

St George's Research Ethics Committee

Annual Report 2015 - 2016

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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, 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 one and two respectively.

A list of projects reviewed, their SGREC reference numbers and summaries can be found in appendix three.

Reporting Period

Annual reports from the SGREC cover the calendar year. However, as this is the first report of the SGREC, the reporting period is extended retrospectively to cover studies that were approved by the fast track process when the system was first established early in 2015. Therefore the reporting period covered by this report is from January 2015 until December 2016.

Types of membership

During the reporting period, SGREC membership totalled 9 members. 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 lay members.

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 June 2016 and a meeting was held in July 2016, with the next meeting in September 2016. Meetings were not held if there were no projects requiring full review by the committee.

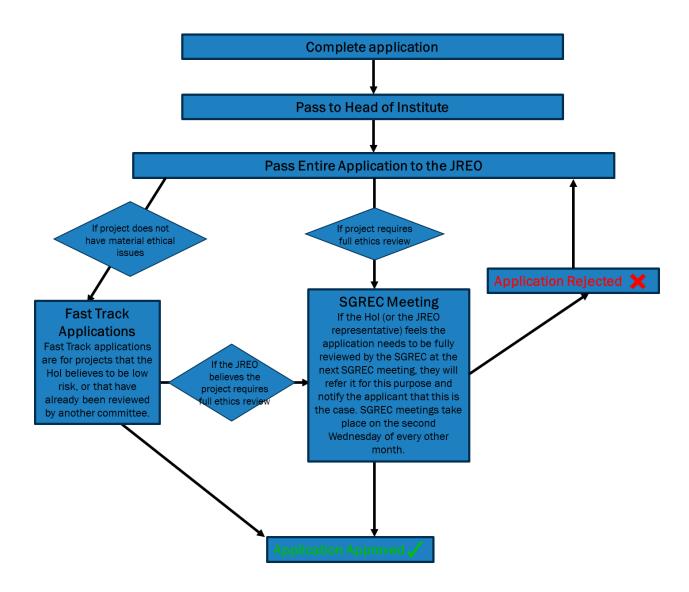
2015		
	9 th December 2015	
2016		
	10 th February 2016	

13 th April 2016	
7 th June 2016	
13 th July 2016	
14 th September 2016	

SGREC process

The flowchart below describes the SGREC process during the reporting period.

Chair's Action has been used on occasion during exceptional circumstances (see *Modus Operandi* for further information).

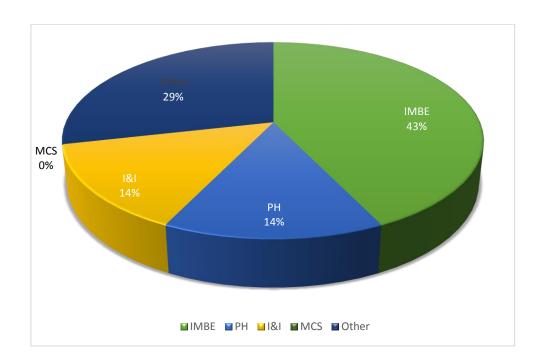


Breakdown of projects reviewed in the reporting period

2015:

The total number of studies approved in 2015 was 7. All studies were approved by the fastrack process in 2015 and no studies received provisional approval from the committee. No studies in 2015 involved block released, student projects.

Breakdown by Institute	
Institute of Medical and Biomedical Education	3
Molecular and Clinical Sciences	0
Infection and Immunity	1
Population Health	1
Other	2



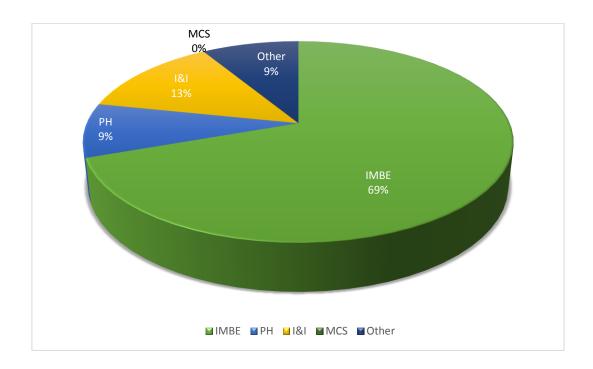
2016:

