

**TITLE: Human Research and Ethics Committee (HREC)**

Document Type:	Terms of Reference	Approved by:	Chief Executive/ Chair ECSQP
Committee:	Executive	Section:	Human Research + Ethics
Author/Prepared by:	Dr Md Rafiqul Islam	Position:	Director of Research

1. PURPOSE:

To receive, consider and assess research proposals involving human participants and provide ethical approval in accordance with the National Health and Medical Research Council (NH&MRC) guidelines for those research proposals.

Research proposals that have gained multi-site ethics approval including approval for research at Goulburn Valley Health (GV Health) from a NH&MRC certified Ethics Committee under National Mutual Acceptance will not require ethical approval from the GV Health Human Research and Ethics Committee ("the HREC") but shall require governance approval (site specific assessment) for the conduct of the Research from the Research Governance Officer (RGO) of GV Health.

To comment on and make decisions on any ethical issue where requested by GV Health.

2. OBJECTIVES:

To protect the welfare and the rights of participants in research. To independently decide, whether the conduct of each research proposal submitted to the Human Research and Ethics Committee will appropriately protect participants and is otherwise ethically acceptable.

3. ORGANISATIONAL RELATIONSHIPS:

The GV Health Human Ethics and Research Committee is a formally constituted committee of GV Health. It has external, community representatives providing pro bono membership commitments. GV Health has legal responsibility and liability for anything done or omitted to be done by the HREC and its members including but not limited to for decisions, approvals and advice given by or made by the Committee and indemnifies its members.

4. REPORTING:

The Committee will provide a copy of all minutes to the Strategy People and Planning Executive through the Chairperson or the EDMS/CMO bi-monthly and an annual report to the Board in November.

Reporting downwards:

An executive summary will be provided to the Primary Care and Population Health Committee of the Board and the Clinical Directors (CDs) and Divisional Clinical Directors (DCDs) Committee through the Chief Medical Officer (CMO), if required.

5. MEMBERSHIP:

Save as otherwise provided in this clause 5, the members of the Committee including the Chairperson shall be appointed by the Chief Executive (CE). During any period that there would otherwise be no Chairperson, the Chief Medical Officer (and where there is no Chief Medical Officer, the Acting Chief Medical Officer) shall be the Chairperson of the Committee until a Chairperson of the Committee is appointed by the Chief Executive. No member shall be appointed to fill more than one of the categories as per the National Statement paragraph 5.1.30. As far as possible, there should be equal numbers of men and women on the HREC and at least one third of the members should be from outside the institution for which the HREC is reviewing research. Wherever possible, one or more of the members who form the minimum membership of the HREC by virtue of clause 5.1.30 of the National Statement should



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be experienced in reflecting on and analysing ethical decision making. The membership shall include:

- Chairperson: With suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under the National Statement;
- At least one (1) member with knowledge of, and current experience in, the professional care, counselling or treatment of people, (e.g. medical practitioner, clinical psychologist, social worker, nurse, as appropriate);
- At least one (1) member who is a minister of religion, or a person who performs a similar role in a community such as an Aboriginal elder;
- At least one (1) member who is a lawyer;
- At least two (2) members who are lay people, one male and one female, who have no affiliation with the institution or organisation, who are not involved in medical, scientific, or legal work, and who are from the local community;
- At least two (2) members, preferably from the Divisional Clinical Directors (delegated by CMO) with research knowledge and/or current research experience;
- Chief Nursing & Midwifery Officer or representative;
- Chief Allied Health Officer or representative;
- One (1) Senior Medical Staff Employee Representative at Senior Consultant level (delegated by CMO);
- One each of (1) Senior Nursing and (1) Allied Health Staff Employee Representatives;
- One (1) member, preferably from a University that has a Shepparton campus at which the member works and which University has an Association with GV Health;
- The Director of Research at GV Health;
- Director of Nursing & Midwifery Practice, Education and Research.
- Allied Health Education & Research Manager
- Executive Director of Medical Services (EDMS) & Chief Medical Officer (CMO)/Acting EDMS & CMO.

