0	3
Population Health	0	2	2
Infection and Immunity	0	0	0
MCS	0	0	0
			5

In the reporting period a similar number of studies have appeared before the full committee from both IMBE and PH. All applications from IMBE were from students, one of which was rejected (see pg. 16.) PH applications were from academic staff.

Project summaries:

IMBE

Full title of project:	Reference no:	SGREC16.0012
Case and scenario based learning perceptions and integration		
Project summary:		
To investigate the extent to which students integrate their learning for case and scenario based learning (C/SBL) with learning from other sources. Do students see the learning they do for C/SBL as separate or complementary to e.g. learning from lectures or		

textbooks? This is a baseline study, designed and conducted collaboratively by a staff member and 2 student researchers to investigate whether there is a need for more explicit teaching on how to study across the curriculum in an integrated way. The expected outcomes will be a more informed view on how students use their study for C/SBL to develop their knowledge and prepare for assessment. If it is found that students keep this learning separate from lecture based teaching then proposals will be made for curricular and teaching and learning interventions to support the development of an integrated approach to study and maximise the resource currently invested in C/SBL.

This project is intended to provide students with an opportunity to develop their knowledge of educational research method. Therefore an aim of the project is to provide students with the opportunity to develop and implement knowledge of survey methods to produce a questionnaire and ethical issues, including appropriate ways to obtain and document consent via Participant Information Sheets.

Full title of project:	Reference no:	SGREC17.0014
National survey of UK medical students on the perceptions and interests of cardiothoracic surgery		

Project summary:

Research has shown that the popularity of cardiothoracic surgery among UK medical graduates has declined significantly. Currently only 32% of trainee surgeons are UK graduates (Westby *et al.* 2014). Researchers have postulated what factors may have played into the decline in popularity of cardiothoracic surgery. The aim of this study is to assess the interested in cardiothoracic surgery amongst UK medical students. By assessing student exposure to the speciality and the influence of student perceptions of the speciality (such as salary, work life balance, and prestige) on speciality choice, we hope to assess whether there has been a decline in the popularity of cardiothoracic surgery as well as what factors may have played into that. We also hope to determine if there are any measure which can be put in place to improve student interest in cardiothoracic.

Rejected

Full title of project:	Reference no:	SGREC17.0016
Vertical and horizontal facial proportions in black professional models: comparison with the golden proportion and perceptions of facial attractiveness		

Project summary:

The aim of the project is to evaluate the correlation of facial proportions with beauty perception in black origin professional models. That is because current research has focused on white models in terms of ideal facial proportions, and thus the results of these are used inter-exchangeably in clinical practice and research, which is a potential source of error. Using photographs that are provided to the public online, and thus are under the

exempt of UK Data Protection Act for research purposes,– ensuring these are of models-, a survey will be created inviting participants to complete it. Participants will be anonymous and no data will be able to be tracked back to the responder. Some demographic information will be asked (Age, Gender, Ethnicity, Occupation), followed by a section in which they will be asked to rate 20 male and 20 female photographs from 1 (not very attractive) to 10 (very attractive).

Consent will be implied, as participants may choose whether they want to complete it after receiving an email. An introductory page of the survey will describe the aims of this project clearly, and participants may stop the survey at any points should they wish to do so.

The data will then be collected, and the pictures with higher average ratings will be compared to those with those with the lowest rating average in terms of specific anthropometric landmarks. The aim is to identify any differences in these ratios that may correlate with perception of beauty.

There are already theories regarding 'The Golden proportion', a ratio of 1.618, that is suggested that is correlated with beauty. This hypothesis will also be tested. Furthermore, any differences in grading between different demographic groups will also be evaluated (such as gender and age)

The expected outcomes of the study are to try and identify any correlations between facial proportions and beauty perception. Currently, there are no guidelines for reconstructive and aesthetic facial surgery, and what we hope for in this study is to provide some preliminary background to guide further research.

PH

Full title of project:	Reference no:	SGREC17.0007

Development of a randomized controlled trial to increase cereal fibre intake to reduce insulin resistance in children.

Project summary:

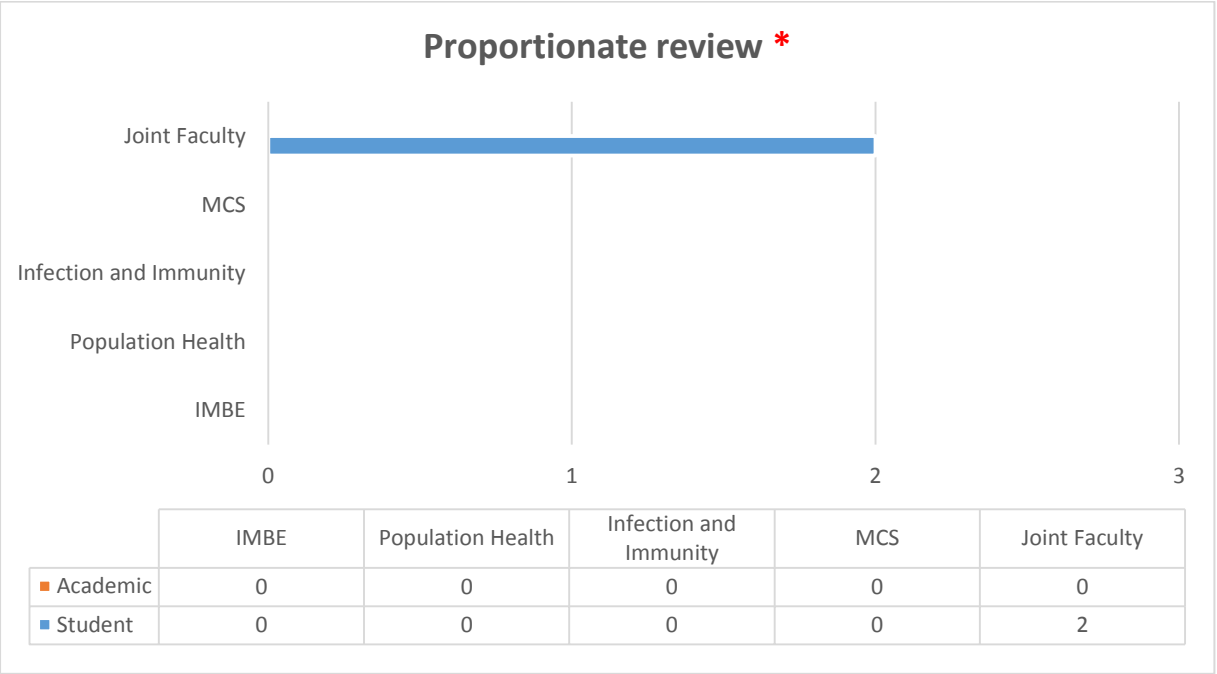
Type 2 diabetes (T2D) is a major public health challenge. T2D risks begin to emerge in childhood, with the development of insulin resistance. In the UK, T2D risk markers (including insulin resistance) are particularly high among South Asians, who already have high insulin resistance in childhood. High cereal fibre intake may protect against T2D. A `proof of concept' efficacy trial is needed to show whether increasing cereal fibre intake reduces insulin resistance in children. The present investigation will prepare for such a trial by developing and evaluating the feasibility, acceptability and fidelity of an intervention aiming to increase breakfast cereal fibre intake in children (including South Asian children) aged 9-10 years, who have a low cereal fibre intake at entry. The intervention will provide commercially available high fibre cereal free to participants in the intervention group. The main outcome (cereal fibre intake) will be assessed using detailed dietary assessment and a blood biomarker, plasma alkylresorcinol.

