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CHIEF SCIENTIST OFFICE

PUBLIC ENGAGEMENT GROUP

INFORMATION PACK AND TERMS OF REFERENCE



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1.0 Introduction and Welcome

Dear CSO PEG Member,

If you are a new member of the PEG, a very warm welcome to you. I hope that this information pack will assist you in establishing yourself as a valued Member of the Group. If you are an established member of the Group, I am sure that this will be a useful reminder to you of Group policies and procedures.

The aim of the pack is to provide you with some general information and to put your role and the organisation into context. It is a resource that you can dip into at any time along with information that is provided on our [website](#).

The CSO actively encourages you to ask questions, seek clarification, make suggestions and challenge our practices as your contributions as a member of our team are valued and respected.

I hope that you find your time with us is stimulating and enjoyable and thank you for becoming part of the team.

Yours sincerely

Euan Dick
Head of CSO

2.0 Chief Scientist Office (CSO)

The CSO ambition is to place Scotland at the international forefront of clinical research. To achieve this we are building on past success, are focussing on excellence and continue to build capacity and capability in key skills and disciplines. We aim to ensure strong and productive partnerships among funders and funded alike and are looking beyond our borders to work with the best in world.

2.1 Funding Schemes

Some of the main funding schemes run by CSO are listed below:

2.1.1 Health Improvement, Protection and Services Research Committee

The Committee considers applications for research aimed at improving or protecting population health or improving the quality, safety and/or effectiveness of healthcare in Scotland. Applications must demonstrate the relevance and importance of the research and its potential for significant impact on health in Scotland. A clear pathway for translation of the results into policy and/or practice must be presented.

2.1.2 Translational Clinical Studies Research Committee

The Committee considers applications for research aimed at improving treatments and/or diagnostic approaches for conditions of clinical importance to the population of Scotland. Applications must demonstrate the clinical relevance of the research and its potential for translation into clinical practice. Applications that seek to address questions of clinical importance in small patient groups (e.g. rare diseases) are welcomed.

2.1.3 Clinical Academic Fellowships

The aim of this scheme is to build research capacity in the Scottish NHS, as such it provides the opportunity for clinical professionals early in their career to undertake a PhD. This scheme has been adapted over time to offer wider eligibility than in previous years, now including Nurses, Midwives, Allied Health Professionals and Healthcare Scientists, in addition to previous eligibility for doctors in training, GPs and dentists.

2.1.4 Early Postdoctoral Fellowships

This scheme is designed to build health research capacity in Scotland as such it provides the opportunity for both clinical professionals and health researchers to develop their research following successful completion of a PhD. This scheme provides 3 years of salary and consumable support to early career health researchers to enable them to develop their careers.

Further information on these committees and groups, in addition to other funding initiatives can be found on the [CSO website](#).

3.0 Public Engagement Group (PEG)

Volunteers are normally appointed to become a member of CSO's PEG group for an appointment period of three years. They can, however, leave at any time if they so wish. Appointments can be extended beyond three years up to a maximum of six years, subject to agreement. Members are also invited to become members of one of the funding committees, or fill other lay vacancies in the work of the office.

Where possible, members are expected to attend the group information events, which are usually held three to four times per year. These events are usually in the form of updates and include details on current research policy initiatives being undertaken by CSO and the research community, short presentations from guest speakers on current research activities in particular disease areas and on research processes. We hope these events provide Members with a greater understanding of research matters, providing useful background knowledge when attending the Committees and Groups to which they have been appointed.

PEG Members are normally appointed by the Chief Scientist to one of the various CSO Committees and Groups. Details and frequency of these Committee and Group meetings can be discussed with CSO if Members are interested in a particular position. Members should be aware that their input is valued and appreciated, no matter how little the contribution. CSO distributes significant sums of public money and PEG members represent the public in these discussions. Members attend these Committees to provide a lay perspective and to ensure that the outcomes of discussions are transparent and fair.

Individuals are regularly asked to partake in particular tasks such as reviewing Lay Summaries, Final Project Summaries, or other CSO documentation to ensure that it can be understood by the lay person. This documentation is shared with the Group using a browser-based system known as Objective Connect. Full instruction and supplementary guidance notes will be provided on how to navigate this system.

On occasions, Members may be asked to attend additional/ad hoc meetings, or other events and activities which CSO may be involved in.