Total number of studies reviewed	23
Type:	
Student	1
Block release	6
Other	16

Comparison of fast-tracked studies versus reviewed by full committee		
Fastrack	15	
Review by full committee	6	

Outcome of review	
Approved	18
Provisional approval	4
Rejected	1

Breakdown by Institute	
Institute of Medical and Biomedical Education	16
Molecular and Clinical Sciences	0
Infection and Immunity	3
Population Health	2
Other	2



Appendix One: Summaries of Projects Reviewed in the Reporting Period

2015

Full title of project:

Reference no:

SGREC15.0001

Rethinking the assessment of applied anatomy knowledge of medical students: An investigation of the effect of visual resources, through contextually rich single best questions, on their performance and their views on anatomy

Project summary:

The purpose is to contribute towards the design of a robust anatomy assessment system that assesses applied knowledge of anatomy.

The aim is to investigate how anatomical visual resources used in contextually rich single best questions, that assess applied knowledge of anatomy, affect medical students' scores. Moreover, the scores will be further related to participants' views collected on a closed-ended questionnaire.

A quasi-experimental design will be employed. Internal validity will be maximised by having the participants act as their own controls. Each students will take the online test once. In the same exam condition, these students will answer questions with no visual resources (as controls), and with body images (as test 1) and radiological images (as test 2). The order of the questions will be randomised for each user to avoid conditions like fatigue, boredom and lack of interest in the topic to have a significant effect on any one category of the question-design. Moreover, equal number of "easy" and "difficult" questions will be used for each category (absence and presence of visual resources).

Full title of project:

Reference no:

SGREC15.0002

Evaluating the Mind peer support programme

Project summary:

The project aims to evaluate a service delivery programme sponsored by the mental health charity Mind that itself aims to provide new peer support for mental health projects in nine regions nationally. The evaluation will take place in three strands: outcomes; principles and process; health economics. Strand one aims to measure the extent to which increased uptake of peer support improves a range of outcomes at an individual levels, including wellbeing, hope, self-efficacy and strength of social networks. Projects will provide opportunities for people to make use of a number of different approaches to peer support as and when they chose. As such a conventional experimental design will not be appropriate. We will use an internally-controlled which will compare consecutive periods where participants make more use of peer support with periods when they do not. We will also make comparisons between different approaches to peer support (individual, group, online), and population (rural, urban; ethnicity). Data will be collected using a monthly online tool with paper versions and/ or support provided for people less comfortable with the online format.

The health economic strand will measure the cost of providing peer support, including volunteer time and other resource inputs and use the online tool to make quarterly measurements of quality of life and of use of mental health and social care services, and other community support and activity in the preceding quarter. Qualitative interviews will elicit understanding of 'typical' pathways of use of peer support (alongside other services) in order to model the economic benefits and impacts of widespread introduction of peer support.

In the 'principles and process' strand qualitative interviews with people giving and receiving peer support will be used to test the extent which a framework of principles (developed from existing literature and consultative work) underpin peer support available through the programme. Qualitative interviews will also be used with managers and team leaders of project providing peer support to understand the processes involved in building peer support capacity at an organisational level, in order to inform the widespread roll out of peer support post-evaluation.

Full title of project:

Reference no: SGREC15.0003

Investigation of stress and coping among First Year students studying medicine or biomedical sciences at St. George's, University of London

Project summary:

A study carried out by the National Union of Students in 2013 reported that 80% of participants felt stressed, 55% felt anxious, and 40% had feelings of worthlessness and hopelessness (Kerr 2013). Dyrbye et al (2008) reported that 11% of students said they had experience 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 to name a few.

Burnout is described as emotional exhaustion result in an unfeeling and impersonal response to patients and reduced sense of personal achievement (Maslach 1982). It is characterised by emotional exhaustion, depersonalisation, and a reduced sense of personal accomplishment. It is most likely to occur when there is significant stress without adequate support (Santen et al 2010). Students experience emotional exhaustion and depersonalisation are less able to be empathic (Santen, Holt, Kemp and Helhill 2010). It is unsurprising that burnout seems to be associated with students reporting serious thoughts of dropping out of medical education (Dyrbye et al 2010). Current research has shown a significant increase in levels of burnout as students progress through their medical training from 21% in Year one to 41% in Year two to 43% in Year three and 31% in Year four (Dyrbye et al 2006; Santen, Holt, Kemp and 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 (Santen, Holt, Kemp and Hemphill 2010). Resilience is a psychological characteristic that enables individuals to continue to thrive even after exposure to a stressful event, elements of which may be

learned. Indeed Dunn et al (2008) suggest a conceptual model whereby increased resilience may help prevent the development of burnout (Dunn et al 2008).

