



St George's Research Ethics Committee
Annual Report 2017-2018

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St. George's Research Ethics Committee

Background

St. George's University of London Research Ethics Committee (SGREC) was formed in 2015 to review research projects that did not fall under the National Health Service Research Ethics Committee (NHS REC) remit. 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 fall under NHS REC remit.

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 Terms of Reference and *Modus Operandi* were updated and agreed by the committee on 11th July 2018 and can be found here: <https://portal.sgul.ac.uk/research/research-ethics-committee/st-georges-research-ethics-committee-mo-may-2018.docx/view> .
<https://portal.sgul.ac.uk/research/research-ethics-committee/st-georges-research-ethics-committee-tor-may-2018.docx/view>

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

Reporting Period

1st September 2017 to 31st August 2018.

Types of membership

During the reporting period, SGREC membership totalled 14 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, Joint Research and Enterprise Services and external lay members.

Name	Position/ Rep	Membership Type	First meeting attended
Sandra Ashton	SGREC Chair	MCS	19/07/2017
Bridget Bax	Reader	MCS	10/01/2018
Carole Beighton	External member	LAY	09/12/2015
Elena Sviderskaya	Senior Lecturer in Cell and Molecular Biology	MCS	14/02/2018(Att.22/05/2018)
Irina Chis Ster	Senior lecturer	I&I	09/12/2015
John Ward	Student representative	STUDENT	13/04/2016
Michael Perkin	Senior lecturer/consultant paediatrician	PH	10/01/2018
Michelle Harricharan	Research Data Manager	DATA	08/03/2017
Nabilla Waise	Research Ethics Coordinator/ SGREC Secretary	JRES	11/07/2018
Paris Ataliotis	Reader	IMBE	10/01/2018
Peter Brown	Lay member	LAY	09/12/2015
Phil Cooper	Professor of Epidemiology and Infectious Diseases	I&I	10/01/2018
Zoe Ilivitsky	Student Representative	STUDENT	13/04/2016
Sarah Jane White	Senior Lecturer	PH	09/12/2015

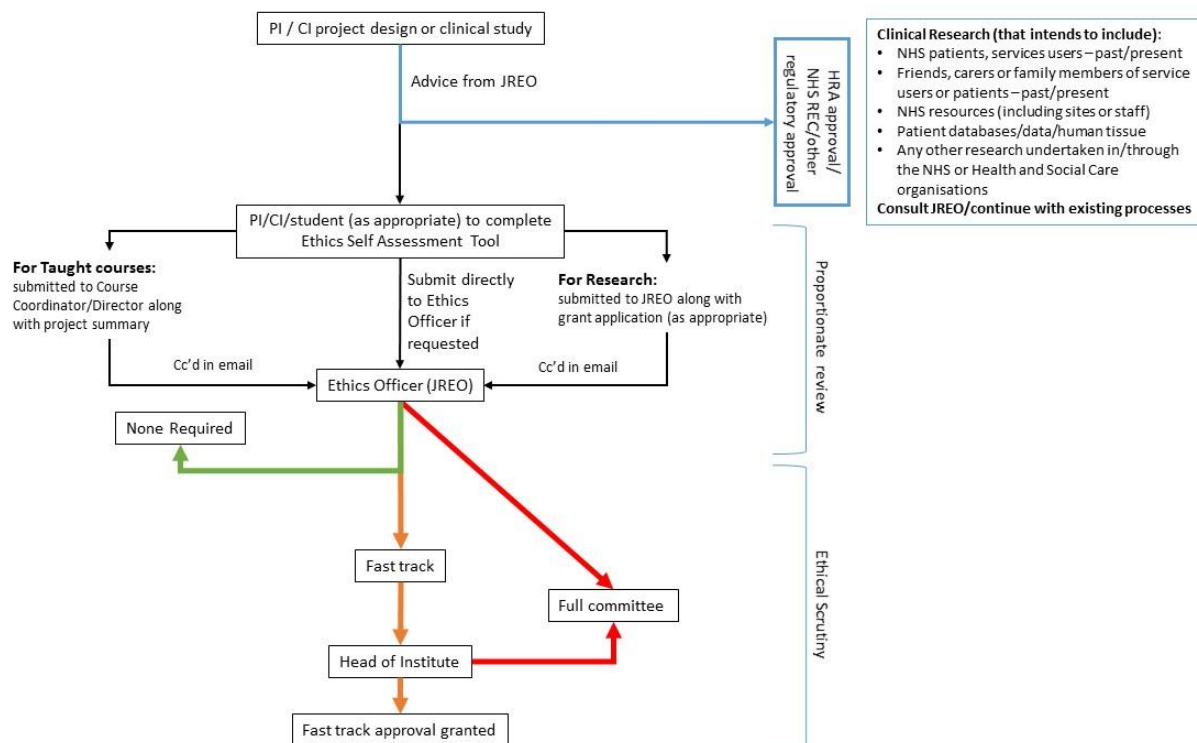
List of meetings scheduled

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 [list extra meetings held outside of those ones that were scheduled at the beginning of the academic year]. Meetings were not held if there were no projects requiring full review by the committee [indicate these in the table].

2017 - 2018
13 th September 2017
11 th October 2017
8 th November 2017
10 th January 2018
14 th February 2018
14 th March 2018 (Meeting not held)
9 th May 2018
11 th July 2018

SGREC process

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



Breakdown of projects reviewed in the reporting period

The total number of studies submitted in reporting period was **55**

[discuss no. studies approved by fast track/reviewed by full committee/discuss results as listed in the tables]

Breakdown by Institute	
Institute of Medical and Biomedical Education	20
Molecular and Clinical Sciences	0
Infection and Immunity	5
Population Health	10
Joint Faculty	12
Other	8

Total number of studies reviewed	55
Type:	
Student	20
Staff/academic	15
External (NHS/ Other)	20

Breakdown of submitted studies	
Fastrack	26
Review by full committee	8
Other (HRA Only, NHS REC)	16

Outcome of review	
Approved	53
Rejected	2

Projects Reviewed in the Reporting Period

(insert project titles and reference numbers)