3.1 CSO PEG Terms of Reference

Role:

The PEG role is to provide a lay perspective on the activities of CSO to ensure that the public view is taken into account in relevant policy and funding issues.

Responsibilities:

- To review and provide recommendations on CSO grant applications ensuring that lay summaries are easily understood; that funded research will provide a positive outcome for patient care; that plans are in place to involve the public within the research project; and that there are appropriate arrangements to disseminate the outcomes of the research.
- To review final project reports, emanating from the results of CSO funded projects, for clarity and readability for public consumption and provide suggested changes without changing the meaning of the report.
- To represent the public at CSO policy and strategy committees. Advising and commenting on the appropriateness of strategic direction, funding initiatives and decision making.
- To be involved in the planning and review process of CSO investments such as funded research units, bio-repositories and CSO Grant focus.
- To be responsible for the content of the Public Engagement Group section of the CSO website.
- Where appropriate disseminate and promote information on CSO policies and initiatives to help raise public awareness and interest in research.

Membership:

- Members shall be recruited through receipt of an expression of interest and discussion with the PEG Chair and CSO colleagues. Appointments to the PEG will generally be for 3 years with an option to extend for a further 3 years. Members can, of course, leave the group at any time.
- Group members will be provided with an induction on joining. This is comprised of informal information sessions, formal meetings with guest speakers, communications and guidance from CSO.
- Where possible, group members will attend PEG meetings three to four times annually. These meetings are generally held in St Andrews House, Regent Road, Edinburgh, EH1 3DG. However, due to the COVID-19 pandemic, are currently being hosted virtually using Microsoft Teams. Looking forward, and as the situation improves, hybrid meetings options will be made available for members.

- Operational issues may also be discussed at PEG meetings and additional meetings may be organised as issues arise. Members may contact CSO between meetings for advice if required.
- Lay members will be appointed by CSO and the Chair of the PEG to a specific CSO function. Rotation of PEG members to functions will be staged to ensure continuity.
- From time to time members may be co-opted to carry out ad hoc tasks or work on specific issues.
- Members will be required to complete an evaluation form for the specific tasks/functions they are involved in. Members will receive yearly feedback on the appropriateness of their input from the PEG chair

3.2 Personal Reflections

“I have been impressed by the working of the group, with meetings well organised, and officials and professional members all very welcoming. It has been most interesting to see the range of research being applied for and undertaken. The meetings/research during the COVID-19 pandemic were of particular importance and it felt an honour to be involved.”

Marilyn Jackson, PEG Member

“During my time with PEG I have been very well supported and welcomed by all members of staff and fellow members of the group. I have found the meetings well organised, paper work out well in advance and the meetings and visits have been very interesting.

I have welcomed all the information and the knowledge on research, which I have gained by being a member of the Public Engagement Group. I look forward to being a member of PEG for the next period of time, and I hope I will be of some benefit to the Group and in a small way to research as a whole ,as it is so vital to us all. I look at being a member of PEG as a privilege, thank you for having me. One thing I would like to say to anyone who is thinking it would be nice to put their name forward as a new member please remember it is a commitment which is well worth while.”

Joanna McGregor, PEG Member

4.0 Travel and Subsistence Expenses and Claims

As a member of the PEG you are eligible to claim travel expenses incurred when attending PEG Meetings, and CSO Committees and Groups and any other CSO meetings and events to which you may be invited. Details of the expenses allowances that may be claimed are shown on the claim form in the Annex.

The following allowances are intended only to reimburse actual expenditure and are in no sense a payment for services. The allowances are applicable only if expenditure has actually occurred.

Travelling Expenses

- Travelling expenses actually incurred as a result of attending a meeting or event will be refunded. Second class rail/bus fares will be reimbursed, if incurred and claimed. Members should take advantage of all fare reductions where appropriate and observe any other normal economies
- Taxi fares will only be permitted when other public transport is not available or in circumstances of extreme urgency.

Private Motor Vehicles

- Members who use their private motor vehicles will be paid the motor mileage rate as detailed in the Annex. A passenger supplement will also be paid in respect of each official passenger whose fare would otherwise be payable from public funds. Passenger supplements are also detailed in the Annex.
- For Members using their private motor vehicle, the requirement of comprehensive insurance cover is not necessary. Members should understand, however, that no liability will be accepted by the Scottish Government in the event of any accident, damage, injury or death.
- No liability will rest on the Scottish Government in the event of accident, damage, injury or death other than to the extent that the liability would exist whether or not the officer had travelled by private motor vehicle.
- Reasonable garage and parking expenses and charges for tolls and ferries will be reimbursed when necessarily incurred. Overnight garaging and parking charges can be reimbursed only when absence overnight is necessary and attracts a 24 hour rate allowance.

