[redacted]

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

23 January 2017

Ms Emel Yorganci BSc MSc
Research Assistant, ImproveCare
King's College London
Cicely Saunders Institute
Department of Palliative Care
Policy and Rehabilitation
[redacted]

Dear Ms Yorganci

Study title:	**The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle.**
REC reference:	**16/LO/2010**
Amendment number:	**SA1**
Amendment date:	**10 January 2017**
IRAS project ID:	**212178**

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of amendment

This amendment was submitted to provide a copy of the consent for non-participatory observational work, as this was omitted from the original submission by accident. Additionally, following advice received the HRA, the Participant Information Sheet was amended to provide greater clarity was provided to individuals who did not want to have their views written down by the researcher during meetings.

Ethical opinion

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee did not raise any ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	SA1	10 January 2017
Participant consent form [Consent Form for Health Care Professionals Attending MDT/Clinical Handover Meeting]	1.0	03 January 2017
Participant information sheet (PIS) [Participant Information Sheet (Non-Participatory Observation of MDMs) - Highlighted Changes]	3.0	03 January 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/2010:	**Please quote this number on all correspondence**

Yours sincerely
pp

[redacted]

Ms Heidi Chandler
Vice Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *The R&D Office, King's College Hospital NHS Foundation Trust*

Dr Jonathan Koffman, King's College London

Mr Keith Brennan, King's College London

[redacted]

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

22 February 2017

Ms Emel Yorganci
Research Assistant
ImproveCare
King's College London
Cicely Saunders Institute
Department of Palliative Care, Policy and Rehabilitation
[redacted]

Dear Ms Yorganci

Study title:	**The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle.**
REC reference:	**16/LO/2010**
Amendment number:	**SA1**
Amendment date:	**27 January 2017**
IRAS project ID:	**212178**

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of amendment

This amendment was submitted following receipt of advice from the HRA Approval team informing the study team of the omission of two Participant Information Sheets for the focus groups with healthcare professionals that would take place on the intervention and control wards. These documents were submitted for review and subsequent approval from the Committee.

Ethical opinion

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Committee did not raise any ethical issues.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	SA1	27 January 2017
Participant information sheet (PIS) [Participant Information Sheet for focus Group Control Ward]	1.0	19 December 2016
Participant information sheet (PIS) [Participant Information Sheet for focus Group Intervention Ward]	1.0	19 December 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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16/LO/2010:	**Please quote this number on all correspondence**

Yours sincerely
pp

[redacted]

Mrs Rosie Glazebrook
Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: The R&D Office, King's College Hospital NHS Foundation Trust
Dr Jonathan Koffman, King's College London
Mr Keith Brennan, King's Collee London

London - Camden & Kings Cross Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held via correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Emily Cadman	Senior Registrar	Yes	
Mrs Rosie Glazebrook	Consumer Marketing	Yes	Chair of the Committee

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kirstie Penman	REC Assistant

[redacted]

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

21 April 2017

Emel Yorganci BSc MSc
Research Assistant
King's College London
Cicely Saunders Institute
Department of Palliative Care, Policy and Rehabilitation
[redacted]

Dear Emel

Study title:	**The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle.**
REC reference:	**16/LO/2010**
Amendment number:	**SA3**
Amendment date:	**30 March 2017**
IRAS project ID:	**212178**

The above amendment was reviewed by the Sub-Committee in correspondence.

Summary of amendment

This amendment sought approval regarding a new study measure referred to as the 'Standard' or 'Usual' Care Questionnaire', which aimed to obtain information from different healthcare professionals of how they understood what was meant by 'standard' or 'usual' care on the ward on which they worked.

In addition to the measure, an accompanying Participant Information Sheet has been developed to briefly describe the purpose of the measure in relation to the wider study. A

consent form had also been developed that would be signed prior to the completion of the measure at each time point.

Additionally, in order to obtain a more comprehensive and an objective measure of standard care in the control wards, and to be able to understand how well the AMBER care bundle wass being used and adapted on the intervention wards, the study team would be using the data collected via a case note review tool and 'heat maps'.

Furthermore additional questions had been included to the topic guides for the focus groups with staff located on the intervention and control wards.

Ethical opinion

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

The Sub-Committee wished to seek clarity regarding how confidentiality of data would be protected using the case note review and heat map.