This study aims to investigate perceptions of stress, anxiety, depression and burnout and the types of coping strategies used to manage stress among undergraduate graduate students studying medicine and undergraduate students studying biomedical sciences at St. George's, University of London.

The study also aims to inform both student and the institution about the experience of stress among students, to increase awareness of effective stress management strategies to 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.

Full title of project:

Reference no:

SGREC15.0004

Are healthcare students' attitudes towards whole body donation influenced by exposure to the dissection room?

Project summary:

A small number of articles have been published worldwide exploring the attitudes of healthcare students towards whole body donation. Little research has been conducted in the UK.

We would like to gather healthcare students' views on whole body donation at different points during the first year of their studies using a short written questionnaire.

Full title of project:

Reference no: | SGREC15.0005

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 an anonymous questionnaire survey of all nurses and doctors employed on a fulltime or part-time contract, to work in the adult Intensive Care Unit (ICU) at St George's NHS Foundation Hospital Trust, seeking to determine whether staff have experienced moral distress and if so, the level of moral distress and how problematic this is within the clinical area. Moral distress is often a product of the constraints within a unit and healthcare environment. According to Hamric et al (2012), a unit with a strong and well developed ethical climate may be less likely to foster situations of moral distress (7). Providing information to staff and managers of how significant this issue is within their particular clinical area may 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.

Full title of project:

Reference no:

SGREC15.0006

Characterisation of human innate immune receptor expression and functions

Project summary:

This project aims to investigate the expression and functions of proteins known as innate immune receptors using cells purified from human blood. There are multiple families of innate immune receptors, some of which are thought to be responsible for triggering immune reactions for example, after encounter with bacteria or viruses. Other innate immune receptor families are thought to play a balancing role, in order to limit the size and/or scope of an immune response and prevent consequent tissue damage. This project will focus on studies of an activating group of receptors known as Toll Like Receptors (TLR) and a group of receptors known as Leukocyte Ig-like Receptors (LILR) which are thought to be able to regulate immune responses in general and TLR expressions and functions in particular. Further proteins which are thought to interact with LILR or TLR will also be characterised as will agents that may inhibit or enhance the activity of TLR and/or LILR.

Blood samples will be taken from healthy individuals and then immune cells separated out rom these samples. Cells may also be separated from blood preparations (Buffy coats of "Cones") obtained form the National Blood Transfusion Service. Immune cell populations will be analysed immediately or cultured for several days prior to analysis. This work will quantify the levels of the immune receptors present in immune cells, and determine what happens to immune cells when the receptors are activated or inhibited by various agents. Any remaining tissue will then be destroyed according to laboratory standard operating procedures. Genomic DNA will not be prepared from donated blood. Protein levels in purified cells may be assessed by amplification of nucleic acid "messages" from expressed genes – these will be used as an indication of protein levels and will not undergo sequence analysis.

Full title of project:

Reference no: SGREC15.0007

A qualitative study into the negotiation of dual identity among British Muslims

Project summary:

Within the UK, we currently have a generation of young adults who are in the unique position of embodying, to a greater or lesser extent, the dual identities of British and Muslim. With the current political and social climate, the Muslim population are often presented in a somewhat demonised way such that the values of being Muslim may be perceived as being opposed to the values of being British. This intra psychic conflict has been seen among other population groups, however an interesting element with this phenomenon is that this is very current. The aim of this research is to attempt to illuminate the internal processes of this group of individuals, to attempt to understand and explain how they negotiate their dual identities. As researcher, and indeed an academic, I am able to recognise that this demonization is not a unique phenomenon, and in fact in various parts of society we has seen similar negative political rhetoric on various subgroups of society-these include (but are not limited to) the Afro-Caribbean and homosexual population in the United States and Europe. Whilst not suggesting causality, with these specific population we have seen an interesting trend with respects to mental health, whereby research has indicated that experiencing social discrimination, as increasingly seen affecting the Muslim population today, can have an impact on psychological distress, with some reach suggesting that the mental health of the 'excluded' population was directly affected by the experience of socially related oppression and rejection (Diaz, Ayala, Bein, Henne & Marin, 2001). If we look at the patterns between these populations, within Counselling Psychology and other mental health services we may well see a marked increase in our contact with British Muslims who are currently moulding their identity under the gaze of current political events and rhetoric. From the outcome of this research, and with further research, we may be able to begin to form infrastructure necessary to work address mental health in both a preventative and reactive way.