Day Subsistence Allowance

- The day subsistence allowance rates are set out in the Annex. For absences which exceed 10 hours and have to start so early in the day that it is not reasonable for the member to have breakfast at home before travelling, a special supplement of the amount of the over 5 hour allowance may be paid in addition to the over 10 hour allowance. 24 hour subsistence rates can be provided if necessary.

Lunch and Refreshments

- On days on which formal meetings are held, lunch may be provided at public expense for Members. When lunch is provided, any day or 24 hour subsistence normally payable will be reduced by the amount of the appropriate day subsistence allowance for an absence of over 5 hours.
- Expenditure on wine or other alcoholic drink is not acceptable as a charge appropriate to a Committee, Group or other event.
- When it is considered that morning or afternoon breaks are warranted, tea or coffee may be provided at public expense.

Payment of Claims

- Copies of receipts should be submitted along with all claims within 1 month of attending a meeting or event. Expenses will be paid to all non-executive Committee Members and claims should be submitted using the claim form in the Annex to this pack.
- Private bank details are requested since we are not in a position to issue cheques; these details are never shared with others and are used purely for the purposes of reimbursing your expenses.
- Further copies of the claim form can be obtained from the address/contact details below and will normally be handed out at meetings and events that you attend, or an electronic copy can be provided.

CSO Public Engagement Group Contacts

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5.0 Glossary of Terms

The following glossary has been prepared to help you become familiar with the most common terms used in research studies/trials.

Active Treatment: Treatment known to be capable of specific effects.

Adverse Event (AE): An AE is any untoward medical occurrence in a patient or clinical investigation where a subject is administered a pharmaceutical product and that does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) product.

Adverse Reaction: An unwanted effect caused by the administration of drugs. Onset may be sudden or develop over time (see Side Effects).

Advocacy & Support Groups: Organisations and groups that actively support participants and their families with valuable resources, including self-empowerment and survival tools.

ARM: Any of the treatment groups in a randomized trial. Most randomized trials have two "arms," but some have three "arms," or even more (see Randomised Trial).

Baseline: 1. Information gathered at the beginning of a study from which variations found in the study are measured. 2. A known value or quantity with which an unknown is compared when measured or assessed. 3. The initial time point in a clinical trial, just before a participant starts to receive the experimental treatment which is being tested. At this reference point, measurable values such as CD4 (glycoprotein) count are recorded. Safety and efficacy of a drug are often determined by monitoring changes from the baseline values.

Bias: When a point of view prevents impartial judgment on issues relating to the subject of that point of view. In clinical studies, bias is controlled by blinding and randomisation (see Blind and Randomisation).

Biorepository: A biorepository is a biological materials repository that collects, processes, stores, and distributes biospecimens to support future scientific investigation.

Blind: A randomized trial is "Blind" if the participant is not told which arm of the trial he is on. A clinical trial is "Blind" if participants are unaware on whether they are in the experimental or control arm of the study; also called masked (see Single Blind Study and Double Blind Study).

Caldicott Guardian: Caldicott Guardians are responsible for agreeing and reviewing internal protocols governing the protection and use of patient-identifiable information by the staff of their organisations.

Care Organisation: The organisation(s) responsible for providing care to patients and/or clients participating in a study.

Chief Investigator: The person designated as taking primary responsibility (in the UK) within the team of researchers for the conduct of a study.

Clinical: Pertaining to or founded on observation and treatment of participants, as distinguished from theoretical or basic science.

Clinical Endpoint: (see endpoint).

Clinical Investigator: A medical researcher in charge of carrying out a clinical trial's protocol.

Clinical Trial: A clinical trial is a research study to answer specific questions about vaccines or new therapies or new ways of using known treatments. Clinical trials (also called medical research and research studies) are used to determine whether new drugs or treatments are both safe and effective. Carefully conducted clinical trials are the fastest and safest way to find treatments that work in people. Trials are in four phases: Phase I tests a new drug or treatment in a small group; Phase II expands the study to a larger group of people; Phase III expands the study to an even larger group of people; and Phase IV takes place after the drug or treatment has been licensed and marketed (see Phase I, II, III and IV Trials).