The fidelity of the intervention (the extent to which it actually increases cereal fibre intake) will be formally examined in a randomized controlled trial providing children with a free supply of breakfast cereal with either high or low fibre content. In participating London primary schools, year 5 pupils will be invited to test a range of high fibre and low fibre breakfast cereals, and also asked about current breakfast habits. Children who currently eat a low fibre breakfast cereal and who find at least one of the high fibre cereals palatable will then be invited to participate further. Participants will have baseline measurements including a fasting blood sample (for plasma alkylresorcinol), basic anthropometric assessments, and dietary assessments. They will then be randomised to either a high fibre breakfast cereal or a low fibre cereal to eat daily for one month, after which follow-up assessments identical to those at baseline will be made. The main outcome will be changes in cereal fibre intake (based on plasma alkylresorcinol and the detailed dietary assessments). The results will inform the development of a definitive large-scale efficacy trial examining the effects of increasing breakfast cereal fibre intake on insulin resistance in children.

Full title of project:	Reference no:	SGREC17.0015
Black and Minority Ethnic Student Attainment Gap Research		

Project summary:

Analysis of student academic attainment data by the SGUL Data Inclusion and Evaluation Officer identified a statistically significant lower attainment among Black and minority ethnic (BME) students compared with White students at SGUL. Further analysis by the SGUL Senior Planning Officer also found an attainment gap for BME students studying biomedical sciences, physiotherapy and radiography undergraduate degrees, with their Value Added Score lower than their White peers. There is also an attainment gap between Black and White students studying MBBS4 and 5. We are therefore conducting research to investigate the causes of the attainment gap by holding audio-recorded semi-structured interviews/focus groups with academic and administrative staff and undergraduate medical and biomedical sciences students at SGUL. We have elected not to involve students from other healthcare courses due to the potential for them to be identifiable given the small number of students on such courses. The focus groups/interviews will be recorded using two dedicated digital audio-recording devices and the audio-recordings will be transcribed by a combination of the research staff and an external professional transcriber, whose transcribing services have been used previously by the team and who will sign a confidentiality agreement. The transcriptions will be anonymised, and then thematically analysed by the research team. The information obtained through this research will then be used in staff development and training to assist in addressing the attainment gap. We also aim to publish our findings in an academic peer-reviewed journal but all quotes will be anonymised and unidentifiable.



Institute	Student	Academic	Institute Total
IMBE	0	0	0
Population Health	0	0	0
Infection and Immunity	0	0	0
MCS	0	0	0
Joint Faculty (FREC)	2	0	2
			2

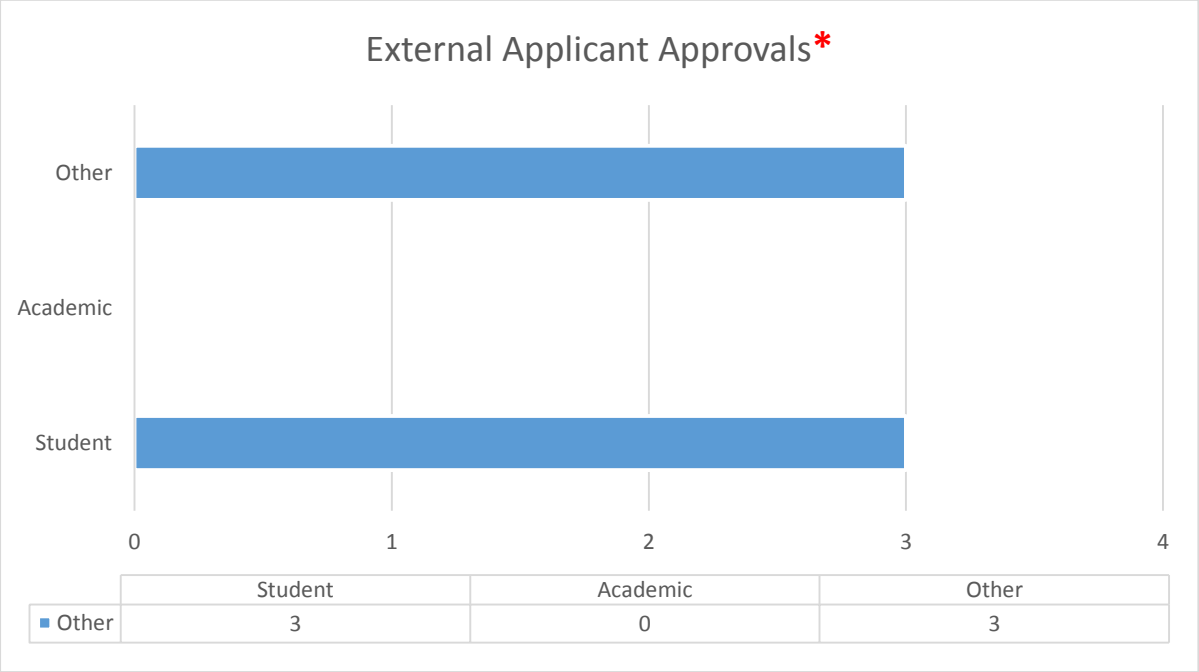
* It is unclear what the definition of "proportionate review" is for these studies, as the collating of this data was performed prior to the tenure of current reporting members of staff. This data has been included however in line with requirements for transparency.