Reference no:

SGREC16.0001

Amount of Ionising Radiation Reaching the Surgeons Cerebral Cortex During Fluoroscopic Guided Orthopaedic Surgery: Simulated Cadaver Experiment

Project summary:

Radiation is used on a daily basis by a select group of surgeons (radiologists, cardiologists, urologists, and orthopaedic and vascular surgeons). These surgeons are at a risk of being chronically exposed to ionizing radiation which could potentially lead to tumour formation.

We want to replicate three common orthopaedic operations to investigate how much radiation reaches the brain of the surgeon during the operation. We want to replicate the most common hip operation, the most common ankle operation and the most common hand operation.

Our project is mainly split up into two separate experiments:

- 1. We will perform each procedure once to work out exactly how much radiation reaches the orthopaedic surgeons brain for that SINGLE procedure.
- 2. We will then expose the surgeon to one years' worth of radiation for each of these procedures and measure how much penetrates to the brain. We will then be able to multiply this up to work out the radiation value over 5, 10 and 20 years.

Our expected outcome is to quantify the amount of radiation that reaches the brain of the operating surgeon. By doing this, we can better estimate if the radiation risk of the surgeon is significant enough to have a causal relationship to tumours in the head and therefore if head protection should become mandatory.

Full title of project:

Reference no:

SGREC16.0002

Do gynaecology teaching associates increase student confidence in performing intimate examinations?

Project summary:

Aim:

To assess whether small group sessions involving gynaecology teaching associates (GTAs) as simulated patients increase student confidence in performing women's gynaecological when added to large group lecture and small group practical session using mannequins.

Glossary:

"Gynaecology Teaching Associate" refers to a person who is trained in participating in or facilitating teaching sessions in which gynaecological examinations are performed on herself.

Summary:

In 2016, Physician Associate Students at SGUL are receiving teaching from GTAs for the first time. We wish to evaluate their experiences of this, comparing it with the

experiences of earlier and future cohorts. We plan to look at their levels of confidence at the time of teaching and at graduation, and to ascertain the number of gynaecological examinations they perform while on clinical placement in their second year. We plan also to compare levels of confidence in PA students with levels of confidence in medical students at SGUL, who currently receive classroom teaching of this exam on synthetic mannequins only.

We will administer questionnaires at several time points to physician associate students and graduates, and medical students before and after their classroom teaching sessions learning gynaecologic examination. We will administer further questionnaires to physician associate students in their final year of study or at graduation in order to ascertain details of their clinical experience and levels of confidence in these skills.

We hypothesis that use of GTAs will improve students' confidence in performing gynaecologic examinations, which may make them more likely to seek out opportunities to practice these skills while on clinical placement.

Full title of project:

Reference no:

SGREC16.0003

Analysing community health in a London Borough (block release)

Project summary:

Undergraduate students will undertake a small piece of qualitative work research as a component of their final year dissertation. Typically this fieldwork will consist of individual interviews with key informants such as public health officials, or an observation of a community group meeting, or focused discussions with a community-based group around a particular public health topic. The objective being to enhance the undergraduates largely literature review-based research dissertation, and additionally to develop undergraduate students fieldwork-based research skills.

Full title of project:

Reference no:

SGREC16.0004

The perceived barriers and facilitators to teenage parents accessing healthcare

Project summary:

I intend to interview up to 10 young mothers or fathers,18 - 30 years old, who are/were teenage parents and work with the charity Straight Talking Peer Education. The interviews will comprise of open ended questions about the facilitators, barriers and difficulties they faced accessing healthcare before, during and after pregnancy, and potentially how they think the health service could better promote and improve care for teenage parents.