Dr Jonathan Koffman, Chief Investigator, explained that the nurse facilitator will conduct the case note review on the two intervention and two control wards. The nurse facilitator would retrospectively examine the clinical notes for a one month period to identify at least of 20 patients (ten patients who would have died in the hospital and ten patients who would have been discharged and died within 100 days of discharge). Dr Koffman confirmed that the data collection tool developed for the review had been designed specifically to collect information that would minimise the possibility of identifying patients; the study team was sensitive about this issue and understood why the Sub-Committee had raised this concern. Dr Koffman stressed that the team did not collect any information that would record the patient's name, hospital number, date of birth, self-assigned ethnicity or postcode. The study team would collect the patient's date of death and their age at that point, their clinical diagnosis, and other information that examined whether they had an advance care plan, and whether this was documented. The study team also wished to find out whether the patient had had a preferred place of death. Each of the electronic forms and the spreadsheet would be saved using an encrypted password-format and would adhere to data protection legislation at all times. The data would only be emailed from and to an NHS email account, and only the nurse facilitator and the study team would have access to this anonymised data.

Dr Koffman went on to provide further clarification with regards to the heat map. Dr Koffman explained that closer examination of the data collection tool used for the 'heat map' would show that no individual and identifiable patient data was recorded. The data collection tool was designed to collect the name of ward and the specialty of the ward. The 'heat map' then quantified the number of patients who had died over a twelve month period, and specifically the number who died within three days of admission, and those within three days of discharge. Dr Koffman confirmed that this Excel spreadsheet would also be saved in an encrypted, password-protected format. The spreadsheet would only be emailed from and to an NHS email account, and only then a facilitator and the research team would have access to these files.

Within the Participant Information Sheet, the Sub-Committee believed that the sentence 'it is likely they will die' should be amended to read 'it is possible they might die' to avoid undue upset to participants.

Additionally, as a minor point with regards to the review of the study within the Participant Information Sheet, the Sub-Committee determined that it should be clarified that the study

had been reviewed by the Camden and Kings Cross Research Ethics Committee and received HRA Approval, as the Sub-Committee agreed that this clearly explained the review process for the study for participants' information.

Dr Koffman provided an amended Participant Information with the changes made and highlighted.

The Sub-Committee was satisfied with the responses and approved the amendment.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Interview schedules or topic guides for participants [Topic Guide For Qualitative Interview HCP AMBER Wards Only - Highlighted Changes]	3.0	20 March 2017
Interview schedules or topic guides for participants [Topic Guide for Qualitative Interview HCP Control Wards Only - Highlighted Changes]	3.0	20 March 2017
Non-validated questionnaire ['Standard' or 'Usual' Care Questionnaire Baseline]	1.0	03 March 2017
Non-validated questionnaire ['Standard' or 'Usual' Care Questionnaire Completion of Patient Recruitment]	1.0	03 March 2017
Non-validated questionnaire ['Standard' or 'Usual' Care Questionnaire Mid Patient Recruiment]	1.0	03 March 2017
Notice of Substantial Amendment (non-CTIMP)	SA3	30 March 2017
Other [Heat Map]	1.0	24 March 2017
Other [Summary of Changes]	Amendment 3	30 March 2017
Other [Case Note Review]	1.0	22 March 2017
Other [ImproveCare Schedule of Events]	2.0	20 March 2017
Participant consent form [HCP Care Questionnaire Consent Form]	1.0	28 February 2017
Participant information sheet (PIS) [HCP Participant Information Sheet (Standard of Usual Care Questionnaire)]	1.0	28 February 2017
Research protocol or project proposal [ImproveCare Study Protocol - Highlighted Changes]	3.0	24 March 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/LO/2010:	Please quote this number on all correspondence

Yours sincerely
pp

[redacted]

Mrs Rosie Glazebrook
Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *The R&D Office, King's College Hospital NHS Foundation Trust*
Dr Jonathan Koffman, King's College London
Mr Keith Brennan, King's College London

London - Camden & Kings Cross Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held via correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Heidi Chandler (Vice Chair)	Deputy Research Delivery Manager	Yes	
Mrs Rosie Glazebrook (Chair)	Consumer Marketing	Yes	Chair of the Sub-Committee

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kirstie Penman	REC Assistant

[redacted]

24 July 2017

Dr Catherine Evans
King's College London
Cicely Saunders Institute
[redacted]

Dear Dr Evans

Study title:	**The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle.**
REC reference:	**16/LO/2010**
Amendment number:	**SA4**
Amendment date:	**10 July 2017**
IRAS project ID:	**212178**

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence.

Summary of amendment

This substantial amendment was submitted to temporarily change the Chief Investigator from Dr Jonathan Koffman to Dr Catherine Evans. Due this change a number of documents had been updated including the participant information sheets, informed consent forms and appropriate letters.