I&I

	Reference no:	SGREC17.0033
Characterisation of novel TB vaccine delivery platforms in human cells		
<p>Three novel mucosal vaccines have been developed against Mycobacterium tuberculosis, liposomes, spores and nanoparticles, and have previously been tested in animal models with positive results. These vaccines act as both an adjuvant and as an antigen delivery system. For this project, we will test the effects of the vaccine delivery systems in human cells to characterize their self-adjuvanting properties. These vaccines have previously never been studied in human cells, and they will be tested in dendritic cells and macrophage cells, as a model for the innate immune cells the vaccine will first interact with after administration. A human macrophage cell line will be used but to characterize the effect of the vaccine delivery platforms on dendritic cells, dendritic cells derived from human blood will be needed. 50-100mls of blood will be required to generate enough cells for one experiment, and will also allow for patient serum to be produced from each sample, which when used in cell culture can reduce background activation. The blood will be collected, cells of interest (CD14+) will be isolated and stimulated to produce dendritic cells. These cells can then be used in the experiments, where the effect of the vaccine delivery platforms will be tested. Cell surface markers will be analyzed using flow cytometry, to determine the effect the vaccine delivery platforms on the dendritic cells. Secondary assays may also be used to assess cytokine or chemokine production after exposure to the vaccine delivery systems.</p>		

	Reference no:	18.0044
Vaccine immunogenicity using tuberculosis and dengue fever as models		
<p>It is estimated that in 2015, 10.4 million people were infected with tuberculosis. Dengue Fever infects an estimated 390 million people each year. The current vaccine against TB, the BCG vaccine, and the Dengvaxia vaccine against dengue, only offer partial protection. New vaccines against TB and dengue are urgently needed. We are testing the effectiveness of new vaccines against tuberculosis and Dengue Fever.</p> <p>For this project we use tonsils maintained in the laboratory to mimic immune system. These tonsils are used as a platform for testing new vaccines. Human tissue from tonsils is a good model of the complex interactions required to control infectious diseases.</p> <p>Mice are usually used to test new vaccines. Unfortunately, mice and humans mount different immune responses against tuberculosis. This work will test whether cell lines and human tissue could be a useful alternative to the use of animals in experiments. Vaccines work by stimulating the immune responses. All vaccines generate different immune responses. To determine which vaccines will be protective, we are measuring</p>		

the activation of immune cells. We are also monitoring the production of cytokines, which cells use to signal to each other. We are gathering information on the levels of antibody generated by each vaccine. We also measure the survival of immune cells and the elimination of Tuberculosis bacteria.

Testing these parameters for all the vaccines currently in development should allow us to select the most effective new vaccines.

Reference no:	SGREC18.0006
Newcotiana	
<p>The Newcotiana project is a four-year programme of work focused on the development of innovative new plant breeding techniques (NPBTs) and their practical application to agriculture. Saint George's University of London is working alongside 18 institutions across Europe – including universities, SMEs and research centres – to deliver a holistic approach to upscaling this promising new suite of technologies, which are being used to enrich plant varieties of the genus Nicotiana with end-value biopharmaceutical products.</p>	

Reference no:	2018.0153
NeoAMR Global Neonatal Sepsis Observational Study (NeoOBS): A prospective cohort study of sepsis in hospitalised neonates	
<p>Amongst the 5.9 million deaths in children under the age of 5 years globally in 2015, 45% were in the neonatal period. The main causes of deaths in infants include congenital anomalies, preterm births, injuries and neonatal sepsis (Liu et al. 2015). There is now evidence that the increasing prevalence of antibiotic resistance is associated with neonatal mortality – a major threat to progress in reducing global neonatal deaths.</p> <p>The NeoAMR project will generate a robust evidence base for managing neonatal sepsis in settings with high resistance rates to the WHO first-line empiric therapy of ampicillin/gentamicin and for infections caused by MDR Gram-negative pathogens. A major objective of this observational study is to collect high-quality observational data (clinical and microbiological) to inform trial design and comparator selection for a clinical trial(s) to assess the efficacy of novel antibiotic regimens in areas with high endemic rates of AMR. It is also designed to evaluate the use of healthcare resources, the current clinical practice, the outcomes and the risk factors for poor outcomes of young infants with significant sepsis (including culture-negative, culture-positive and culture-positive with AMR pathogens).</p> <p>The study will be a prospective, multinational, multicentre, observational cohort study of the inpatient management of neonatal sepsis in approximately 15-20 partner institutions. Babies less than 60 days of age, in-patient in the participating hospital, with clinical suspicion of sepsis will be recruited into the study and followed up until 28 days after enrolment. This study is expected to recruit over a period of 12 months</p>	

	Reference no:	2018.0143
<p>Perceived facilitators and barriers to Plant Molecular Farming product development and marketing in the EU</p>		
<p>PharmaFactory is an EU-Horizon 2020 project that brings together 14 institutions across Europe and Israel – including universities, small and medium-sized enterprises and research centres- active in the Molecular Farming sector.</p> <p>The overarching aim of the project is the creation of versatile, competitive plant-based production platforms that will serve as alternatives to conventional biopharma production systems (i.e. microbial and mammalian cell expression systems). The PharmaFactory project is expected to provide a unique opportunity to accelerate commercialization of new and innovative high-value biopharmaceutical products to the market.</p> <p>The project duration is 48 months. It includes a work package dedicated to public engagement and involvement (WP2), led by St George’s University of London, in collaboration with the University of the Arts London. The objectives of WP2 are to go beyond conventional approaches to public engagement, recognising that Plant Molecular Farming (PMF) has been embroiled within the genetically modified foods debate for almost two decades. Our work aims to identify the barriers and enablers to acceptance of PMF products from relevant stakeholders, end-users and the public at large, and develop innovative tools to facilitate communication about the potential of these new technologies and their potential impacts</p>		