Cochrane Review: Cochrane Reviews investigate the effects of interventions for prevention, treatment and rehabilitation in a healthcare setting. They are designed to facilitate the choices that doctors, patients, policy makers and others face in healthcare. Most Cochrane Reviews are based on randomised controlled trials, but other types of evidence may also be taken into account, if appropriate.

Cohort: In epidemiology, a group of individuals with some characteristics in common.

Community-Based Clinical Trial (CBCT): A clinical trial conducted primarily through primary-care physicians rather than academic research facilities.

Complementary and Alternative Therapy: Broad range of healing philosophies, approaches, and therapies that Western (conventional) medicine does not commonly use to promote well-being or treat health conditions. Examples include acupuncture, herbs, etc.

Confidentiality Regarding Trial Participants: Refers to maintaining the confidentiality of trial participants including their personal identity and all personal medical information. The trial participants' consent to the use of records for data verification purposes should be obtained prior to the trial and assurance must be given that confidentiality will be maintained.

Contraindication: A specific circumstance when the use of certain treatments could be harmful.

Control: A control is the nature of the intervention control.

Control Group: The standard by which experimental observations are evaluated. In many clinical trials, one group of patients will be given an experimental drug or treatment, while the control group is given either a standard treatment for the illness or a placebo (see Placebo and Standard Treatment).

Controlled Trails: Control is a standard against which experimental observations may be evaluated. In clinical trials, one group of participants is given an experimental drug, while another group (i.e., the control group) is given either a standard treatment for the disease or a placebo.

Crossover: A type of comparative trial in which the different treatments being given to (typically) two groups of subjects/patients are switched halfway through the trial. Each subject/patient therefore receives one treatment for one half of the trial and the other treatment for the other half of the trial. Whilst, ideally, this design should be combined with double blinding, it is a useful supplementary means of controlling trials which cannot be blinded (e.g. where drugs are being compared with other kinds of treatment).

Diagnostic Trials: Refers to trials that are conducted to find better tests or procedures for diagnosing a particular disease or condition. Diagnostic trials usually include people who have signs or symptoms of the disease or condition being studied.

Double-Blind Study: A clinical trial design in which neither the participating individuals nor the study staff knows which participants are receiving the experimental drug and which are receiving a placebo (or another therapy). Double-blind trials are thought to produce objective results, since the expectations of the doctor and the participant about the experimental drug do not affect the outcome; also called double-masked study (see Blinded Study, Single Blinded Study, and Placebo).

Double-Masked Study: (see double-blinded study).

Drug-Drug Interaction: A modification of the effect of a drug when administered with another drug. The effect may be an increase or a decrease in the action of either substance, or it may be an adverse effect that is not normally associated with either drug.

Effect: The impact of a particular medical intervention in altering the natural history of a disease for the better.

Efficacy: (Of a drug or treatment) the maximum ability of a drug or treatment to produce a result regardless of dosage. A drug passes efficacy trials if it is effective at the dose tested and against the illness for which it is prescribed. In the procedure mandated by the FDA, Phase II clinical trials gauge efficacy and Phase III trials confirm it.

Eligibility Criteria: Summary criteria for participant selection; includes Inclusion and Exclusion criteria (see Inclusion/Exclusion Criteria).

Empirical: Based on experimental data, not on a theory.

Endpoint: Overall outcome that the protocol is designed to evaluate. Common endpoints are severe toxicity, disease progression, or death.

Epidemiology: The branch of medical science that deals with the study of incidence and distribution and control of a disease in a population.

Epidemiological Study: Study of disease and patterns of health within a population.

Equipoise: Equipoise is a situation in which one does not know whether a new treatment is better than the standard treatment. They may be roughly equal as far as earlier research has shown, or earlier research may show hopeful results for the new treatment or the researcher believe that the new treatment is better.

EU Directive for Clinical Trials: The final version of this was published in the Official Journal of the European Communities on 1 May 2001. The UK Regulations were implemented on 1 May 2004. In the UK the requirements of this Directive are implemented with the UK Medicines for Human Use Regulations 2004. The Directive covers the conduct of all clinical trials in the EU on human subjects involving medicinal products (as defined in Article 1 of Directive 65/65/EEC).