Project summaries:

Full title of project:	Reference no:	SGREC17.0001
Do Goal-focused, Motivational Text Messages Improve Adherence to Inhaled Therapies in Adults with Cystic Fibrosis (CF)? A Feasibility and Acceptability Study		
Project summary:		
Cystic Fibrosis (CF) is a life-limiting condition, where patients die predominately from respiratory failure. Symptoms include breathlessness and excess production of mucus. There is no cure for CF but inhaled therapies aim to reduce symptoms and slow lung function decline by assisting mucus clearance and reducing frequency of chest infections. It is known that adherence to these inhaled drugs is poor, approximately 30-50%. The I-neb nebuliser system stores data detailing the treatment date, duration and dose delivered; When connected to a computer this information can be downloaded by clinicians, therefore it will be used in this study to measure adherence. Telemedicine is used increasingly as a mode of delivering treatment in chronic conditions, especially in young adults who are generally comfortable using technology. One form of telemedicine is goal-focussed, motivational text messaging; This has been trialled in young adults with diabetes and cancer, with positive outcomes. The aim of goal-setting is to give patients a sense of purpose to completing their treatment and improve motivation. Based on the previous research, we feel that Setting goals around inhaled therapy usage, which is then followed up by twice weekly goal-focused, motivational text messages will improve adherence to inhaled therapies.		

Full title of project:	Reference no:	SGREC17.0004
Carers' experiences of ward rounds in mental health inpatient settings: a qualitative study		
Project summary:		
There is a large body of literature suggesting that caring for someone with a mental health problem can negatively impact on the physical and mental health of the carer. Subsequently, there is a drive in UK policy to acknowledge and recognise their needs, and for healthcare staff to strive for a more collaborative way of working. Current literature suggests that through applying such an approach, benefits can be seen for patients, carers and clinicians. However, it seems that in practice collaborative care is not happening. Ward rounds are one of the key times when patients, carers and clinicians come together during hospital admissions. However, there is a gap in the literature looking at carers' experiences of ward rounds and subsequently how they can be utilised to contribute towards a more collaborative way of working. This project will explore how, in beginning to understand carers' experiences of ward rounds, we can look towards improving the way they are delivered. In striving for a more collaborative way of working, we can aim to improve inpatient services for all, enabling carers to feel better supported, informed and actively engaged.		

Participants will be carers of patients who have been admitted to a mental health ward, within the last twelve months, who have attended a ward round. The study will involve a one-off interview, which will explore carers' experiences of ward rounds. The study will look to recruit from South London and Maudsley NHS Foundation Trust and South West London and St George's mental health NHS trust, as well as approaching local independent mental health carer groups. The study is part of a Master's degree program, which is funded by the National Institute of Health Research.



* These applications were submitted through the SGREC full committee process. They are studies where the CI/PI is not an SGUL staff or student. However, in some cases the research may involve university or hospital staff and students.

External Applicant Approvals	Student	Academic	Other	Total
Applications	3	0	3	6

Cardiff University

Full title of project:	Reference no:	17.0089
Early Mobilisation after Thrombolysis: Establishing Current UK Physiotherapy Practice and the Perceived Benefits and Harms - An Exploratory Study using Semi-structured Interviews.		
Project summary:		

This study will, through semi-structured interviews with stroke specialist physiotherapists working in Hyperacute stroke unit (HASU) settings in the United Kingdom, try to establish
What the current physiotherapy practice is with patients who have had their stroke treated with thrombolysis drug therapy. The interviews will explore the perceived benefits and harms of getting this patient group out of bed within the first 24 hours of the thrombolysis treatment. The results will provide information on current practice and guide future research which will help physiotherapists to decide on the best treatments.

University of Warwick

Full title of project:	Reference no:	17.0090
Patterns of mammography attendance over time		

Project summary:

Policy makers have noted a change, hypothesised as a decrease, in uptake patterns within the breast screening programme in the UK. However, when national KC62 data is viewed graphically the pattern of change over time is less clear and needs further in-depth investigation. It is important for screening teams to understand whether the perceived decline is real or whether attendance patterns are changing – are routine attenders now becoming intermittent attenders? It is not known if such a change has occurred, and if so in whom. There is a wealth of research focused on single predictors of uptake in breast screening however there are limited papers investigating multiple adjusted predictors. It is already known that women of different characteristics, such as ethnicity and socioeconomic status attend mammography appointments differently. Whether or not these attendance pattern distributions have changed is also of interest and will be analysed.

This study will be measure the change in uptake in different women attending the SW London centre. SW London is chosen as it routinely records ethnicity data which is a vital variable in the predictor of attendance analysis.