IMBE

	Reference no: 2018.0189
Developing and piloting automated multiple mini interviews (AMMIs) in a United Kingdom (UK) setting.	
<p>This study features the development (Phase 1) and piloting (Phase 2) of a prototype automated multiple mini interview (AMMI) bot designed to augment healthcare student selection processes.</p> <p>The following in black was the original application written for the Phase 1 which received a FAO ref: UEC/2017/111/FHMS. This application relates to Phase 2.</p> <p>AMMIs are a progressive iteration of face-to-face multiple mini interviews (MMIs) being widely used in healthcare professional student selection processes. In face to face (MMIs) applicants are required to respond to scenarios at a series of 'stations' in a timed circuit; typically, seven, four minute stations with one minute between stations for scoring. (Eva et al, 2004a). Each scenario is designed to assess pre-defined values and or attributes.</p> <p>MMI's are demonstrably effective when selecting from large applicant pools with provably enhanced reliability and validity compared with unstructured interviews. However, limitations include: resource intensiveness; difficulties in consistency in decision making and unconscious bias of interviewers.</p> <p>Automated MMIs (AMMIs) represent a progressive iteration of face to face MMIs designed to address such limitations. AMMIs are MMI scenarios converted to computerised format facilitating automated interactions using chatbots which simulate conversation with human users across the Internet. Conversational and text analysis tools then evaluate the content of these interactions.</p> <p>To develop an AMMI prototype it is necessary to programme a computer. This application seeks permission (Phase 1) to audio-record face-to-face MMI scenario responses by healthcare professional applicants. These will be computed by IT experts and examined for indicative phrases/themes. Coding will be developed, designed to enable the automated assessment of applicants by a computer and not a human. Participants will not be identifiable; their spoken word is needed to write the computer code which will be anonymous.</p> <p>Following the development of a prototype, phase 2 will involve piloting to explore concurrent validity with face-to-face MMIs.</p>	
	Reference no: 18.0006
Can VO2 maximum be used as an indicator for CRT response?	
<p>The study will take place in a tertiary centre hospital in South London using retrospective data from patients who had a CRT implant between the years of Jan 2013-Jan 2015. The data collected will include, ECG's, date of implant, echocardiogram reports and NYHA classification.</p>	

The study will assess whether a VO2 maximum value obtained from a Cardiac Pulmonary Exercise Test can be used to assess the response a patient may have to a Cardiac Resynchronisation Therapy (CRT) device. VO2 maximum is a value which provides information on how well the heart muscle, lungs and muscles work in allowing oxygen to move around the body during exercise.

CRT is the chosen management option for patients who suffer from systolic heart failure. Zannad et al (2007) found that 25% of patients who suffer from HF. Many HF patients also have a left bundle branch block whereby there is a delay in the activation of the left ventricle. Abraham, W. T, Hayes, D. A, (2003) reported that a CRT device works by re-establishing the mechanical synchronisation of the heart through electrical activation, thus allowing for the synchronous contraction of both ventricles, in turn allowing for improvement in ejection of blood and thus patient symptoms, which will be measured using an echocardiogram and NYHA class.

This study may help triage patients to allow those patients who truly need a CRT to be put first, reducing the waiting times for a CRT on the NHS and reduce NHS costs as the average cost of a complete CRT-P system is estimated around £3411 and a CRT-D is estimated around £12,293.

Reference no: SGREC18.0001

To what extent is the rapid access chest pain clinic effective at identifying patients with CHD?

This project aims to establish if the rapid access chest pain clinic (RACPC) at Royal Surrey is effectively identifying patients with coronary heart disease (CHD). To do so the study is identifying if patients that have little indication are going on to have the gold standard of diagnostic tests for CHD, the coronary angiogram. As well as being the gold standard coronary angiogram is one of the more expensive tests for coronary heart disease. The study aims to establish if patients are being referred appropriately for this test. The study is also looking at the outcomes for patients after attending the RACPC to identify if there were patients that were not sent for coronary angiogram during the study period that went on to have a major adverse cardiac event. Data is going to be collected from patient letters and the clinical database, where necessary data may also be collected from patient notes. To evaluate outcomes a patient questionnaire will be sent out with a pre-paid self-return envelope to encourage a good response rate. Results of the service evaluation will be given to the care group lead and the data will be used to inform the dissertation.

Reference no: 17.0257

Assessment of the risk of ventricular arrhythmias during diagnostic testing in patients with suspected Brugada Syndrome

With this project I intend to look at test outcomes and ECG changes to provide a more extensive electrocardiographic assessment of any changes, which may increase the risk of developing ventricular arrhythmias. Since many patients with BrS present with non-diagnostic resting ECGs, the pharmacological challenge with ajmaline is an important part of the management of these patients and therefore safely conducting the test is also very important.

Reference no:	SGREC17.0024
<p>Research and evaluation of a mindful creativity workshop in the Pathology Museum</p>	
<p>A research and evaluation study to examine the perceived effectiveness and feasibility of a Mindful Creativity workshop in the Pathology Museum with Artist and Positive Psychology Coach, Kate Andrews.</p> <p>The workshop will introduce participants to the sciences of Positive Psychology and Mindfulness through activities ranging from meditation, mindful drawing and the visual arts. Stimulated by the Pathology Museum's specimens, workshop participants will learn first-hand how emotions can be a catalyst for creating art and how essential awareness of emotions, and harnessing one's innate creativity, are for leading a flourishing life.</p> <p>To research the perceived effectiveness of the workshop we will use self-reported questionnaires to provide us with a measure of mindfulness before and after the workshop. We will also evaluate the participant experience in a post intervention questionnaire. To understand who these workshops are of interest to, we will also include a questionnaire on their perceived stress levels before the workshop begins.</p> <p>The workshop will be open to both staff and students at St George's, allowing students to interact with staff outside of the usual student - teacher relationship. The expected outcomes of this study will be to determine the perceived effectiveness of this workshop format and to inform both our future research and future workshops format; including whether it is feasible to hold similar events in the future and whether a change in format is necessary.</p>	

Reference no:	SGREC17.0020
<p>The qualitative development of critical thinking: Student beliefs about the nature of knowledge and knowing</p>	
<p>This proposed project started as a teaching evaluation and learning initiative for the undergraduate research project that I have supervised over the last four years. It focuses on the transition that may or may not occur in the student's critical thinking over the course of the research process. The goal being to evaluate how to most effectively support this situated learning process. The study draws on Perry's (1970/81) much cited educational research which examined undergraduate student perceptions of a whole undergraduate curriculum. The proposed research will focus on just one component of a curriculum, the research dissertation conducted in the final year of the Biomedical Science degree / iBSc. The qualitative methodology consists of pre- and post-research project interviews, and utilises a series of open-ended problems to encourage students to elaborate on their thinking and understanding of the scientific process.</p>	