The interviews will be semi structured. Key questions will be asked to stimulate the flow of conversation but participants will be encouraged to talk about aspects they deem important. This is an opportunity to identify commonly perceived barriers and trends to accessing healthcare services. From the anecdotal experience of the charity and some previous research we expect "feeling judged and stigmatised", "services that appear unapproachable or unfriendly" and "a lack of accessible information in schools" to be among the themes identified (Smith *et al* 2015).

Reference no:

SGREC16.0005

Self-testing for proteinuria in pregnancy – a survey of women's views

Project summary:

Pre-eclampsia is a condition that women can develop in pregnancy, defined by the presence of high blood pressure and protein leaking into the urine. There are trials currently ongoing considering whether pregnant women monitoring their own blood pressure at home during pregnancy can pick up problems earlier and improve outcomes. Alongside this, there is interest in whether women monitoring their own urine for proteinuria could help to pick up problems earlier and ensure things are acted on quickly.

When considering the feasibility of pregnant women self-testing their urine at home, it is important to know what women's views on this are. This is helpful in drawing attention to possible benefits and problems of self-testing, and to inform any future interventions on self-testing.

This study would consist of an online survey publicised through the website 'Action on Pre-eclampsia'. With this we aim to collect a large number of responses from across the UK, to give an overview of women's thoughts about self-monitoring and about any current self-monitoring practices. A link to the semi-structured questionnaire will be posted on the website of *Action on Pre-eclampsia* and an email sent to the mailing list. Responses to the questionnaire will be analysed in excel and STATA.

Full title of project:

Reference no: SGREC16.0006

Undergraduate (3rd Year MBBS 6 weeks) SSCT Research Project - 'Peer to Peer opinion Research Project - in School paper based or On-Line.

Project summary:

Undergraduate MBBS students on the SSCT self-directed study block summer term of transition year have the option of undertaking a small piece of qualitative survey work supervised around a specific and carefully developed focus. It is one of the literature based research components of their SSC programme (self-directed learning) that runs throughout the MBBS programme. Typically this fieldwork will consist of the administration of individual survey questionnaires to peer MBBS medical students during a two week period in summer term or post-examination period block. The topics will explore medical student opinion based responses to contemporary concerns in fields of medical education and the professional practice and policy paradigm of healthcare. The benefits for students of engaging in small scale qualitative survey research at undergraduate level, are firstly that their fieldwork findings can enhance largely literature review-based research presented in poster or PowerPoint formats – a summative test of survey findings and secondly, they are able to develop further qualitative research skills with support from a supervisor.

The benefits for research participants/key informants are less straightforward, but they benefit in knowledge that they have assisted peers in developing a broader understanding of the complexities involved in survey topic that impact the profession/healthcare arena.

Reference no:

SGREC16.0007

Reactogenicity of Diphtheria-Pertussis-Tetanus vaccine in children attending Immunization Centres of the Ministry of Public Health in the Provinces of Esmeraldas and Santo Domingo de Los Colorados in Ecuador

Project summary:

The study aims to identify biological markers (or biomarkers) associated with reactions that follow immunization with a Diphtheria-Tetanus-Pertussis (DTPwc) vaccine containing whole cell Pertussis that is routinely used as part of the infant immunization schedule by the Ecuadorian Ministry of Public Health (MSP). DTPwc is associated with frequent reactions such as fever when administered to infants and young children that have been attributed to the whole cell component of the Pertussis vaccine. DTPwc has now been replaced by a vaccine containing acellular Pertussis (DTPa) in industrialized countries but DTPwc is still used routinely in many non-industrialised countries for reasons of cost and availability. In recent years there has been large increase in Pertussis disease in many countries, an observation attributed to declining immunity associated with the use of DTPa and there is an urgent need to develop new Pertussis vaccines that can maintain long-lasting immunity to Pertussis but which are associated with minimal reactions. This study will measure the type of inflammation that occurs with the development of fever following a 4th booster dose of DTPwc given from 18 months of age according to the MSP immunization schedule. The study is divided into 2 parts: 1) observation of frequency, timing, and type of reactions for 72 hours following immunization in children attending MSP immunization clinics for a 4th booster dose of DTPwc; and 2) study of inflammatory response associated with fever developing within the first 48 hours following immunization in children attending MSP immunization clinics for a 4th booster dose of DTPwc. These data will provide us information on the frequency and timing of adverse events (particularly fever) following immunization with a booster dose of DTPwc and will provide us novel data on the type and causes of inflammation caused by immunization with DTPwc.