The Director of Research at GV Health, the Director of Nursing & Midwifery Practice, Education and Research, the Allied Health Education & Research Manager and the Chief Medical Officer/ Acting Chief Medical Officer shall each automatically become a member of the Committee upon appointment to their respective positions and shall continue as a member until their position terminates at which time their membership of the HREC automatically terminates.

The HREC may continue to carry out all its functions where any membership position referred to in this clause 5 is vacant but shall cease to carry out its functions during any period that the membership of the HREC falls below 8 members or any category of the minimum membership of the HREC as specified in paragraph 5.1.30 of the National Statement is vacant.

All appointments including filling of casual vacancies to the HREC shall be by the CE following consultation with the CMO. The CE and CMO may consider recommendations made by the HREC in the process of appointment.

A pool of members may be appointed to fill the minimum membership of categories of the HREC as per the National Statement Paragraph 5.1.31. Preference shall generally be given to the appointment of members who live or work within 60 kilometres of a facility operated by GV Health provided that there shall be a broad discretion to appoint a person who both lives



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and works outside a radius of 60 kilometres of any facility operated by GV Health including by reason of the knowledge, skills, expertise, reputation, public profile or other attribute of a person under consideration for appointment to the Committee.

All appointments to the HREC shall be made for a term of three years save that the term of a person filling a casual vacancy shall be the balance of the term of the member he/she is replacing. Members may be appointed for additional terms each of three years.


The Chairperson of the HREC may terminate the membership of a member of the HREC:

- (i) where a member has failed to attend four or more meetings of the HREC in any period of twelve months;
- (ii) based on misconduct by a member;
- (iii) based on the doing of anything or the failure to do something by a member (whether or not in connection with that members membership of the HREC) which in the opinion of the Chairperson reasonably held makes it inappropriate for that member to continue as a member;
- (iv) where a member ceases to live or reside within 60 kilometres of a facility operated by GV Health provided that the Chairperson in making a decision under this sub-clause (iv) shall have a broad discretion to take account of a person’s contribution to the Committee and their knowledge, skills, expertise, reputation, public profile or other attribute or matter which the Chairperson considers of relevance to the Chairperson’s decision.

Notwithstanding anything to the contrary in this paragraph contained, the Chairperson may excuse a non-attendance at a meeting where a member had a reasonable excuse for the non-attendance at that meeting, reviewed the applications and documents forwarded with the Agenda for that meeting and sent comments for the consideration of the Committee concerning the applications and documents to be considered at the meeting.

Members are to be given formal notification of appointment and are to be indemnified by GV Health to the maximum extent permitted by law against legal liability for anything done or omitted to be done by a member in the course of or in connection with a members membership of the HREC save only to the extent that a member has failed to act in good faith. Where GV Health is obliged by this paragraph to indemnify a member, GV Health shall pay all costs and expenses incurred by a member in defending any claim made against a member and shall maintain insurance which covers all members of the HREC (including but not limited to members of the HREC who are not employed by GV Health) against the legal liability of members for which GV Health is obliged to indemnify members pursuant to this paragraph at least to the extent of the indemnity to members provided for in this Clause 5 with an extension to cover the costs and expenses incurred by a member which by this paragraph are to be paid by GV Health.

A member shall not vote on any decision of the HREC where that member has a material conflict of interest with respect to the subject matter of the vote whether or not that member is a part of the minimum membership of the HREC, shall declare any conflict at the first available opportunity and shall leave the room when any application regarding a matter for which a member has a conflict of interest is being discussed if requested to do so by any member of the HREC.

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6. COMMITTEE PROTOCOLS:

6.1. Procedures

The agenda, including copies of research proposals, shall be distributed to all members so far as is reasonably practical two weeks prior to the meeting provided that the failure to distribute the Agenda and/or the whole or some of the applications and documents to be considered at the meeting so far as is reasonably practical two weeks prior to the meeting shall not prevent the holding of that meeting or invalidate any decision made at that meeting where it is resolved that the meeting is to proceed.

Applications lodged less than three weeks before the date of a meeting will generally not be considered until the following meeting provided that in an appropriate case the Committee may agree to expedite the consideration of an application.