Reference no:	17.0169
Vascular dysfunction as a predictor of Acute Kidney Injury	
<p>Acute kidney Injury (AKI) affects 20% of all hospitalised patients in the UK and is associated with an increased risk of early death and future development of chronic kidney disease (CKD).</p> <p>Many risk factors are associated with AKI development post-operatively but there is no accepted method to predict which patients are at highest risk. In addition it is unclear why some surgical patients develop AKI while others do not despite similar risk factors and health problems.</p> <p>Blood vessel 'arterial stiffness' is a measure of a person's vascular health and has been shown to predict chronic decline in cardiac and kidney function. Arterial stiffness is reflected by measurement of an individual's 'Pulse Wave Velocity' index (PWV). This non-invasive test involves a probe placed on the skin to assess blood flow in the neck and groin while being attached to a cardiac monitor.</p> <p>This pilot study aims to investigate if this measurement may also help predict a person's risk of development of AKI following cardiac surgery. This may allow future development of a risk stratification model for patients with regards to development of AKI following major operations and potential reduction in the incidence and severity of AKI by perioperative measures and closer monitoring in high-risk patients.</p> <p>Furthermore few studies have truly correlated measurements of blood vessel 'stiffness' with actual 'true' changes within major human blood vessels. This project will retrieve redundant human aortic artery tissue from the cardiac operations which will undergo specialised staining in the histology department. This will allow determination of calcification and loss of elasticity in blood vessel walls to allow a true correlation between parameters of vascular integrity with real life changes in human blood vessel tissue. Correlation between tissue changes and non-invasive measures of vascular health may potentially highlight new therapeutic targets that are involved in the development of AKI.</p>	

Reference no:	SGREC17.0018
Longitudinal study of self-reported wellbeing of 3rd year BMS/iBSc students	
<p>This study aims not only to observe the level of wellbeing among undergraduate students, but also to observe whether participation in an educational programme which provides a higher level of knowledge regarding positive and negative health behaviours and strategies to increase levels of wellbeing has an influence on wellbeing over the duration of the year. It is anticipated that there will be a significant difference in wellbeing in the group of students exposed to the module compared to those who do not experience it.</p>	

If there is a significant difference however, it will not be possible from this study to identify which component may be influencing wellbeing and so this will be investigated in future research.

Reference no: SGREC17.0019

Stress and coping among final year students studying MBBS/BMS

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.

Reference no: SGREC18.0005

Service Evaluation: Comparing the experience of the users in utilising a 7-days ambulatory ECG monitor in a clinical setting: Holter monitor, Carnation ambulatory monitor (CAM) and Event recorder

This is a service evaluation study to compare the experience of the users in utilising a 7-days ambulatory ECG monitor in a clinical setting. The 7-days ambulatory ECG monitor that are being used in the Non-invasive Cardiology in Royal Brompton Hospital

are the following: Holter monitor, carnation ambulatory monitor (CAM) and event monitor. Three questionnaires will be designed for this study:

Questionnaire A will assess the patient's feedback in wearing a 7-days ambulatory monitor.

Questionnaire B will assess the Cardiac Physiologist's feedback in setting up, explaining and attaching the 7-days monitor to patients.

Questionnaire C will assess the Cardiac Physiologist's feedback in analysing the 7-days monitor.

This study aims to compare the experience of the users in using 7-days ambulatory ECG monitor using a feedback questionnaire and therefore provide an insight on the ideal 7-days ambulatory monitor to be used on other patients and the department's future purchases

	Reference no:	SGREC17.0030
Ultrasound guided genicular nerve treatment: a feasibility study in cadavers		
<p>Pain related to degenerative osteoarthritis of the knee can have a huge impact on the patient's daily life. If conservative measures fail, total knee arthroplasty is currently the gold standard treatment. However some patients are not eligible for surgery due to their co-morbidities.</p> <p>Radiofrequency (RF) ablation of the nerves, that innervate the anterior knee capsule (called "genicular nerves"), is a validated, low risk intervention for alleviating pain in these patients.</p> <p>Traditionally the placement of cannulas for this procedure is performed with fluoroscopy guidance. Although, since ultrasound devices are more reliable, clinicians tend to perform this procedure ultrasound guided. This is advantageous as it has lower dose of radiation exposure for patients and healthcare staff. It also provides better visualisation of soft tissue structures, such as nerves, blood vessels, muscles and tendons, which can not be visualised with fluoroscopy.</p> <p>In this cadaver study, the researchers aim to investigate and validate a new approach of ultrasound-guided placement of cannulas using soft-fix cadavers.</p>		

	Reference no:	17.0262
Cardiac events and complications following ICD implantation in HCM CLINICAL AUDIT		
<p>This study aims to assess the outcomes (complications and ICD therapies) in HCM patients at low, intermediate, and high risk of SCD, indicating appropriateness of ICD implantation in these patient groups. The study also aims to assess whether late gadolinium enhancement (LGE) additionally increases the risk in these patients.</p>		

Reference no:	SGREC17.0029
<p>Barriers and facilitating factors in the integration of the first UK-trained Physician Associates</p>	
<p>I will interview Doctors and Physician Associates (PA) about their experiences with implementing the PA role into new health care settings. I will inquire about their experiences and expectations. We will include only PAs who have been trained in the United Kingdom. The data will be evaluated through a special research method called “grounded theory” which involves transcribing what people say in the interview and looking for common themes in their statements which may help us develop a beginning theory about the issues with implementing PAs into health systems that have never had PAs before.</p>	