The aim of the research is to identify the predictors of uptake in the UK in different population sub-groups, and measure how this is changing over time. The research question will be how and in whom are patterns of mammography attendance changing over time?

Data will be obtained by Crystal Report extractions of data from SW London. Analyses will be conducted to measure the change in uptake across time and across women with different personal characteristics such as age, socioeconomic status (Index of Multiple Deprivation by proxy of postcode, previously created prior to receipt of data), ethnicity and previous attendance.

The research team mentioned above will only have access to fully anonymised data.

University of Warwick

Full title of project:	Reference no:	17.0102
Process mapping the patient flow of post bone marrow transplant services to understand operational variations in a NHS hospital in London		

Project summary:

Care processes involving post-bone marrow transplant are complex. Evidence indicates that the use of quality management systems can contribute to better service delivery (Ryan, 2013; Cole, 2011). In England, all transplant centres specializing in hematopoietic stem cell transplantation are accredited by Joint Accreditation Committee of the International Society for Cell Therapy and the European Group of Blood and Marrow Transplantation (JACIE), and meet NICE's Improving Outcomes Guidance (IOG). While these broad quality management systems ensure that care processes carried out are in line with clinical expectations, it will be equally important to gain better understanding of the actual processes of care that are then carried out by staff when operationalizing the quality management steps within a hospital. Hence, this study will map the processes of care that are followed by staff when providing care for post bone marrow transplant (PBMT) patients. It will involve talking with PBMT unit staff at NHS hospital in London, with the information gathered via semi-structured interviews. The information derived from the interviews will then be analysed to understand the patient flow of PBMT patients. Results can provide important information involving the care journeys of PBMT patients for quality improvement.

Royal Trinity Hospice

Full title of project:	Reference no:	SGREC17.0017
Unlocking the Potential of Virtual Reality in Palliative Care: A Qualitative and Quantitative Study		

Project summary:

Virtual reality (VR) is a technology which generates realistic 3D and 360-degree images and sounds that replicate a real environment and give the viewer a sense of physical presence in that environment through the use of a headset. VR has shown to have positive effects in pain management, post-traumatic stress disorder, and anxiety but VR has the potential to be used for many other symptoms. At Royal Trinity Hospice we have been using VR with some of our patients. Through VR we have been able to give patients experiences they miss, wish they had done or could do again. VR allows our patients do what they can't. So far, we have had extremely positive feedback from the patients who have experienced this new technology, an example of such a patient experience can be seen on BBC's Inside Out (http://www.bbc.co.uk/programmes/p04yxc8z). The last patient to receive a VR experience on our inpatient ward shared with us that we had given her "moments of joy" something she had not had for a long time. Now, through the research proposed in this application, we would like to study and understand the impact of virtual reality on symptoms in palliative care patients. Existing research has shown that personally emotive images trigger stronger physical and psychological responses in people, and with that in mind we wish to compare the impact of personalized VR experiences vs. non-personalized experiences on a variety of well-being symptoms. We hope that this study will help us obtain a better understanding of how best to use VR

and how to use it to positively help symptom control in patients. Positive results from this study could provide the evidence required for VR to be used alongside current symptom control measures provided by hospices and palliative care teams to manage symptoms at the end of life.

University of Maastricht

Full title of project:	Reference no:	SGREC17.0013

Recruitment of newly qualified doctors in Wales: What factors influence medical students' decision to move to Wales to complete the Foundation Programme?

Project summary:

All medical graduates must complete an integrated two year Foundation Programme to practice in the UK. However, Foundation Programmes in Wales are significantly undersubscribed, newly qualified doctors are not choosing to train in Wales. In order to create a sustainable NHS, the Welsh deanery must be able to attract more foundation doctors.

This research looks at the factors which influence final year medical students' decisions on where they will complete their foundation training. The research will ascertain whether there are key barriers to students selecting the Wales Deanery. Factors explored include; those directly related to the training placements, available career opportunities, quality of living, family factors, personal factors such as location of medical school and, marketing and reputation.

Middlesex University

Full title of project:	Reference no:	SGREC16.0021

An exploratory study to examine whether nurse mentors deliver culturally competent and compassionate mentorship to pre-registration nursing students.

Project summary:

The quality of nursing care in the United Kingdom has been under scrutiny following reports of care failings in the NHS. Compassion was highlighted as lacking in the care given (Francis, 2013). Consequently, there is increasing emphasis on compassion and the 6Cs was launched in 2012 (DoH, 2012). However it is evident in the literature that defining and conceptualizing compassion is challenging, so further studies are needed as empirical research on compassion is still very limited (Curtis, 2012; Dewar et al, 2011; Harrison, 2009). In addition, an increasingly diversified culture in the UK means that the perception of compassion varies among people. As Papadopoulos (2014) argues that cultural competence is an essential element of compassion. However, to date there is limited study on cultural competence and compassion. Nurse mentors are known to be role models for their mentees; therefore they have a vital role in promoting culturally competent and compassionate care through mentoring. Similarly, study on the role of nurse mentor in compassionate care has not been documented. Moreover patients who are undergoing general anaesthesia and surgery are vulnerable in the

perioperative environment. Hence, the aim of this study is to explore how and whether peri-operative nurse mentors provide culturally competent and compassionate mentorship to pre-registration nursing students.

The study will utilize non-participant observations and semi-structured interviews to collect data. Purposive sampling will be used to recruit nurse mentors and pre-registration nursing students who can provide insightful information into the subject of interest. From both nurse mentors and pre-registration nursing students, 10 to 15 participants will be recruited. The participants will be observed on three different occasions using an observation schedule, which are supplemented by short interviews to clarify what has been observed. Each paired observation will last approximately 30 – 45 minutes. At the end of all the three paired observations, both the nurse mentor and mentee will be interviewed individually using a semi-structured questionnaire. The interviews will last approximately 45 – 60 minutes.