The Committee shall inform researchers in writing of decisions and, in the event of rejections or recommended amendments, the reasons for those decisions. The Committee should endeavour to reach decisions by general agreement which need not involve unanimity.

An applicant may in writing seek reconsideration by the HREC of a decision to reject or impose a condition or conditions on a research project as per GV Health's 'appeal against the HREC's decision' procedure. Where necessary, the Committee may seek advice and assistance from experts to assist with consideration of research proposals or an appeal against a HREC's decision.

The Committee shall/may have MOU's with subregional centres and University rural academic Networks and centres that require GV Health's assistance and collaboration with research subjects and projects.

6.2. Recording of Decisions

The Committee shall maintain a record of all research protocols received and reviewed, including:

- Name of responsible institution or organisation;
- Project identification number(s);
- Principal researcher(s);
- Title of the project;
- Ethical approval or non-approval with date;
- Approval or non-approval of any changes of the protocol;
- The terms and conditions, if any, of approval of any protocol;
- Whether approval was by expedited review;
- Whether the opinion of another HREC was considered;
- Action taken by the HREC to monitor the conduct of the research;
- The relevance, if any, of the Guidelines for the Protection of Privacy in the Conduct of Medical Research.

For multi-centre research proposals, the Committee shall also record, from information provided from the researcher:



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- Details of other centres involved;
- The approval status of the Study at each centre;
- Details of any amendments required at other centres;
- Whether the conditions of any approval were changed or an approval revoked.

The Committee shall retain on file a copy of each research protocol and application for HREC approval, including any information sheets, consent forms or relevant correspondence, in the form in which they are approved.

6.3. Monitoring

The Committee shall ensure that there is appropriate monitoring of research projects until their completion. To achieve this, the Committee must require at regular periods, at least annually, reports from principal researchers on matters including the progress to date or outcome in the case of completed research.

The Committee shall, as a condition of approval of each protocol, require that researchers report anything which might warrant review of ethical approval including:

- Serious or unexpected adverse effects on participants;
- Proposed changes in the protocol;
- Unforeseen events that might affect continued ethical acceptability of the project.

The Committee shall, as a condition of approval of the research proposal, require researchers to inform the HREC if the research project is discontinued before the expected date of completion.

The HREC may terminate or suspend a research approval for any valid reason including but not limited to where it is established or suspected on reasonable grounds that a researcher is not a fit and proper person to conduct the research or there has been:

- a) misconduct or serious negligence in the conduct of the research;
- b) a failure to provide required progress reports;
- c) serious adverse effects or suspected serious adverse effects on subjects of the research or other people impacted by the research.

The HREC shall advise of the above powers to terminate or suspend the research approval in the written approval given to the Researcher."

6.4. Complaints

The Committee has established the following procedures for receiving and handling complaints about the conduct of an approved research project:

- Any complaint from research participants, researchers, or other interested persons should be directed to the Director of Research. However the Chairperson may direct that any complaint is to be made to another person where the Director of Research has a conflict of interest. The complaint may need to be referred to the chairperson and or the Committee for resolution.



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6.5. Compliance Reports to the NHMRC

The Committee shall provide information from its records to the NHMRC on request.

The Committee shall report annually to the NHRMC as per the NHMRC requirements.

6.6. Chairperson and Secretary

The Chairperson shall generally be sourced from the existing membership of the Committee and, in appointing the Chairperson, the Chief Executive may consider any recommendation made by the Committee.

The Chairperson shall chair meetings of the HREC with meetings of the HREC to be chaired by the Deputy Chairperson in the Chairpersons absence provided that in the absence of both the Chairperson and the Deputy Chairperson or where otherwise appropriate the Chairperson may delegate another member of the HREC to chair the whole or any part of a meeting of the HREC.

The chair of the whole or any part of any meeting of the HREC shall have a deliberative vote and in the event of equality on any question may in the chairs discretion exercise a casting vote.

The CMO (or where there is no CMO, the acting CMO) shall be the Deputy Chairperson of the HREC provided that during any period that the CMO or the Acting CMO is the Chairperson of the Committee, the Director of Research shall be the Deputy Chairperson of the Committee. The Deputy Chairperson shall assume all functions and have all powers of the Chairperson in the Chairperson’s absence.