Reference no:	SGREC18.0007
<p>Healthcare staff experiences in London prisons and immigration removal centres: a qualitative study</p>	
<p>The study proposes study of up to 77 face to face, qualitative interviews across 11 custodial sites. It explores the range of healthcare staff experience and stress, specifically with reference to deaths in custody, in the current ‘very much ongoing, crisis across our prison estate’. The study will utilise the pre-existing body of quantitative data to contextualise the qualitative work proposed and will use statutory reports or Freedom of Information requests as necessary.</p> <p>The study sites are: one pilot site (HMP Downview), eight London prisons and the two London immigration removal centres (IRCs), sometimes jointly known as Heathrow IRC. There is a paucity of research around IRCs, particularly re: healthcare and any deaths that happen there. The study is explicitly interested in every kind of death in custody, as well as near misses. There is little research on the impact of these on staff, so it’s crucial to include these within the study.</p> <p>The research will investigate healthcare staff training, support and other workplace stresses, both in prisons and in a comparative environment of IRCs. The study is only concerned with all kinds of staff working in healthcare who are delivering healthcare in these very particular environments. Prison healthcare staff are little researched. The study seeks to understand why these staff continue to work in an environment which involves very particular pressures and stressors, often including a high level of exposure to those who die in custody.</p> <p>The thematic analysis will be fed back to NHSE Health in Justice commissioners to inform their commissioning in London in the first instance. It will also include recommendations for best practice, to be disseminated more widely in order to promote mechanisms that staff find useful by way of support and enabling provider organisations to target training needs, including fostering resilience and successful stress management.</p>	

Reference no:	18.0026
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A study of depression in patients with Interstitial Lung Disease

This study will aim to identify if there is an association between depression and interstitial lung disease (ILD).

Very little research has been conducted into this area but a link between ILD and depression is often observed. ILD is a chronic disease with few effective treatments available for patients. Therefore, importance must be placed in identifying and managing the burden of other diseases (i.e. depression) that ILD patients present with. Studies investigating into this matter constantly state that little is known about this link. Furthermore, research findings are often contradictory so it is very difficult to draw conclusions. For example, a study found that more females scored higher for depression whereas another study states that depressive symptoms are more common in men. Therefore, the results from this study will either back up or challenge previous published findings. Also, this study will focus on finding out the prevalence of depression in ILD and discovering which particular ILD patients are more likely to experience depression. Patients participating in this study will learn more about their condition and the findings from this study will raise awareness for depression in ILD to the department. The department should consider routinely screening all ILD patients for depression, as this does not currently take place in this hospital. This could help improve quality of life for ILD patients.

ILD patients that attend a lung function appointment in the respiratory medicine department at Guy's hospital will be given the choice to participate in this study. Patients will perform lung function as part of routine clinical care and will then be given various questionnaires to complete regarding depression and ILD symptoms. This study will take place over approximately a week and a half, with data collection occurring on a Monday and a Tuesday.

Reference no:	SGREC18.0004
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An investigation into the management plans the US, Japanese and Egyptian Governments implement to deal with cardiovascular disease related to obesity

Non-communicable diseases such as heart disease, diabetes and cancer tend to be associated with a high morbidity. Their aetiology is a combination of genetic, physiological, environmental and behavioural factors. NCD's are collectively responsible for approximately 70% of all deaths worldwide, with an average death toll of 40 million per year according to the World Health Organization.

Studies have shown that cardiovascular diseases account for most NCD deaths worldwide, with an estimated 17.7 million fatalities annually according to the WHO. Significant risk factors include: tobacco, alcohol, diet, exercise, sugar and salt.

Obesity places a heavy burden on healthcare systems and has a significant economic impact. It is estimated to account for up to 2.8% of a country's total healthcare

expenditures, with a 2007 study showing that the direct cost of people being overweight and obese to the NHS was £5.1 billion. Throughout their lifetime, obese individuals are on average likely to accrue medical costs approximately 30% greater than their normal weight peers. For this reason, obesity is a significant contemporary health concern in every facet of every society in the world.

Obesity is inexorably related to atherosclerosis, with atherosclerosis being the main underlying cause of cardiovascular disease. With the incidence of cardiovascular disease being continuously exacerbated with the ever-increasing tendency to resort to unhealthy 'junk food' diets, I would like to focus my research on the relationship between cardiovascular disease and obesity in the United States, Japan and Egypt.

During the study I will be conducting a student questionnaire to assess attitudes to obesity policy and management using standardized approaches. I chose to conduct this students with Medical/Biomedical Students rather than members of the public as I thought they would be more informed on the subject matter and could provide a fresh outlook.

	Reference no:	SGREC17.0032
Survey on the UK's policy and practice regarding contraception		
Perform a student survey amongst current SGUL students on their attitudes towards fertility control policies and services in the UK, and potential improvements. The survey will be distributed online to all first, second and third year students at St Georges to gain a rounded perspective on different people's attitudes towards contraception policy and practice in the UK. This data will help me to suggest improvements to the current UK contraception policy in order to reduce teenage abortion and pregnancy rates.		

	Reference no:	SGREC17.0025
What are Healthcare professionals doing to help combat human trafficking in the UK?		
This study is an analysis of the role of healthcare workers in protecting victims of human trafficking. It will consist of a literature review and a short survey of medical students at St George's, University of London and doctors and nurses at St George's University Hospital Foundation Trust. The survey will explore what medical students, doctors and nurses know about the signs of human trafficking, what they know about the actions to take when encountering victims of human trafficking, and an evaluation of how much education the participants have had about human trafficking. The study will also involve an ethical analysis of human trafficking.		

Population Health

	Reference no: SGREC18.0003
To understand and analyse global and public health policies for the management of the mental health crisis within the child refugee population	
<p>This dissertation will be about finding out, what systems and policies are out there to deal with the current child refugee crisis and their mental health support. I will begin by doing a systematic literature review, to really understand what current global policies are in place and how they've worked so far. I will also use the literature review to find out how the NHS and UK Government are involved in providing mental health care for the refugees, if at all. I then will be conducting interviews with Somali Community Leaders, NGO workers, Refugee Rights activists and other key informants in understanding what the specific needs are of this population of children and how we can create global and public health policies to meet these needs. I will analyse the data collected from these interview and conclude by highlighting what the most prevalent issues were and writing up the suggestions made by my participants on what can be done to solve them.</p>	