Exclusion/Inclusion Criteria: (see inclusion/exclusion criteria).

Experimental Drug: A drug that is not licensed for use in humans, or as a treatment for a particular condition (see off-label use).

Funder: Organisation(s) providing funding for the study through contracts with the researchers and/or their employers and/or the care organisation.

HRA: Health Research authority was established in December 2011 to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research. It oversees arrangements for Research Ethics Committees and the Ethical Approval Process.

Hypothesis: A supposition or assumption advanced as a basis for reasoning or argument, or as a guide to experimental investigation.

Inclusion/Exclusion Criteria: The medical or social standards determining whether a person may or may not be allowed to enter a clinical trial. These criteria are based on such factors as age, gender, the type and stage of a disease, previous treatment history, and other medical conditions. It is important to note that inclusion and exclusion criteria are not used to reject people personally, but rather to identify appropriate participants and keep them safe.

IND: (see investigational new drug).

Informed Consent: The process of learning the key facts about a clinical trial before deciding whether or not to participate. It is also a continuing process throughout the study to provide information for participants. To help someone decide whether or not to participate, the doctors and nurses involved in the trial explain the details of the study.

Informed Consent Document: A document that describes the rights of the study participants, and includes details about the study, such as its purpose, duration, required procedures, and key contacts. Risks and potential benefits are explained in the informed consent document. The participant then decides whether or not to sign the document. Informed consent is not a contract, and the participant may withdraw from the trial at any time.

Intent to Treat: Analysis of clinical trial results that includes all data from participants in the groups to which they were randomized (see Randomisation) even if they never received the treatment.

Intervention Name: The generic name of the precise intervention being studied.

Interventions: Primary interventions being studied: types of interventions are Drug, Gene Transfer, Vaccine, Behaviour, Device, or Procedure.

Investigational New Drug: A new drug, antibiotic drug, or biological drug that is used in a clinical investigation. It also includes a biological product used in vitro for diagnostic purposes.

In Vitro: Experiments conducted outside of living organisms, such as in cell culture. (literally “in glass”).

In Vivo: When experiments are performed on living organisms.

Masked: The knowledge of intervention assignment (see blind).

Matched Controls: Patients are healthy volunteers whose characteristics of age, sex, weight, clinical condition, etc. closely resemble those of the patients or healthy volunteers receiving the treatment being studied, but who do not themselves receive that treatment (they receive instead either an alternative existing treatment, or an inactive treatment).

MHRA: Medicines and Healthcare products Regulatory Agency.

Natural History Study: Study of the natural development of something (such as an organism or a disease) over a period of time.

Non-Therapeutic Research: Clinical or other research involving human subjects from which there is no prospect, and/or no intention, that the subject could directly obtain clinical benefit. For instance, research on healthy subjects is by definition non-therapeutic, as is exploratory research into the understanding of untreatable conditions for the patients on whom it is conducted. Research into diagnostic procedures may carry no benefit in terms of the clinical management of the subjects, etc. Subject information sheets and consent forms should make it clear to prospective subjects that the research does not offer them the prospect of clinical benefit.

NRS: NHS Research Scotland.

Open Label: A comparative study of two (or more) treatments in which it is either unnecessary or impossible to conceal from the patient which treatment he/she is receiving.

Open-Label Trial: A clinical trial in which doctors and participants know which drug or vaccine is being administered.

Peer Review: The process of obtaining the views of independent experts on the quality of a research proposal or journal article.

Pharmacokinetics: The processes (in a living organism) of absorption, distribution, metabolism, and excretion of a drug or vaccine.

Phase I Trials: Initial studies to determine the metabolism and pharmacologic actions of drugs in humans, the side effects associated with increasing doses, and to gain early evidence of effectiveness; may include healthy participants and/or patients.

Phase II Trials: Controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common shortterm side effects and risks.

Phase III Trials: Expanded controlled and uncontrolled trials after preliminary evidence suggesting effectiveness of the drug has been obtained, and are intended to gather additional information to evaluate the overall benefit-risk relationship of the drug and provide an adequate basis for physician labelling.

Phase IV Trials: Post-marketing studies to delineate additional information including the drug's risks, benefits, and optimal use.

PIL/PIS: Patient information leaflet / Patient information sheet.