This substantial amendment was also submitted to seek approval to change the general planned procedures for the feasibility cluster randomised control trial, the addition of EQ-5D measure to other time points, and a change in the post-bereavement survey data collection time points, due to these changes the protocol and questionnaire booklets had been updated.

This amendment also includes an extension to the study end date with a planned revised end date of 31 October 2018.

Ethical opinion

The Sub-Committee did not raise any ethical issues.

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
GP/consultant information sheets or letters [GP letter - tracked]	3.0	10 July 2017
Non-validated questionnaire [Questionnaire - proxy 10-15 days - tracked]	3.0	16 June 2017
Non-validated questionnaire [Questionnaire - proxy baseline - tracked]	3.0	10 July 2017
Non-validated questionnaire [Questionnaire - patients 3-5 days - tracked]	3.0	16 June 2017
Non-validated questionnaire [Questionnaire - patients 10-15 days - tracked]	3.0	16 June 2017
Non-validated questionnaire [Questionnaire - patients baseline - tracked]	3.0	10 July 2017
Non-validated questionnaire [Questionnaire - proxy 3-5 days - tracked]	3.0	16 June 2017
Non-validated questionnaire [Questionnaire - standard or usual care - baseline - tracked]	2.0	13 July 2017
Non-validated questionnaire [Questionnaire - standard or usual care - completion of patient recruitment - tracked]	2.0	10 July 2017
Non-validated questionnaire [Questionnaire - standard or usual care - mid patient recruitment - tracked]	2.0	10 July 2017
Notice of Substantial Amendment (non-CTIMP) [Substantial amendment form]	SA4	10 July 2017
Other [Letter to relatives - female - tracked]	3.0	07 July 2017
Other [Letter to relatives - male - tracked]	3.0	07 July 2017
Other [Summary of changes]		10 July 2017
Participant consent form [Consent form - consultee approval continued participation loss of capacity]	3.0	10 July 2017
Participant consent form [Consent form - consultee approval for participation study]	3.0	10 July 2017
Participant consent form [Consent form - HCP care questionnaire - tracked]	2.0	10 July 2017
Participant consent form [Consent form - HCP focus group - tracked]	3.0	10 July 2017
Participant consent form [Consent form - HCP MDT - tracked]	2.0	10 July 2017
Participant consent form [Consent form - patient - tracked]	3.0	10 July 2017
Participant consent form [Consent form - relative - tracked]	3.0	10 July 2017
Participant information sheet (PIS) [Participant information sheet - care questionnaire HCP - tracked]	2.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet - HCP for MDMs - tracked]	4.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet - sontrol - tracked]	3.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet - sheet version intervention - tracked]	30	07 July 2017
Participant information sheet (PIS) [Participant information sheet - relative or close friend - tracked]	3.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet - focus group control ward - tracked]	2.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet - focus group intervention ward - tracked]	2.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet -	3.0	07 July 2017

consultee control ward - tracked]		
Participant information sheet (PIS) [Participant information sheet - consultee intervention ward - tracked]	3.0	07 July 2017
Participant information sheet (PIS) [Participant information sheet - relative or close friend - intervention - tracked]	3.0	07 July 2017
Research protocol or project proposal [Protocol - Distress - tracked]	3.0	10 July 2017
Research protocol or project proposal [Protocol - Improve care study - tracked]	4.0	16 June 2017
Summary CV for Chief Investigator (CI) [CV - C Evans]		

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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16/LO/2010:	**Please quote this number on all correspondence**

Yours sincerely
pp

[redacted]

Mrs Rosie Glazebrook
Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *The R&D Office, King's College Hospital NHS Foundation Trust*
Dr Jonathan Koffman, King's College London
Mr Keith Brennan

London - Camden & Kings Cross Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Rosie Glazebrook	Consumer Marketing	Yes	Chair of the Sub-Committee
Mr Jonathan Simons	Investment Manager	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Rheanneon Fuller	REC Assistant

[redacted]

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

01 November 2017

Dr Catherine Evans
King's College London
Cicely Saunders Institute
[redacted]

Dear Dr Evans

Study title:	**The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle.**
REC reference:	**16/LO/2010**
Amendment number:	**SA5**
Amendment date:	**29 September 2017**
IRAS project ID:	**212178**

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence.

Summary of amendment

This substantial amendment was submitted to seek approval to amend the bereavement questionnaire to include two health measures for health economic evaluation and to improve the layout of the questionnaire.

Ethical opinion

The Sub-Committee did not raise any ethical issues.