	Reference no: SGREC18.0002
Why has the SAFE strategy for trachoma been successful in some countries but not others?	
<p>Trachoma is the world's leading cause of blindness and impacts on the lives of those already living within extreme poverty. This eye disease is reported to be present in up to 50% of children between the ages of 1-9 years in some countries, such as Ethiopia 1. With the continent of Africa having the youngest population in the world 2, this poses detrimental effects for many sub-Saharan states. Trachoma control is of interest to study because it has successfully been eliminated from a few countries by implementing the WHO's SAFE strategy, but not all affected countries.</p> <p>This study will combine mixed methods, including a systematic review of peer-reviewed literature, grey literature and policy documents relevant to trachoma control supplemented with key informant interviews with eye specialists and trachoma experts. It will use a case study approach, looking at the 'success' of trachoma control in Ghana and the challenges to trachoma control in Ethiopia. It is hoped that this study will shed light upon the current drive for trachoma elimination and identify lessons that can be learnt from reviewing successful country control programmes and the ongoing challenges faced. Participant interviews</p>	

Reference no:	SGREC17.0036
<p>What makes a valuable clinical attachment? Perceptions of Physician Associate Students</p>	
<p>The project aims to identify factors that physician associate students consider to be valuable to their learning whilst on clinical attachments. The expected outcomes are that the students will highlight what makes a good placement and the elements that enhance their learning, leading them to be better prepared for professional practice, and deliver service on graduation.</p> <p>Following a thorough literature search on this topic, development and piloting of the research tool, undertaking semi-structured interviews through the medium of a focus group to:</p> <ul style="list-style-type: none"> • Identify the main factors that PA students believe contribute to the value of the clinical placement • Define other factors considered valuable by PA students that may in addition to the current literature <p>Following the focus group the data will be analysed to identify themes and patterns emerging and any new information as to what students consider to be valuable in clinical rotations. It is anticipated that from this study we will be able to better prepare students for rotations and for professional practice, advise and recommend changes to practice for the clinical placements and to enable students to have consistent quality placements resulting in an improvement in clinical practice.</p>	

Reference no:	SGREC17.0021
<p>Leanne's Amazing Medics</p>	
<p>This research project is studying the effectiveness of the 'Leanne's Amazing Medics' (LAM) programme. The LAM programme is an intervention designed to increase the number of students applying to medicine from low-socioeconomic backgrounds. This is important because there is a lack of diversity across UK medical schools – only a minority of medical students come from low-socioeconomic backgrounds which does not mirror society. The LAM programme aims to address this issue by targeting year nine students interested in healthcare in the hope of increasing their aspirations, self-confidence, and knowledge.</p> <p>This research study will be assessing how effective the LAM programme is at meeting its aims as previously listed. It will do this by conducting a pre- and post-programme questionnaire as well as focus group interviews after the programme. The pre- and post- programme questionnaires are a mixture of both qualitative and quantitative questions whilst the focus group interviews will provide qualitative data. The results from both the questionnaires and focus group interviews will help to shed light on whether the LAM programme has any effect on increasing students' aspirations, self-confidence, and knowledge. In addition, it will help to highlight any other challenges,</p>	

not previously considered, that may deter students from low-socioeconomic backgrounds from pursuing medicine as a career. In doing so, this will help to inform the LAM programme organisers so that it can be further developed to more effectively meet its objectives.

Reference no: SGREC17.0027

Knowledge and awareness of Deep Brain Stimulation (DBS) amongst medical students

Deep brain stimulation (DBS) is a common neurosurgical procedure that improves the symptoms for a significant number of patients suffering from essential tremor (ET), Parkinson's disease (PD), idiopathic dystonia and severe obsessive-compulsive disorder (OCD). The procedure is emerging as an important treatment modality, hence very important to be covered as part of neuroscience teaching for medical students at St George's University of London. The aim of our study is to assess knowledge, attitude and awareness towards DBS procedure amongst medical students at St George's University in order to address any gaps in education and curriculum design with regards to neurosurgical procedures especially DBS. The study will be conducted through an anonymous online voluntary survey of all medical students currently enrolled at St George's University.

Reference no: SGREC17.0031

How can the healthcare pathway for Alzheimer's disease be improved in the United Kingdom?

This study is being carried out as part of a research project for final year BSc Biomedical Science degree being undertaken at St George's University of London. The purpose of the study is to identify the major shortfalls in the healthcare pathway and management of Alzheimer's disease patients and potential options as to how these shortfalls can be improved.

Reference no: SGREC17.0028

Genital microbiota in women who did and did not develop clinical pelvic inflammatory disease: proof of principal, matched cohort study using novel sequencing technology

This study is being carried out as part of a research project for final year BSc Biomedical Science degree being undertaken at St George's University of London. The purpose of the study is to identify the major shortfalls in the healthcare pathway and management of Alzheimer's disease patients and potential options as to how these shortfalls can be improved.

Reference no:	SGREC17.0026
Digital technology in language impairment therapy: clinician review	
<p>According to an annual study by OFCOM, almost half of all children aged 8-11 now have their own tablet computer, whilst 80% use a tablet at home. Furthermore recent survey data suggest that over 70% of UK primary schools use tablets in the classroom. In contrast, nearly a quarter of Speech and Language Therapists do not use technology as part of their practice and a similar number do not consider technology use important.</p> <p>As long as this mismatch exists, children with communication difficulties will be restricted in the extent to which they can access digital technology to improve their functioning and reduce the burden of their underlying impairment.</p> <p>This focus group study aims to interview a sample of paediatric Speech and Language Therapists based in one NHS Trust to gain their views on important factors to consider with regards to the use of digital therapy techniques. The focus will be specifically on digital interventions for language impairment as this is the area that the highest proportion of UK therapist's support.</p> <p>The focus group will take place in a meeting room at the clinician's central healthcare base as a familiar environment is considered important by experts in the field to encourage open discussion. The rationale for group rather than individual interview is that the literature indicates that a joint forum encourages greater generation of ideas and consensus.</p> <p>The feedback from the focus group will be analysed qualitatively to identify the key themes relating to areas of most importance with regards to digital therapy. The results will be used to design a survey of digital practice which will be open to all paediatric therapists supporting language impairment within the UK.</p>	

Reference no:	SGREC17.0035
The further implementation of the Global WHO policies on the prevention of mental health problems needs improvement.	
<p>The implementation of the Global WHO policies on mental health problems is deficient and needs to be improved.</p> <p>The aim of this study is to critically analyse the systematic application of global policies for tackling mental health problems in individuals and the society. These include: plans for services, and strategies to promote and prevent (in places such as schools, universities and the workplace) mental health conditions. Two aspects of the hypothesis will be discussed, one being why and how the implementation is deficient, and the other being why it needs improvement and what the improvements could be.</p> <p>A systematic literature review of pre-existing papers and publications will be carried out. These papers include publications from: individual researchers, NGOs and mental health foundations (such as the World Federation of mental health and the Royal College of Psychiatry). This review will also look at whether the plans are cost efficient</p>	

and stigma of attitudes of mental health in different countries, including low to middle income countries.