The Chairperson may appoint another member of the HREC to act as Chairperson of the HREC during any period that both the Chairperson and the Deputy Chairperson are absent and during any period that the person so appointed is acting as Chairperson that person shall assume all functions and have all powers of the Chairperson.

The Chairperson has the responsibility for managing the agenda and making sure that all relevant items are covered and adequately recorded. The Chairperson may delegate functions including the preparation of the Minutes and Agenda to the Secretary.

The Chairperson shall:

- Consider whether the Committee is sufficiently informed on all aspects of research protocols;
- Oversee arrangements for meetings;
- Ensure that all views of absent minimum members have been received and considered;
- Preside over decision making;
- Invite researchers to attend meetings;
- Seek advice from experts;
- Monitor conflicts of interest;
- Oversee recording of decisions;
- Establish a complaints process;



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- Invite researchers to attend meetings if their project demonstration is advised by the Committee.

6.7. Quorum

A quorum for meetings of the HREC shall be 8 (eight) **members present**.

6.7.1 Ideally the following categories of membership shall be present in each meeting (the minimum membership as provided for in National Statement paragraph 5.1.30) which are:

- A Chairperson, with suitable experience, whose other responsibilities will not impair the HREC’s capacity to carry out its obligations under the National Statement.
- At least two lay people, one man and one woman, who have no affiliation with the institution and do not currently engage in medical, scientific, legal or academic work.
- At least one person with knowledge of, and current experience in, the professional care, counselling or treatment of people; for example, a nurse or allied health professional.
- At least one person who performs a pastoral care role in a community, for example, an Aboriginal elder, a minister of religion.
- At least one lawyer, where possible one who is not engaged to advise the institution.
- At least two people with current research experience that is relevant to research proposals to be considered at the meetings they attend. These two members may be selected, according to need, from an established pool of inducted members with relevant expertise.

In the event that the whole of the minimum membership of the HREC is not present at a meeting, no item of business shall be conducted unless the Chairperson is satisfied that all of the minimum membership not present at the meeting have received all of the papers before the meeting for that item of business, those of the minimum membership not present have had an opportunity to contribute their views and their views are considered at the meeting.

6.8. Frequency and Mode of Meetings

- The HREC shall meet on the dates from time to time approved by the Committee and generally shall meet either bi-monthly or monthly as may be determined from time to time by the Committee. The Committee may further resolve that there is to be no meeting in a particular month and the Chairperson may for valid reason decide that a scheduled meeting is not to proceed or is to be postponed or brought forward and may schedule additional meetings.
- All attendances at any meeting of the HREC shall be in person save only that the Chairperson and in his absence the Deputy Chairperson (and in the absence of both the Chairperson and the Deputy Chairperson the member delegated by the Chairperson to chair the whole or any part of a meeting of the HREC) may in their absolute discretion decide to hold a meeting, or permit members to take part in a meeting, by using any technology that allows members to clearly and



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simultaneously communicate with the other participating members. In the case where a meeting takes place by technology or members are permitted to take part by technology, a member who participates in a meeting by technology is deemed to be present in person at the meeting, and, if the member votes at the meeting, is taken to have voted in person.

6.9. Low or Negligible Risk Sub-Committee

6.9.1 There shall be a Sub-Committee of the HREC known as “The Low or Negligible Risk Sub-Committee” (“the Sub-Committee”) which shall have all the powers of the HREC but only with respect to applications which are agreed by both the Sub-Committee and the applicant to be low or negligible risk research applications or low or negligible risk audit applications and which in the case of research the National Statement in the form current when an application is lodged and considered permits that application to be dealt with by the Sub-Committee. The Sub-Committee shall consider the variation of approved research applications/amendments, noting of final or progress reports except the research governance reporting which shall be noted by the RGO.