Full title of project:

Reference no:

SGREC16.0008

Exploring the health and wellbeing of people who use foodbanks in London

Project summary:

Food banks are charities that provide emergency food parcels for people considered to be in 'food crisis' i.e. they possess no or very limited access to food due to lack of funds. There are approximately 300 UK food banks, with London having more food banks than any other city in the UK. Overall in the UK, over a million people were given emergency food parcels in a one year period from 2014-2015, of which 104,799 were distributed in London.

Currently, while there is data available on the numbers of food bank users, and some data on their background, data on their physical and mental health is largely non-existent. Hence, a study into the health of food bank users would garner valuable information on how the health of a food bank's clients is impacted by their use of food banks.

This is an exploratory study. We will use face-to-face in-depth interviews to explore acute and chronic illnesses including mental health problems that the participant has been experiencing to understand how being a foodbank user impacts on health and well-being. This study will not only begin to address a gap in our knowledge of health and well-being of foodbank users, but it also aims to expand our understanding of how food poverty can have health-related sequelae. It is hoped that it will identify areas for further research to be carried out in the future.

This study will be conducted with the prior agreement of a locally-based London foodbank. People using the foodbank will be invited to participate in the study voluntarily. Interviews will last approximately 1.5 hours and all data will be anonymised (no identifiable information will be recorded) and stored in a secure location. If the participant consents, a recording of the interview will be taken, otherwise, notes will be taken during the interview.

The interview transcripts will be analysed afterwards to identify the issues surrounding health and well-being that the foodbank users experience. The findings will be written up into a report and presentation. Once the study is completed the findings will be fed back to the foodbank staff and study participants, while maintaining participant anonymity.

Full title of project:

Reference no:

SGREC16.0009

Investigations into the use of immunotherapy in cancer

Project summary:

This application is to cover projects supported by the Cancer Vaccine Institute (CVI). Our current goal is to investigate the sue of immunotherapy, which is the recruitment of the body's defence process, to combat cancer. The projects have been running for a number of years and we have needed to use blood samples, taken from healthy volunteers, to isolate and investigate the component cells of the immune system and determine how we can use these cells to target cancer. The projects currently consist of three studies looking at the mechanism by which tumour cell lines can be targeted by killer cells. The first is investigating how drugs might result in the removal of certain "brakes" in the tumour site, the second looking at how a common vaccine might activate a population of cells to kill tumour, and a third to look at ways in which the killer cells and tumour cell might come together.

In addition two projects are investigating the use of drugs to increase the susceptibility of cancer cells to immunotherapy.

All of these projects required blood cells to be isolated from healthy volunteers.

Reference no:

SGREC16.0010

Integrating the diagnosis and management of HIV-associated central nervous system (CNS) infections into routine health services in low and middle income countries (LMICs)

Project summary:

HIV-associated central nervous system (CNS) infection causes significant mortality and places a high burden on limited health care resources in Sub-Saharan Africa (SSA). Cohort and autopsy studies estimate that CNS infections cause up to 25% of HIV-related deaths. In addition, the HIV and TB epidemics have led to marked changes in the causes of adult CNS infections, with cryptococcal meningitis and tuberculous meningitis established as leading causes of HIV-associated meningitis in SSA. Delays in diagnosis are key causes of poor patient outcomes for tuberculous and bacterial meningitis, and cryptococcal meningitis patients present late and with advanced disease. Additional causes of high cryptococcal meningitis-induced mortality in low and middle income countries (LMICs) include poor monitoring facilities and inadequate access to diagnostic tests and essential antifungal drugs. Diagnosis of CNS infection is commonly not pursued in LMICs, and HIV-infected patients presenting with suspected CNS infection often receive empiric treatment with broad spectrum antibiotics to cover the commonest bacterial pathogens, in keeping with 2007 WHO bacterial meningitis guidance, and/or empiric fluconazole monotherapy (sub-optimal treatment for *Cryptococcus*).