- Key informant interviews will be carried out with people such as: mental health councillors, psychiatrist, therapists and mental health volunteers. This will be done to observe the extent to which the policies for services are put into effect, and to find out about how the practitioners of mental health feel about these policies.
- I will endeavour to establish two focus groups at a university to examine the execution of policies for preventing mental health in schools and universities. These focus groups will survey the stigma towards mental health amongst first year students and compare it with final year students.

Reference no: SGREC17.0022

Empowering women survivors of domestic violence

Domestic violence and abuse (DVA) is an abuse of human rights and a major public health problem with devastating health consequences and enormous costs to the National Health Service (NHS). In addition to immediate physical injuries and long term conditions such as chronic pain (e.g. back or neck), gynaecologic problems such as chronic pelvic pain or sexually-transmitted diseases and hypertension, DVA is associated with a range of psychosocial and mental health problems, including loneliness, anxiety, depression, post-traumatic stress disorders, substance abuse and psychosis which can be transient as well as chronic. A variety of different services can play an essential role either in responding to and helping to prevent DVA or by providing specialist supportive services.

This study seeks to evaluate a domestic violence programme which primary aim is to empower women and to provide them with insights into abusive relationships. Domestic violence programs are facing enormous pressure to demonstrate the impact of their work, therefore, with this study we attempt to make a contribution to, and describe whether this local DVA programme can make a positive difference for survivors, and whether it meets the outcomes it was designed to achieve. To this end, the proposed study adopts a pre/post study design to provide a summative evaluation of the 12-week Women's Support Group offered to women survivors of domestic violence in South West London. Pre/post evaluation allows a comparison before the "event" is launched and after it has concluded to show the true impact of the event. The "pre" baseline wave serves as a control group to judge the "post" outcomes wave against. Baseline data will be collected before the commencing of session one of the WSGP and after the conclusion of session 12.

We intend to collect outcome data on the following measures: Measure of Victim Empowerment Related to Safety (MOVERS) (Goodman et al., 2015); Customer Satisfaction Survey (Nguyen et al., 1983); General Self-Efficacy Scale (Schwarzer and Jerusalem, 1995); General Anxiety Disorder Screener (Lowe et al., 2008); Patient Health Questionnaire (PHQ-9)(Pfizer Inc., 1999). Data analysis will consists of descriptive statistics – e.g. frequencies and means, to compare the before administration and after administration.

Prior research shows that for DV survivors, support group programme can lead to empowerment which, in turn, paves the way for longer-term outcomes such as safety and emotional wellbeing.

N/A

	Reference no:	SGREC18.0011
ORaCIES: A trial to improve prognostication		
<p>This will be a double-blind randomised controlled trial of an online training resource. The web-based trial will recruit medical students in their penultimate or final year.</p> <p>The method of disseminating the link to the relevant survey will differ slightly between medical schools to comply with their ethical requirements. These methods may include 1) the palliative care lead at each participating medical school introducing the study to students; 2) The course leader or administrator at each participating medical school distributing an email to all penultimate and final year students; and (3) Advertising the study using newsletters, virtual notice boards and student associations. Participants will receive information about the study and will be able to access the study online. Prior to this RCT, we conducted a study which had identified the symptoms or signs that were most influential in forming expert doctors' decisions about whether or not palliative care patients were imminently dying (i.e. within 72 hours). The findings of this study provided the content for the online training resource.</p> <p>The intervention arm in the current study will receive an online training resource about how expert palliative care doctors recognise which palliative care patients are imminently dying. The control arm will receive no additional training. Both arms will complete a number of prognostic assessment tasks using case vignettes.</p>		

	Reference no:	2018.0303
How and why do neonatal trainees and consultants feel videolaryngoscopy supports clinical skills learning in intubation?		
<p>Laryngoscopy and intubation are procedures which involve the visualisation and placement of a tube into the airway to support airways and breathing. Normally the person performing intubation looks down the laryngoscope in a technique called "direct laryngoscopy", to guide a tube through the vocal cords into the lungs. This is a difficult procedure in a baby, and junior doctors often fail at attempts to perform this procedure. Consultants who supervise junior doctors performing intubation are unable to visualise the airways as the trainees intubate. In addition babies' are usually very fragile patients, which limits the time to attempt intubation, and for the consultant to instruct and correct the junior doctor. This delays the trainee's learning and moreover repeated unsuccessful intubations are traumatic for the patient. Video laryngoscopy has become available in recent years. The advantage with this tool over direct laryngoscopy is that these devices transmit images from the blade tip to a nearby monitor. This means the consultant can see what the trainee is seeing down the laryngoscope when they intubate. A recent Cochrane systematic review comparing</p>		

video to direct laryngoscopy in babies, showed that the time to successful intubation was similar, but video laryngoscopy improved the success of intubation at the first attempt. Trainees normally have limited experience in this procedure, and it is unusual that practice in the St George's neonatal unit routinely uses the technique. I plan to explore how and why video laryngoscopy support clinical skills teaching using interviews of stakeholders.

Reference no:	2018.0201
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The relationship between communal and agentic values and onward disclosure of human immunodeficiency virus (HIV) status in young adults with perinatally acquired HIV

An essential area of HIV research concerns the process of telling others about one's HIV status (onward disclosure) as this can facilitate reductions in HIV transmission and enhance social support. Values have been consistently associated with social and health behaviours and are involved in successful illness adjustment. Despite this, theories which explain what contributes to individuals' decisions to disclose have not considered the role of values. This study aims to fill a gap in disclosure theory by examining the relationship between communal and agentic values and onward disclosure in the PAH population.