6.9.2 “Low risk research” means research in which the only foreseeable risk for participants is discomfort and the expression “negligible risk research” means research in which there is no foreseeable risk of harm or discomfort for participants and any foreseeable risk is no more than inconvenience. Low risk audits and negligible risk audits are to have similar meanings to low risk research and negligible risk research. The following areas of research and audit are not to be considered to be low risk unless those areas of research or audit relate solely to collections of non-identifiable data and their use satisfies the requirements of relevant paragraphs of the National Statement:

- (i) Women who are pregnant and the human foetus (Chapter 4.1 of the National Statement);
- (ii) People highly dependent on medical care who may be unable to give consent (Chapter 4.4 of the National Statement);
- (iii) People with a cognitive impairment, an intellectual disability, or a mental illness (Chapter 4.5 of the National Statement);
- (iv) Aboriginal and Torres Strait Islander Peoples (Chapter 4.7 of the National Statement).

Some categories of research and audit the subject of which is people who may be involved in illegal activities are not to be considered low risk research, negligible risk research, low risk audits or negligible risk audits (Chapter 4.6 of the National Statement for details).

6.9.3 The membership of the Sub- Committee shall comprise of the following:

- (i) The CMO/Acting CMO (as may be applicable) who shall act as the Chairperson of the Sub-Committee at all meetings at which he or she is present;
- (ii) The Director of Research who shall act as acting chairperson in the absence of the chairperson;



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- (iii) One person appointed by the HREC from the institutional (GV Health) HREC members;
- (iv) One additional member being a non-institutional member of the HREC appointed by the HREC;
- (v) The Chairperson of the HREC.

A member who becomes a member of the Sub-Committee by virtue of the position he/she holds with Goulburn Valley Health shall cease to be a member upon that member ceasing to hold that position. A member appointed to the Sub-Committee by the HREC shall cease to be a member of the Sub-Committee upon removal of that member by the HREC or upon resignation of the member.

6.9.4 The quorum of the Sub-Committee shall be at least two members present either in person or by being present by participating by one of the other methods permitted by Sub- Clause 6.9.4.4. One of the members present at a meeting of the Sub-Committee must be the chairperson or acting chairperson of the Sub-Committee.

6.9.4.1 The Sub-Committee may at any time transfer any application which comes before it to the HREC and must transfer any application to the HREC if it considers at any time that an application is beyond the powers of the Sub-Committee to deal with.

6.9.4.2 The HREC may of its own motion direct the Sub-Committee to transfer any application which is before the Sub-Committee to the HREC.

6.9.4.3 Subject always to clause 6.3, upon transfer of an application from the Sub-Committee to the HREC any approval given by the Sub-Committee prior to the transfer shall be binding on the HREC.

6.9.4.4 For the purposes of this Clause, a meeting of the Sub-Committee may be held by:

- i) all participating members being present in person;
- ii) one, some or all participating members participating being present in person or by one of the methods set out in sub-clauses iii) or iv) below;
- iii) one, some or all members participating by use of technology in the same manner as meetings and attendance at meetings of the full HREC may be permitted by use of technology as provided for in Clause 6.8 of these Terms of Reference with permission for the use of technology for a meeting of the Sub-Committee or permission for attendance at meeting of the Sub-Committee to be given by the person chairing that meeting of the Sub-Committee;
- iv) attendance by one, some or all participating members by way of a series of telephone calls or an exchange of emails so long as the Sub-Committee reaches a unanimous or majority decision as to the outcome of an application which is communicated to all participating members.

A member of the Sub-Committee who attends a meeting in person shall be considered to be present at that meeting as shall a person who



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participates in the meeting by one of the methods set out in Sub-Clauses iii) or iv) of this Clause.

- 6.9.5 The Sub-Committee shall provide to the HREC a copy of all its meeting outcomes as well as such verbal or written briefings, documentation and records which in any way relate to the work of the Sub-Committee and which are requested by the HREC.
- 6.9.6 The Sub-Committee shall call meetings (physical or online or in a form permitted by sub-clause 6.9.4.4 iv) of the Sub-Committee as and when required to enable the business of the Sub-Committee to be conducted in a reasonably timely manner.
- 6.9.7 The HREC may appoint additional Sub-Committees to advise , investigate or report to the HREC (but not to make any decision on behalf of the HREC) on any matter which falls within the purposes of the HREC and may determine the membership of those Sub-Committees and any other matter which in any way relates to the business of those Sub-Committees.
- 6.9.8 All members of Sub-Committees including but not limited to the Low or Negligible Risk Sub-Committee shall be indemnified by GV Health against legal liability for anything done or omitted to be done by a member in the course of or in connection with a members membership of a Sub-Committee (whether or not a member of a Sub-Committee is a member of the HREC) save only to the extent that a member has failed to act in good faith.