It is expected that the study will add on to the body of knowledge in understanding culturally competent and compassionate care. It will also highlight the role that nurse mentors have in enabling culturally competent and compassionate care within the workplace.

References

- Curtis, K. (2012) 'Keep compassion alive', Nursing Standard, 26 (44), p64
- Dewar,B., Adamson,E., Smith, S., Surfleet, J. and King, L (2013) 'Clarifying misconceptions about compassionate care', Journal of Advance Nursing, 70 (8), p1738-1747
- Department of Health (2012) Compassion in Practice (Online). Available at: https://www.gov.uk/government/news/top-nurses-announce-new-strategy-to-build-culture-of-compassionate-care-across-the-nhs (accessed on 6.10.16)
- Francis, R (2013) Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry (Online). Available at: http://www.midstaffspublicinquiry.com/report (Accessed on 10.03.16)
- Harrison, P. (2013) Compassionate care takes on new significance. Gastrointestinal nursing, 11 (4), pp49

Appendix 1

St George's Research Ethics Committee (SGREC)

Terms of Reference

The original Terms of Reference were approved by the SGREC committee at a meeting in December 2015.The adopted Terms of Reference are listed below.

The St George's Research Ethics Committee can:

1. Review research projects requiring ethical approval or which involve security-sensitive research to be carried out by University staff, or students under the supervision of University staff, including projects being undertaken overseas, unless:

- They fall under the remit of the Department of Health's Governance Arrangements for Research Ethics Committees (GAfREC)
- They involve animal subjects.

2. Following review:

- Favourable opinion: the project is approved and may begin. No additional conditions are imposed on the research, apart from those standard ones listed in the approval letter
- Favourable opinion with additional conditions: the project is approved subject to additional conditions imposed by the Committee. These conditions must be met (and in most cases, evidence of them being met submitted to the Committee) prior to the start of the project.
- Provisional opinion: the project is provisionally approved subject to minor changes being made to the project. The changes must be submitted to the Research Ethics Coordinator for review. A final favourable opinion must be received from the Committee before the project can start.
- Unfavourable opinion (rejection, with option to resubmit with revision)

3. Demand or initiate another review at any point in the life of a project previously approved by the Committee and/or an Institute Director, and revoke approval if necessary, in circumstances where:

- There have been relevant or material changes to the personnel or the protocol
- Concerns have arisen (e.g. via research misconduct procedure or whistleblowing) about the conduct of the researchers or of the research
- Incidents of concern have been reported to the Committee
- More than 5 years have passed since the last ethical approval, unless satisfactory annual progress reports (APRs) have been submitted

Serious concerns identified by the Committee with regards to research compliance or adverse events should be reported to the approving Institute Director and provide advice on corrective actions.

4. Establish, implement and keep under review the codes of practice, procedures and policy guidelines for the consideration, approval and monitoring of research projects, including adherence to the International Conference on Harmonisation's Good Clinical Practice (ICH GCP) guidelines.

5. The SGREC can review and comment on the ethical issues in a project with respect to health and safety of potential participants and researchers, however investigators should seek consultation from the University's Safety, Health and Environment office with regards to health and safety issues in a project.

6. Assess the ethical concerns of research projects submitted for review and approval by SGREC.

7. Review the Terms of Reference at the first Committee Meeting of each academic year.

Appendix 2

St George's Research Ethics Committee (SGREC) v.5

Modus Operandi

a. Quorum

A meeting shall be considered quorate if at least 5 members of the Committee are present (including at least one lay member and two Institute members), one of whom must be either the Chair or Deputy Chair).

If the Chair is not present, the Deputy Chair shall take the role and powers of the Chair for the duration of that meeting.

If quorum is not reached, the meeting shall go ahead as planned, but any decisions reached will be subject to subsequent ratification by other members of the Committee.

b. Student Representation

The Committee shall have at least 2 SGUL students sit as active members of the Committee. Student representatives will take part in project discussion and approval decision making in line with other members.

Students wishing to observe the Committee as part of their course requirements or for their own development must make a request to the Research Ethics Coordinator. The Committee should provide their agreement for observers to attend meetings. They will not form part of the quorum or discussion for the meeting.

c. Term of Office

The Term of Office for Committee members is 3 years, renewable once. The Term of Office shall begin on the date of the first meeting attended. The Research Ethics Coordinator will seek renewed terms of office from members two months in advance of the 3rd anniversary of the member's start of office.

Committee members should attend at least 60% of meetings scheduled in a given year.

If a Committee member wishes to resign from the Committee before their Term is completed or due for renewal, they should give at least 2 meetings' notice in writing to their Institute Director. External members should give 2 meeting's notice in writing to the Chair and the Research Ethics Coordinator. They should also notify the Research Ethics Coordinator and the Chair of the SGREC.

d. Institute Director Approval

Before a project is sent to SGREC for ethical review, it will be reviewed by the Research Ethics Coordinator. After initial review and validation of a project, the project will be sent to the Institute Director (ID) of the Chief Investigator (CI) involved for fast track approval (if appropriate). If approved via the fast track route, the Research Ethics Coordinator will provide the applicant with an approval letter.

At this stage the ID, their nominee or a committee set up by them for the purpose of reviewing the ethical aspects of projects has the right to approve the ethics of the project without SGREC if they feel the research fits one or more of the following criteria:

- Involves the collection or study of existing data, documents or records which are publicly available (non-NHS sources);
- Involves the use of existing data, documents or records where participants cannot be identified in any way;
- Involves the use of educational tests, surveys, interview procedures or observations of public behaviour where participants cannot be identified in any way, and where they are at no risk of adverse treatment through participation (e.g. criminal investigation);
- Has no controversial ethical aspects;
- Has already received ethical approval from another body (for example, if the St Georges, University of London researcher is a Co-Investigator, and the Chief Investigator has gained approval from their own University; and this university's approval standards are satisfactory to SGUL).