It is predicted that greater endorsement of communal values (which focus on others) will be associated with higher rates of disclosure, whereas greater endorsement of agentic values (which focus on the self) will be associated with lower rates of disclosure. Participants will complete questionnaires which quantify their disclosure behaviour, satisfaction with disclosure decisions, disclosure intention and their communal and agentic values. Correlational analysis will be completed to assess if the proposed relationship between these variables is found. Exploratory analysis will be undertaken to assess whether these relationships are independent of disclosure self-efficacy, a known correlate of disclosure. The study aims to contribute to our theoretical understanding of disclosure.

Reference no:	SGREC17.0017
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Unlocking the Potential of Virtual Reality in Palliative Care

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.

Reference no:	18.0043
Surgical training in ENT	
<p>Our principle aim is to improve the quality of postgraduate training in single-surgeon operations. In depth investigation and evaluation of the current techniques and models used to teach single-surgeon operating in ear, nose and throat surgery will aim to provide a structure that trainers can adopt in their day-to-day teaching. I intend to use a mixture of methods to record my findings including, audio recording of the interviews, observations between trainee and trainer and taking hand-written notes logging the environment.</p>	

Reference no:	SGREC18.0010
Exploring "lightbulb moments" in Medical Student Simulation	
<p>St. George's Medical Students attend clinical placements at East Surrey Hospital, at which I work as a clinical teaching fellow. During their placements, they have regular simulation-based teaching as part of their timetable. I wish to use an interpretive phenomenological approach from an ontological stance to explore themes related to Threshold Concepts that medical students experience during this mode of teaching. Threshold Concepts are defined as moments experienced by a learner during which they undergo a moment of transformation in their learning, for example a challenge to their perceptions or an integration of knowledge. This initially stemmed from Mezirow, who discussed how adult learners undergo transformative learning by being challenged by or by incorporating new information into their existing frame of reference to move from 'having knowledge' to 'applying knowledge' (Mezirow, 1997). This has the aim of transforming learners into becoming 'autonomous, responsible thinkers.' Based on the initial work by Perkins on 'troublesome knowledge' (Perkins, 1999) Meyer and Land defined and identified components of 'Threshold Concepts' in a report looking at "characteristics of high quality learning environments in higher education." (Meyer & Land, 2003) Their findings - essentially the various characteristics that are included in the term 'Threshold Concepts' - describe a number of common experiences seen across a range of undergraduate fields, including topics such as 'transformative learning' (a change in stance or development in the field),</p>	

‘troublesome learning’ (an unexpected challenge faced) and ‘integrative learning’ (bringing together different aspects of a subject). With regards to the medical field and specifically the use of simulation in medical education, R. Kneebone describes how a simulation-based approach can help medical trainees explore these issues in a clinically-based setting, integrating knowledge with practical experience (Kneebone, 2009). He also explains that in order for teachers to assist and support students through these sometimes-challenging transformative moments, we as teachers should aim to “understand the learner’s perspective.

Reference no:	18.0062
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Follow up studies on known copy number gains using WGS to ascertain a diagnosis

Copy number changes (CNVs) are changes in the number of parts of the genome. They are thought to be the likely cause for intellectual disability, autism spectrum disorder and congenital abnormalities. More recently there has been evidence to suggest CNVs also play a role in schizophrenia, epilepsy and some auto immune diseases. The effects of deletions are more obvious, they can be predicted to cause an insufficient amount of gene product (haploinsufficiency). However, duplications are less obvious; symptoms could be caused by an increased amount of gene product being produced (triplosensitivity), gene disruption or fusion of two different genes causing production of an abnormal protein and in some cases the gain may be inverted. Much of the current literature has identified that although array CGH is great at detecting CNVs in the genome the genomic arrangement is not provided which may be key to working out the underlying cause.

Previous scientific studies have used various different methods to show that in some patients gene regulation is disrupted due to the abnormal rearrangement of the genomic information. There is only one study which has investigated the benefits of using WGS for the detection of CNVs, for both detection and evaluation of duplications. It is evident the arrangement of clinically relevant duplications is yet to be investigated further by WGS.

The research project will investigate the genomic arrangement of duplications previously identified using array CGH in a cohort of patients, it will ascertain how the gains affect gene function and will use the data in conjunction with relevant literature to assess if the disruption of genes contributes to the phenotype of the individuals. The project will provide me, the student, the opportunity to conduct my own research and provide me with an opportunity to familiarise myself with WGS data and enhance my skills in using bioinformatics tools for analysis. As it is being undertaken in an NHS genetics department who routinely provide testing for patients, the project could also lead to a change in testing pathways to include WGS for patients like the ones used in this project. Provide any relevant background information to support the research area, the area to be studied and trial population.

Withdrawn IMBE

	Reference no:	2018.0114
The Flesh Becomes Word: Matrescent Theory, the Ethical Imperative of Narrative Agency, and World Health Organization Natal Policies		
<p>This research project will consider the manner in which sovereign narrativity matrescence ultimately informs international obstetric policy and global health for maternal health. The premise of my thesis asserts that theoretical frameworks shape and inform policy; matrescent narrativity is an epistemology and is critical in the development of ethical global health policy.</p> <p>Advocacy is invariably linked with narrative agency; narrative autonomy is both a political and ethical act. Policy-making in maternity can only be ethical through the consideration of subjective narrativity; it is critical to support intersectional and pluralist, polyphonic maternal narrativities to inform World Health Organization (WHO) policy, addressing the sociological, psycho-social and political implications of the matrescent period; this ultimately supports development.</p>		

	Reference no:	17.0265
Does CPAP Treatment Reduce Depression in OSA?		
<p>Obstructive sleep apnoea (OSA) is a sleeping disorder brought about by the collapse of an individual's airways during sleep. The collapse of the airway starves the individual of oxygen causing them to wake up. As a result, the individual doesn't get a good night sleep and feels fatigued throughout the day. Daytime fatigue has been known to reduce someone's quality of life which could lead to depression. CPAP (Continuous positive airway pressure) is commonly used to treat OSA, this machine prevents the airways from collapsing during sleep. My aim is to investigate CPAP treatment and its effect on depression and quality of life in patients with OSA.</p>		

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 (GfREC)
- 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.

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

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, such as where a project suitable for Fast Track approval is not able to be approved by an Institute Director or one of their Nominated Representatives

f. Monitoring of Projects

CI's, 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.