Where GV Health is obliged by this paragraph to indemnify a member of the Subcommittee, GV Health shall pay all costs and expenses incurred by a member in defending any claim made against a member and shall maintain insurance which covers all members of the HREC Subcommittee (including but not limited to members of the Subcommittee who are not employed by GV Health) against the legal liability of members for which GV Health is obliged to indemnify members pursuant to this paragraph at least to the extent of the indemnity to members provided for in this Clause 6.9.8 with an extension to cover the costs and expenses incurred by a member which by this paragraph are to be paid by GV Health.

7.0 Research Governance

The Research Governance will function in accordance with the Department of Health, Victoria’s Research Governance and Site Specific Assessment Process and Practice Handbook and all relevant National (including National Statements with all updates) and State guidelines and the NHMRC Research Governance Handbook. The GV Health Director of Research is the Research Governance Officer (RGO). The RGO or its office will review all research governance applications and authorize the applications and consult with the Chief Medical Officer. The RGO or its office will review all interim, progress and annual reports for multisite study projects including clinical trials. The RGO or its office will note all lead HREC approved amendments for all multisite and clinical trial studies and will provide site amendment approvals and

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inform/update the Chief Medical Officer in weekly meetings. The RGO or its office may conduct audits for all ongoing/previous multisite, single site research, clinical trials, clinical audits or any other types of research or evaluations at GV Health.

7.1 HREC and RGO Review Fee


The office of the Research and Ethics will invoice HREC and RGO review fees as per the most updated fee schedule. The Office of the Research and Ethics after consulting with the Chief Medical Officer, the Committee or the Chair, HREC may contact the investigators (site or lead) or sponsors for an amended review fee. The Office of the Research and Ethics may provide a waiver to the fee after consulting either with the Chief Medical Officer, the Committee or Chair of the HREC.

7.2 Scope of HREC and Governance Review for Internal and External Research

The GV Health HREC will provide ethical review to all applications that are submitted to the HREC irrespective of their organisational origin. Subject to any law or binding guideline to the contrary, the HREC shall provide ethical review and the RGO Governance review (as may be applicable) for all applications that are submitted to the HREC or the RGO (as may be applicable) for research to be conducted primarily on GV Health patients and/or staff and may provide ethical review at the discretion of the HREC or the RGO (as may be applicable) for research which is not to be carried out primarily on GV Health patients and/or staff.

The GV Health RGO may provide governance review on behalf of other health organisations when they seek such assistance. The GV Health RGO will advise the applicant to submit a request letter from their Chief Executive or delegate with the governance application and documentation. The GV Health RGO can advise the review outcome letter with the following sentence or similar that “the application met/did not meet the requirements to conduct the study at GV Health. It is the responsibility of the governing body of your organisation to determine the outcome of the application to your organisation”.

Where applicable and if required, a MoU (memorandum of understanding) can be developed between GV Health and the organization seeking HREC review and/or RGO governance review by the GV Health HREC and/or the RGO as may be applicable.

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REFERENCES:

NHMRC Human Research Ethics Handbook

NHMRC Research Governance Handbook

NHMRC National Statement on Ethical Conduct in Human Research 2007 (updated 2018)

Research Governance and Site Specific Assessment Process and Practice Handbook, Department of Health, Victoria

Contributors to the document

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Committees	Human Research & Ethics Committee		
	Safety, Quality & Performance Committee – December 2021		
	Approved by Dr John Elcock, Chief Medical Officer & ED Medical Services		
	Approved by Matt Sharp, Chair ECSQP & Chief Executive – 10 February 2022		