Where the ID is named as CI or co-investigator, the project will be referred to the next full Committee meeting to avoid conflicts of interest.

If the research involves anything else, the project must be sent to the SGREC.

e. Chair's Action

Chair's Action is defined as a decision taken by the Chair and one other Committee member (subject to any conflicts of interest that may arise). The Chair can only take action if:

1. A SGREC meeting is cancelled and, following email consultation with members, it is felt that a project can be approved before the next meeting.
2. In any other circumstances deemed appropriate by the Committee.

f. Monitoring of Projects

CIs, once given approval, are obliged to report to the Committee:

- Any exceptions, adverse or unforeseen events which occur during the research;
- Any relevant or material changes to the protocol or personnel;
- Any external information likely to have a bearing on the research in question.
- An Annual Progress Report (APR) within 30 days of the anniversary of the date ethical approval was originally given, where the duration of the project is at least 12 months.

The Committee has the power to initiate a review of the ethical approval at any time it sees fit.

Committee approval lasts for five years; projects that wish to last longer than this may do so as long as satisfactory Annual Progress Reports and other reporting requirements (e.g. protocol deviations) are reported to the Committee.

g. Specialist Advice

If necessary, the Committee can invite a specialist to give information on a project. Any such individuals will be invited for that project only, and shall not participate in the final decision of the Committee.

h. Presence of Chief Investigators

All CI's whose projects are being discussed shall be invited to attend the meeting, to give explanations/clarification if necessary. They can register their willingness to attend on the application form. **The named CI should make every effort to attend, although they can bring any other relevant people (including students) as appropriate. This also stands with student projects where the named CI is the supervisor.**

The CIs shall be present in the room only for the question/answer session, and shall not participate in the final decision of the Committee.

A speaker phone can be made available if necessary.

i. Declaration of Interest

Committee-members must provide details of their interests for a SGREC members' register, which will be held by the Research Ethics Coordinator and updated at least on an annual basis. If any member has a financial or personal interest in any project or project sponsor under scrutiny, they must declare this before discussion of the project commences. Member conflicts of interest with respect to specific projects will be considered on a case-by-case basis. If an individual declares a conflict of interest, they may contribute to the discussion of that project but must not participate in the final decision.

j. Confidentiality

The University seeks to undertake an agreement of confidentiality with committee members who are not currently employed by the university. Where applicable, members will be asked to complete the Confidentiality Undertaking Form. This will be held by the Research Ethics Coordinator for the term of the members' office.

k. Frequency of Meetings

At present, the Committee shall meet a minimum of eight times a year according to a published schedule. Papers for the meeting must be circulated to the members no less than 7 days before the meeting, and must be received by the Research Ethics Coordinator no less than 14 days before the meeting.

In normal circumstances, all projects will be discussed at the next available meeting. However, in any situation deemed extraordinary, projects can be dealt with in one of the following ways:

- An email correspondence or teleconference to discuss the specific project. At least 4 members, including 2 lay members and 2 members (one of whom must be either the Chair or Deputy Chair), must contribute to the discussion; or
- The decision can be devolved to an extraordinary sub-committee of no less than 2 people approved of by a quorum of the Committee; or
- Chair's Action can be recommended by the Committee.

l. Modification of Projects

If a project receives provisional approval from the SGREC, and therefore requires modification before it is approved by SGREC, the revised application will be sent to the Research Ethics Coordinator to review against the provisions issued by the Committee.

m. Process of Appeal

If a CI feels the decision of the SGREC is unjustified, they have the right to a single appeal at the University's Research Strategy Committee (RSC). SGREC shall provide an explanation of its decision, and the CI must provide evidence to counteract that. The CI and a representative of the SGREC and Research Ethics Coordinator shall be invited to attend the next meeting of the RSC to discuss and answer questions on the papers and the case. The decision of the RSC is final.

n. Annual Report to the Research Strategy Committee

The Committee will produce an Annual Report to be presented to the University's RSC, and submitted to the Management Board. The Annual Report should outline issues such as the work of the Committee, the names of the members of the Committee, the number of meetings, any protocol deviations and the number of applications submitted and approved by IDs and SGREC.

o. Indemnity for Members

The University will indemnify members of SGREC against legal liability claims made against them which arise in respect of their membership of SGREC, provided that members have acted in good faith.

p. Validation of applications

The CI will be informed within 5 working days of whether their application is valid or not. If the application is valid, it will either go through the fast track process if appropriate or go to the next Committee meeting if the submission deadline has been met. If the application is not valid, the CI will be invited to correct the application and resubmit.

q. Decision-Making

The decision of the SGREC is final, subject to a single appeal by a CI as detailed above. The Committee shall inform the CI of its decision, with explanations where appropriate, normally within 10 working days following the meeting.