Placebo: A placebo is an inactive pill, liquid, or powder that has no treatment value. In clinical trials, experimental treatments are often compared with placebos to assess the treatment's effectiveness (see Placebo Controlled Study).

Placebo Controlled Study: A method of investigation of drugs in which an inactive substance (the placebo) is given to one group of participants, while the drug being tested is given to another group. The results obtained in the two groups are then compared to see if the investigational treatment is more effective in treating the condition.

Placebo Effect: A physical or emotional change, occurring after a substance is taken or administered, that is not the result of any special property of the substance. The change may be beneficial, reflecting the expectations of the participant and, often, the expectations of the person giving the substance.

Preclinical: Refers to the testing of experimental drugs in the test tube or in animals - the testing that occurs before trials in humans may be carried out.

Prevention Trials: Refers to trials to find better ways to prevent disease in people who have never had the disease or to prevent a disease from returning. These approaches may include medicines, vitamins, vaccines, minerals, or lifestyle changes.

Protocol: A study plan on which all clinical trials are based. The plan is carefully designed to safeguard the health of the participants as well as answer specific research questions. A protocol describes what types of people may participate in the trial; the schedule of tests, procedures, medications, and dosages; and the length of the study. While in a clinical trial, participants following a protocol are seen regularly by the research staff to monitor their health and to determine the safety and effectiveness of their treatment (see Inclusion/Exclusion Criteria).

Qualitative Research: Involves non-numerical data collection usually through, interviews or questionnaires, in order to understand experience and meanings.

Quality Of Life/Supportive Care Trials: Refers to trials that explore ways to improve comfort and quality of life for individuals with a chronic illness.

Quantitative Research: Research using numerical methods with a focus on measurement.

Randomisation: A method based on chance by which study participants are assigned to a treatment group. Randomisation minimizes the differences among groups by equally distributing people with particular characteristics among all the trial arms. The researchers do not know which treatment is better. From what is known at the time, any one of the treatments chosen could be of benefit to the participant (see ARM).

Randomised Trial: A study in which participants are randomly (i.e., by chance) assigned to one of two or more treatment arms of a clinical trial. Occasionally placebos are utilized (see Arm and Placebo).

Research Governance Framework: The Research Governance Framework sets out standards for good practice for research quality and patient care.

Risk-Benefit Ratio: The risk to individual participants versus the potential benefits. The risk/benefit ratio may differ depending on the condition being treated.

Safe Havens: Safe havens provide a platform for the use of NHS electronic data in research feasibility, delivery and pharmacovigilance. They provide a safe facility for health and social science researchers to conduct research that involves the linkage of data from various sources. It enables researchers to create better opportunities to link data and influence policy and practice to improve healthcare and public health, nationally and internationally.

Screening Trials: Refers to trials which test the best way to detect certain diseases or health conditions.

Side Effects: Any undesired actions or effects of a drug or treatment. Negative or adverse effects may include headache, nausea, hair loss, skin irritation, or other physical problems. Experimental drugs must be evaluated for both immediate and long-term side effects (see Adverse Reaction).

Single-Blind Study: A study in which one party, either the investigator or participant, is unaware of what medication the participant is taking; also called single-masked study (see Blind and Double-Blind Study).

Single-Masked Study: (see single-blind study).

Sponsor: Individual, organisation or group taking on responsibility for securing the arrangements to initiate, manage and finance a study. (A group of individuals and/or organisations may take on sponsorship responsibilities and distribute them by agreement among the members of the group, provided that, collectively, they make arrangements to allocate all the responsibilities in this Research Governance Framework that are relevant to the study).

Standard Treatment: A treatment currently in wide use and approved by the FDA, considered to be effective in the treatment of a specific disease or condition.

Standards Of Care: Treatment regimen or medical management based on state of the art participant care.

Statistical Significance: The probability that an event or difference occurred by chance alone. In clinical trials, the level of statistical significance depends on the number of participants studied and the observations made, as well as the magnitude of differences observed.

Study Endpoint: A primary or secondary outcome used to judge the effectiveness of a treatment.

Study Type: The primary investigative techniques used in an observational protocol; types are Purpose, Duration, Selection, and Timing.

Toxicity: An adverse effect produced by a drug that is detrimental to the participant's health. The level of toxicity associated with a drug will vary depending on the condition which the drug is used to treat.