The project is African investigator driven and will take place in collaboration with Institut Pasteur and Centre for Disease Control and Prevention (CDC) in three LMIC sites in central, eastern and southern Africa (Tanzania, Cameroon and Malawi) and include three phases: observation, training, and algorithm implementation. The hypothesis of the project is that point-of-care tests (rapid HIV, cryptococcal antigen lateral flow assay (CrAg LFA), Gene Xpert) nested within clinical management algorithms and improved training and support of regular hospital staff have the potential to significantly reduce CNS infection-related mortality by reducing delays in proven diagnosis and initiation of effective treatments. A semi-quantitative CrAG LFA developed in collaboration with Institut Pasteur will be evaluated. The primary study outcome is all cause mortality at 2 and 10 weeks. Study and local hospital staff will benefit from a laboratory and clinical training program on HIV-associated meningitis. In parallel, focused work with African investigators will improve access to diagnostic tools and treatments, notably essential antifungal drugs, for the commonest HIV-associated CNS infections in accordance with latest available local and WHO guidelines.

Full title of project:

Reference no:

SGREC16.0011

Training against medical error – pilot study

Project summary:

Errors by clinicians are one of the most common causes of harm to patients, but there is potential to reduce the incidence of error by providing appropriate training. This project aims to develop an improved understanding of the current training in medical error provided to undergraduate medical students at St George's, University of London (SGUL), and to pilot an e-Learning intervention designed to improve student awareness of how to avoid and understand medical errors.

The first part of the study will be a qualitative case study, examining the existing error training in the Problem-Based Learning (PBL) cases in the Transition-year of undergraduate medicine. We will examine decision points in the cases using established instruments; a classification of errors from a clinical practice perspective [1] and a taxonomy of the cognitive causes of errors [2]. Interviews with case authors or PBL tutors may also be used if further data is required to develop our understanding. The expected outcome is improved knowledge of the current provision for error training in the undergraduate PBL curriculum at SGUL, and development of a mapping between the practical and cognitive descriptions of error.

The second part of the study will pilot a series of purpose-designed error Virtual Patients (VPs) as a means of delivering error training in small group teaching sessions. The participants will be Penultimate-Year undergraduate medicine students as part of their Paediatrics attachment. The VPs to be used are interactive, scenario-based e-learning interventions, and represent a new way of delivering material that is already provided to learners through other means. Surveys will be provided to participants to provide feedback on learner acceptance, motivation and self-efficacy. The error VP cases will be made available as additional resources to all students after the pilot, regardless of their participation. The expected outcomes will be evidence to support the use of error VPs in this context, and an understanding of how learners respond and interact with the resource.

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.

Reference no:

SGREC16.0013

Characteristics of Physician Associate Programmes 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.

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 missed methods approach, combing 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 interviews 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:

SGREC16.0017

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:

SGREC16.0018

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

Global Health student projects (block release)

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.

- 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

Reference no: SGREC16.0020

Student projects (block release)

Project summary:

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

Full title of project:

Reference no: SGREC16.0022

Global Health student projects (block release)

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.

Project titles:

- 1. Evaluating the effect of cosmetic lenses on global eye health
- 2. The policy approaches to the Prevention and Management of Diabetes through Reductions in a Variety of Country Settings
- 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.

Reference no:

SGREC16.0023

A critical review of global initiatives for neglected tropical diseases.

Project summary:

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

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. Individual project summaries are attached to this application.

Appendix Two: Terms of Reference

St George's Research Ethics Committee (SGREC)

Terms of Reference

The 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 Georges Research Ethics Committee shall:

- 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, unless:
- a. They fall under the remit of the NHS or Clinical Trial Regulations on human subjects, tissues or databases of personal information.
- b. They involve animal subjects.
- 2. Following review:
- a. Approve the proposal without requiring any amendment;
- b. Require clarification or modification to any part of the proposal;
- c. Reject the proposal in part or in whole.
- 3. Demand or initiate another review at any point in the life of a project previously approved by the Committee or a Head of Institute, and revoke approval if necessary, in circumstances where:
- a. There have been relevant or material changes to the personnel or the protocol.
- b. The Committee has concerns about the conduct of the researchers or of the research.
- c. Adverse events have been reported to the Committee (in line with SGREC SOP).
- d. More than 5 years have passed since the last ethical approval.
- 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. Use the criteria for the evaluation of proposed research activities as set out in the National Institutes of Health (NIH) guidelines for the conduct of research involving human subjects and the associated NIH Multiple Project Assurance.
- 6. Consider and coordinate training arrangements for those involved in research that requires ethical approval.
- 7. Ensure applicants have made arrangements for independent peer-review of their research projects, prior to submission (if required).
- 8. Where SGREC is concerned with the review and approval of ethical issues relating to participant safety and research integrity, the committee requires that Head of Institute

and/or Academic Supervisor take responsibility for any general health and safety aspects of the research activity and conduct.