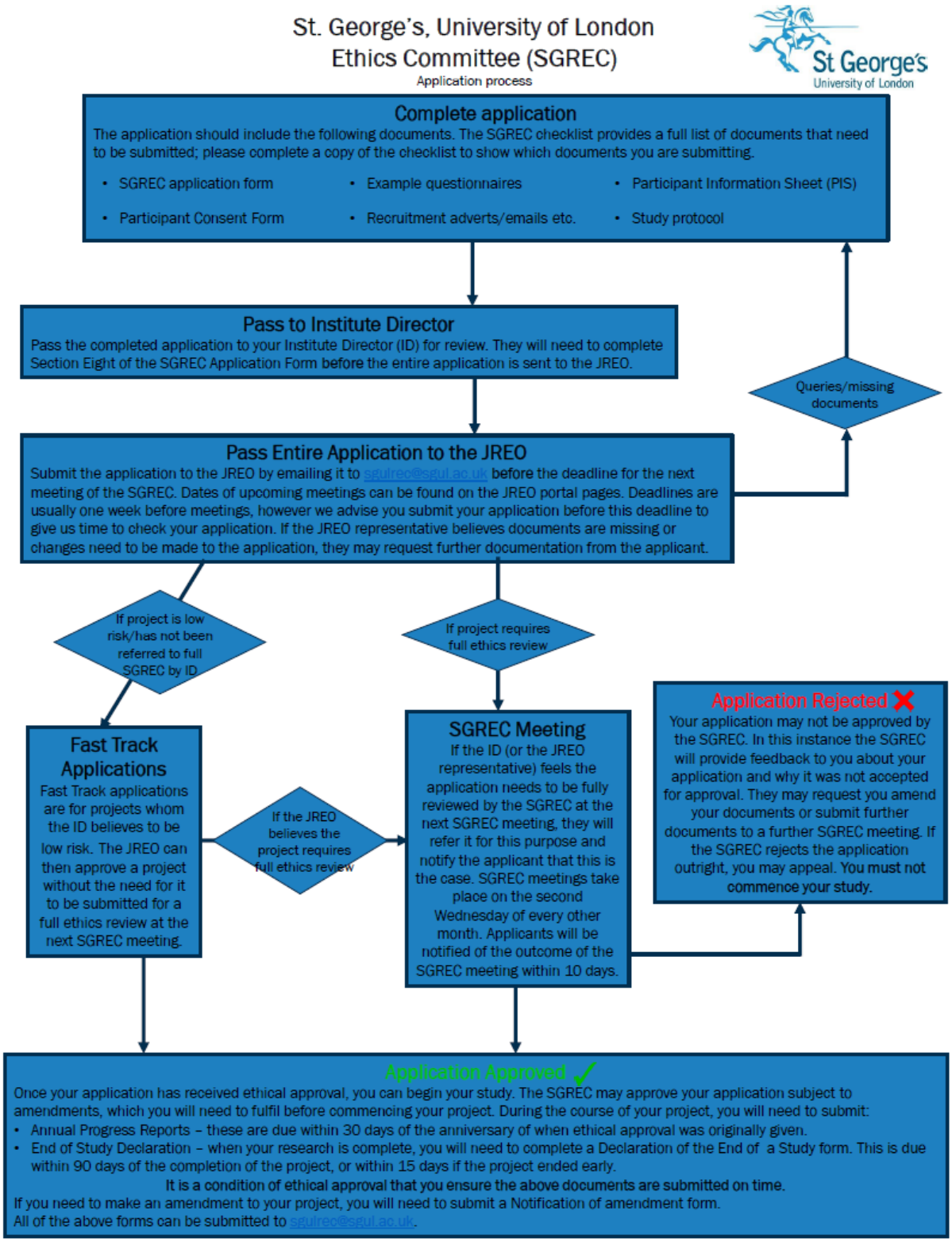
r. Research Conducted Overseas

Studies where the research takes place overseas are required to apply for two-fold approvals:

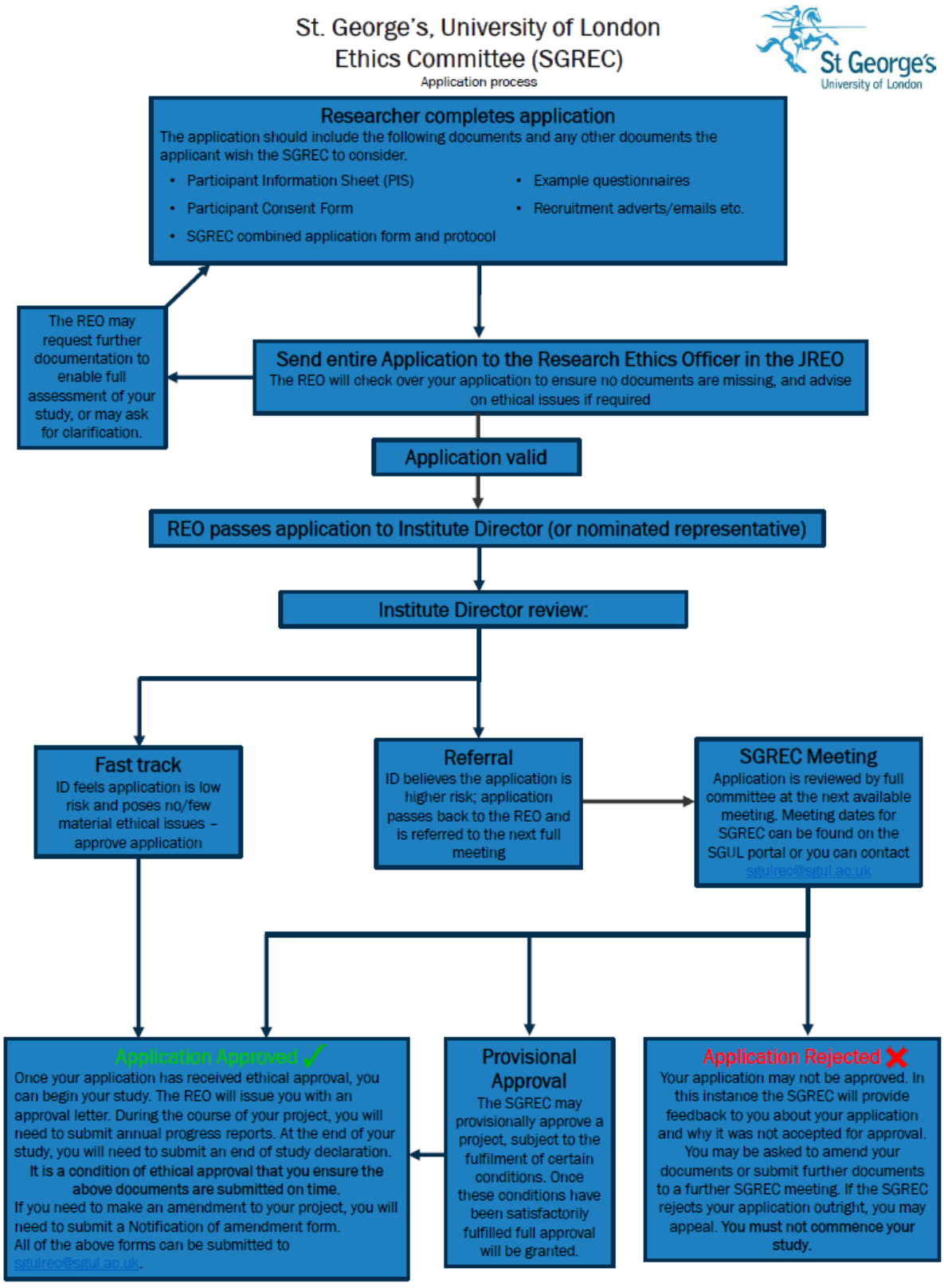
1. St Georges Research Ethics Committee review
2. Country-Specific, local ethics review