Treatment Trials: Refers to trials which test new treatments, new combinations of drugs, or new approaches to surgery or radiation therapy.

6.0 Appendices

6.1 Appendix 1 – Travel and Subsistence Claim Form

Account of travelling, costs incurred of unpaid members or witnesses of commissions, committees etc.

Rules for claims for costs incurred on public service

1. Please submit your claim promptly, preferably as soon as you return but if you are making repeated journeys at intervals not in excess of one week, you may submit monthly claims. Delays in submitting claims cause processing difficulties and can delay payment.
2. Please complete the form in block capitals. If we can't read your writing it will delay your payment.
3. If there is not enough space for details of all your travel details please complete another form.
4. Claimants are requested to see that rules below are strictly observed. Any failure in this respect is liable to cause correspondence and inconvenience, and may delay the allowance of the claim. The Secretary can provide further details of the allowances if required.
5. Every claim should show in Columns 2 and 3 the times at which the claimant left home, and at which he returned.
6. Please complete all the requested details as any omissions will delay the payment. Bank details have been requested so that we can pay your claim directly into your bank account.
7. The completed form should be sent to the Secretary of the Committee who will arrange for payment to be made.

Travel and Subsistence Allowances

Night Allowances

Accommodation costs and a night allowance may be claimed for necessary overnight absence from home. This allowance covers a period of 24 hours plus any additional period not long enough to count for day allowance (see below).

Day allowances

A day subsistence allowance may be claimed for an absence from home of more than 5 hours or a balance of time, of more than 5 hours beyond a complete period of 24 hours during which night subsistence is paid. Any claim for day subsistence should be supported by the inclusion of receipts showing expenditure has been incurred.

Travel

Claims should be limited to the actual fare for all necessary travel on public business. Unless there are exceptional circumstances, the presumption should be that any rail travel within Scotland should be standard class. Taxi fares are not admissible except where heavy luggage has to be transported to or from terminal stations, where there is no other suitable method of public transport, or where the saving of official time is of paramount importance. Gratuities to porters, stewards, etc cannot be reimbursed from public funds.

Receipts must be produced to back up any claim for travel costs incurred.

If you use a private motor vehicle on public business you may claim a mileage allowance. The rate that can be claimed is detailed on the next page.

The type of conveyance ('R' – Railway; 'C' - Cab; 'O' – Omnibus; 'M' – Motor car; 'B' - Bicycle; 'S' – Ship; 'A' – Aircraft) and the class of railway travel used should be shown in column 5, and the places from and to which the journey is made shown in column 4 in each case.

Other Expenditure

Claims for postage and other incidental expenditure should be limited to costs incurred necessarily incurred. The separate items should be detailed in the claim and supported by receipts

Travel and Subsistence Expense Types/Limits/Rates effective from 01 March 2012

Expense Type	Expense Code	Rate	Unit
Bed and Breakfast Elsewhere (receipted up to £75.00)	BBER	None	Per Night
Car Hire (including related fuel)	TRCH	None	None
Car Parking	TRCP	None	None
Day Subsistence -> 5hrs (receipted up to £4.90)	DSFH	None	Per Day
Day Subsistence -> 10hrs (receipted up to £10.70)	DSTH	None	Per Day
Leased Car	MMLC	£0.08	Per Mile
Lodging Allowance - Elsewhere (receipted up to £37.40)	LAER	None	Per Night
Meals Allowance Elsewhere (receipted up to £23.50)	MAER	None	Per Day
Motor Cycle Allowance	MCMR	£0.24	Per Mile
Motor Mileage Rate	MMRT	£0.45	Per Mile
Overnight by Train or Boat (receipted up to £24.10)	NSTB	None	Per Night
Pedal Cycle Allowance	PCMR	£0.20	Per Mile
Personal Incidental Expenses (receipted up to £5.00)	PIEA	None	Per Night
Public Transport Air Travel	TRAT	None	None
Public Transport Bus	TRBU	None	None
Public Transport Ferry	TRFE	None	None
Public Transport Rail (Standard)	TRRS	None	None
Public Transport Taxi	TRTX	None	None
Public Transport Tube	TRTU	None	None
Telephone Calls On Official Business	TELE	None	None
Toll Charges	TRTC	None	None

Please note that the above rate are subject to change and any claims will be limited to the rate in effect when claims for travel and subsistence.