The members of the Committee taking part in the review gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Non-validated questionnaire [Bereavement questionnaire]	3.0	27 September 2017
Notice of Substantial Amendment (non-CTIMP) [Substantial amendment form]	SA5	29 September 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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16/LO/2010:	**Please quote this number on all correspondence**

Yours sincerely
pp

[redacted]

Ms Heidi Chandler
Vice Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *The R&D Office, King's College Hospital NHS Foundation Trust*
Dr Jonathan Koffman, King's College London
Mr Keith Brennan

London - Camden & Kings Cross Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Ms Heidi Chandler	Deputy Research Delivery Manager	Yes	Chair of the Sub-Committee
Mrs Julia Crenian	Volunteer with Home-Start	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Rheanneon Fuller	REC Assistant

[redacted]

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

14 December 2017

Ms Emel Yorganci
Research Assistant
ImproveCare
King's College London
Cicely Saunders Institute of Palliative Care, Policy & Rehabilitation
Florence Nightingale Faculty of Nursing, Midwifery & Palliative Care
[redacted]

Dear Ms Yorganci

Study title:	**The management of clinical uncertainty in end of life care: a feasibility cluster RCT of the AMBER care bundle.**
REC reference:	**16/LO/2010**
Amendment number:	**Substantial Amendment 6, 09/11/17**
Amendment date:	**14 November 2017**
IRAS project ID:	**212178**

The above amendment was reviewed at the meeting of the Sub-Committee held in correspondence.

Summary of amendment

This amendment was submitted in order change the inclusion criteria at control sites, improve the patient and relative participant information sheets and letters, conduct qualitative interviews with patients and families over the telephone, and implement 'AMBER readiness' criteria.

Ethical opinion

The Sub-Committee reviewed the amendment and wished to seek further clarification before coming to an opinion on this amendment.

The Sub-Committee noted some typographical errors in the documentation and had suggested that these be amended.

The Sub-Committee noted that in the consultee participant information sheet, the patient participant information sheet and the relative/friend participant information sheet, under the heading of 'What is the purpose of the ImproveCare study' it stated 'we want to understand is how to best support, and suggested that this was changed to 'we want to understand how to best support'.

The Sub-Committee noted that in the Consultee Participant Information Sheet where it stated 'intervention' it might be more user friendly to change this to 'professional support/help'.

The Sub-Committee noted that in the Consultee Participant Information Sheet (intervention) and the relative/friend participant information sheet at the end of the second paragraph, it stated 'quality of life and care of patients who recovery are uncertain' and suggested that this be amended to state 'quality of life and care of patients whose recovery is uncertain' or 'when recovery is uncertain'

In response to the Sub-Committees comments you agreed with the Sub-Committees comments and updated the documents accordingly.

The members of the Committee taking part in the review were satisfied with the response and gave a **favourable ethical opinion** of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Notice of Substantial Amendment (non-CTIMP)	Substantial Amendment 6, 09/11/17	14 November 2017
Other [Summary of changes]	1.2	09 November 2017
Other [Case note review]	2.0	13 October 2017
Other [Letter to relatives at female]	4.0	13 October 2017
Other [Letter to relatives at male]	4.0	13 October 2017
Other [Letter to telephone interview participant]	1.0	09 November 2017
Participant consent form [Patient for qualitative interview]	1.0	09 November 2017
Participant consent form [Relative]	4.0	09 November 2017
Participant information sheet (PIS) [Patient - intervention]	4.0	13 October 2017
Participant information sheet (PIS) [Relative - intervention]	4.0	13 October 2017
Participant information sheet (PIS) [Participant information sheet - Professional support - consultee - tracked]	4.0	13 October 2017
Participant information sheet (PIS) [Participant information sheet - patient - control - tracked]	4.0	13 October 2017

Participant information sheet (PIS) [Participant information sheet - relative - control - tracked]	4.0	13 October 2017
Participant information sheet (PIS) [Participant information sheet - control - consultee]	4.0	13 October 2017
Research protocol or project proposal	5.2	03 November 2017

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Statement of compliance

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16/LO/2010:	**Please quote this number on all correspondence**

Yours sincerely
pp
[redacted]
Ms Eleni Yerolaki
Alternate Vice Chair

E-mail: [redacted]

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Jonathan Koffman, King's College London*
Mr Keith Brennan

London - Camden & Kings Cross Research Ethics Committee

Attendance at Sub-Committee of the REC meeting held in correspondence

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Elizabeth Landers	Tutor	Yes	
Ms Eleni Yerolaki	Specialist Counsellor	Yes	Chair of the Sub-Committee

Also in attendance:

Name	*Position (or reason for attending)*
Miss Rheanneon Fuller	REC Assistant