In the circumstance where there is no local ethics committee, proof of evidence that this is the case must be provided to the SGREC committee. In the circumstance of no local ethics available, site specific approval to conduct research should be sought and demonstrated to the committee as part of the application process before favourable review can be given. Evidence of Local ethics review must be submitted as part of the SGREC application.

Appendix 3


St. George's, University of London
Ethics Committee (SGREC)
Application process
St George's University of London
Complete application
The application should include the following documents. The SGREC checklist provides a full list of documents that need to be submitted; please complete a copy of the checklist to show which documents you are submitting.
• SGREC application form
• Example questionnaires
• Participant Information Sheet (PIS)
• Participant Consent Form
• Recruitment adverts/emails etc.
• Study protocol
Pass to Institute Director
Pass the completed application to your Institute Director (ID) for review. They will need to complete Section Eight of the SGREC Application Form before the entire application is sent to the JREO.
Queries/missing documents
Pass Entire Application to the JREO
Submit the application to the JREO by emailing it to sgulrec@sgul.ac.uk before the deadline for the next meeting of the SGREC. Dates of upcoming meetings can be found on the JREO portal pages. Deadlines are usually one week before meetings, however we advise you submit your application before this deadline to give us time to check your application. If the JREO representative believes documents are missing or changes need to be made to the application, they may request further documentation from the applicant.
If project is low risk/has not been referred to full SGREC by ID
If project requires full ethics review
Fast Track Applications
Fast Track applications are for projects whom the ID believes to be low risk. The JREO can then approve a project without the need for it to be submitted for a full ethics review at the next SGREC meeting.
If the JREO believes the project requires full ethics review
SGREC Meeting
If the ID (or the JREO representative) feels the application needs to be fully reviewed by the SGREC at the next SGREC meeting, they will refer it for this purpose and notify the applicant that this is the case. SGREC meetings take place on the second Wednesday of every other month. Applicants will be notified of the outcome of the SGREC meeting within 10 days.
Application Rejected ✗
Your application may not be approved by the SGREC. In this instance the SGREC will provide feedback to you about your application and why it was not accepted for approval. They may request you amend your documents or submit further documents to a further SGREC meeting. If the SGREC rejects the application outright, you may appeal. You must not commence your study.
Application Approved ✓
Once your application has received ethical approval, you can begin your study. The SGREC may approve your application subject to amendments, which you will need to fulfil before commencing your project. During the course of your project, you will need to submit:
• Annual Progress Reports – these are due within 30 days of the anniversary of when ethical approval was originally given.
• End of Study Declaration – when your research is complete, you will need to complete a Declaration of the End of a Study form. This is due within 90 days of the completion of the project, or within 15 days if the project ended early.
It is a condition of ethical approval that you ensure the above documents are submitted on time.
If you need to make an amendment to your project, you will need to submit a Notification of amendment form.
All of the above forms can be submitted to sgulrec@sgul.ac.uk.

Appendix 4


St. George's, University of London
Ethics Committee (SGREC)
Application process
St George's
University of London
Researcher completes application
The application should include the following documents and any other documents the applicant wish the SGREC to consider.
• Participant Information Sheet (PIS)
• Participant Consent Form
• SGREC combined application form and protocol
• Example questionnaires
• Recruitment adverts/emails etc.
The REO may request further documentation to enable full assessment of your study, or may ask for clarification.
Send entire Application to the Research Ethics Officer in the JREO
The REO will check over your application to ensure no documents are missing, and advise on ethical issues if required
Application valid
REO passes application to Institute Director (or nominated representative)
Institute Director review:
Fast track
ID feels application is low risk and poses no/few material ethical issues – approve application
Referral
ID believes the application is higher risk; application passes back to the REO and is referred to the next full meeting
SGREC Meeting
Application is reviewed by full committee at the next available meeting. Meeting dates for SGREC can be found on the SGUL portal or you can contact sgulrec@sgul.ac.uk
Application Approved ✓
Once your application has received ethical approval, you can begin your study. The REO will issue you with an approval letter. During the course of your project, you will need to submit annual progress reports. At the end of your study, you will need to submit an end of study declaration.
It is a condition of ethical approval that you ensure the above documents are submitted on time.
If you need to make an amendment to your project, you will need to submit a Notification of amendment form.
All of the above forms can be submitted to sgulrec@sgul.ac.uk.
Provisional Approval
The SGREC may provisionally approve a project, subject to the fulfilment of certain conditions. Once these conditions have been satisfactorily fulfilled full approval will be granted.
Application Rejected ✗
Your application may not be approved. In this instance the SGREC will provide feedback to you about your application and why it was not accepted for approval. You may be asked to amend your documents or submit further documents to a further SGREC meeting. If the SGREC rejects your application outright, you may appeal. You must not commence your study.