- 9. Assess the ethical concerns of research projects submitted for review and approval by SGREC.
- 10. Escalate serious concerns regarding research compliance or adverse events to the approving Head of Institute and advise on corrective actions.
- 11. Review the Terms of Reference at the first Committee Meeting of each calendar year.

Appendix Three: Modus Operandi

Version 2, February 2017

St George's Research Ethics Committee (SGREC)

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

A post-graduate research level student representative, or nominated alternative, shall be invited to attend the Committee as an observer. They will not form part of the quorum for the meeting.

c. Term of Office

The Term of Office for Committee members is 3 years, renewable once.

d. Head of Department Approval

Before a proposal is sent to SGREC for ethical review, it will be sent to the Head of Institute (HOI) of the Principal Investigator (PI) involved.

At this stage the HOI, his nominee or a committee set up by him/her for the purpose of reviewing certain types of proposals has the right to approve the ethics of the proposal without SGREC if he/she feels the research:

- 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 Principal Investigator has gained approval from his/her own University).

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

If the HOI does approve a proposal, it will pass to the Joint Research and Enterprise Office (JREO) for a 2nd opinion. The JREO can either approve the ethics or override the decision of the HOI and refer the proposal to the SGREC for discussion.

e. Chair's Action

Chair's Action is defined as a decision taken by the Chair and one other Committee member. The Chair can only take action if:

- 1. A SGREC meeting is cancelled and, following email consultation with members, it is felt that a proposal can be approved before the next meeting.
- 2. The Committee, following their review of a proposal, asked for amendments or additional information, but gave the Chair the power to approve the proposal subsequently once those amendments or the information had been provided.

f. Monitoring of Proposals

Pls, once given approval, have the obligation 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.

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; any project longer than five years must then be resubmitted for approval.

g. Specialist Advice

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

h. Presence of Principal Investigators

All PI's whose proposals 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, although the Deputy Chair can filter these before a meeting. The named PI must attend, although they can bring any other relevant people as appropriate. This also stands with student projects where the named PI is the supervisor.

The PIs 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 SGREC Co-ordinator and updated at least on an annual basis. If any member has a financial or personal interest in any proposal or project sponsor under scrutiny, the Chair will decide whether the interest disqualifies the member from discussion. If this proves to be the case, that member cannot participate in any final decision.

j. Frequency of Meetings

At present, the Committee shall meet a minimum of five 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 secretary no less than 14 days before the meeting.

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

- An emergency meeting, with the same quorate requirements; or
- An email correspondence or teleconference to discuss the specific proposal. 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 the whole Committee; or
- Chair's Action can be recommended by the Committee.

k. Modification of Proposals

If a proposal requires modification before it is approved by SGREC, the revised application will normally be sent to the next available meeting. However, if this is deemed unsuitable or unnecessary by the Committee, one of the following options can be proposed:

- · Chair's Action:
- Teleconference or email approval by Committee members;
- A meeting of an extraordinary sub-committee of no less than two people.

I. Process of Appeal

If a PI feels the decision of the SGREC is unjustified, he/she has the right to a single appeal at the University's Research Strategy Committee (RSC). SGREC shall provide an explanation of its decision, and the PI must provide evidence to counteract that. The PI and a representative of the SGREC 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.

m. Annual Report to the Strategic Research 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 and the number of applications submitted and approved by HOIs and SGREC.

n. 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.

o. Validation of applications

The PI 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 PI will be invited to correct the application and resubmit.

p. Decision-Making
The decision of the SGREC is final, subject to a single appeal by a PI. The Committee shall inform the PI of its decision, with explanations where appropriate, no more than 10 days following the meeting.