Part of the research infrastructure for Wales funded by the National Institute for Social Care and Health Research, Welsh Government.
Yn rhan o seilwaith ymchwil Cymru a ariannir gan y Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd, Llywodraeth Cymru

Wales REC 6
Floor 8
36 Orchard Street
Swansea
SA1 5AQ

Telephone : 01792 607416
Fax : 01792 607533
E-mail : penny.beresford@wales.nhs.uk
Website : www.nres.nhs.uk

08 May 2015

Miss Emily Kenefick
Trainee Clinical Psychologist
Royal Holloway, University of London
Egham Hill
Egham
TW20 0EX

Dear Miss Kenefick

Study title:	**Coping and Adjustment in People with Chronic Obstructive Pulmonary Disease (COPD)**
REC reference:	**15/WA/0175**
IRAS project ID:	**178444**

The Proportionate Review Sub-committee of the Wales REC 6 reviewed the above application on 06 May 2015.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Penny Beresford, penny.beresford@wales.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. The Information Sheet should add information on Who has reviewed this study? To identify the REC reviewing body as Wales REC 6 Proportionate Review Sub-Committee.

2. The information sheet should record what will happen to the data if a participant is unable to complete the rehabilitation course.

3. The Consent Form should be provided on letterhead paper and include a box for the name of the person taking consent to sign.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

***Sponsors are not required to notify the Committee of approvals from host organisations*.**

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites
The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion").

Summary of discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The proposed sample size for this study is 50 participants – the PRSC felt that this may be too ambitious for a small scale study and that the researcher may have difficulty in writing the thesis.

Suitability of supporting information

It was noted that the Information Sheet was not set out in the usual standard format, however, this was considered to be acceptable. The information sheet should identify the REC reviewing body as Wales REC 6 Proportionate Review Sub-Committee.

The Consent Form should include a box for the name of the person taking the consent and be provided on letterhead paper.

Other general comments

The SC agreed that the study may include patients with acute illness and non completion of the rehab course. It was agreed that it should be recorded as to what will happen to this data.

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Professional indemnity schedule]	1	09 April 2015
IRAS Checklist XML [Checklist_29042015]		29 April 2015
Participant consent form [Participant consent form]	1	24 April 2015
Participant information sheet (PIS) [Participant information sheet]	1	24 April 2015
REC Application Form [REC_Form_29042015]		29 April 2015
Referee's report or other scientific critique report [Peer-review approval]	1	24 April 2015
Research protocol or project proposal [Research Protocol]	1	24 April 2015
Summary CV for Chief Investigator (CI) [Chief investigator: CV]	1	29 April 2015
Summary CV for supervisor (student research) [Academic Supervisor: CV]	1	29 April 2015
Validated questionnaire [Behavioural Responses to Illness Questionnaire (BRIQ)]	1	27 April 2015
Validated questionnaire [Chronic Respiratory Questionnaire (CRQ)]	1	27 April 2015
Validated questionnaire [Hospital Anxiety and Depression Scale (HADS)]	1	27 April 2015
Validated questionnaire [Inness Cognition Questionnaire (ICQ)]	1	27 April 2015
Validated questionnaire [Illness Perception Questionnaire-Revised (IOQ-R)]	1	27 April 2015
Validated questionnaire [MRC Dyspnea Scale]	1	27 April 2015
Validated questionnaire [Self-Compassion Scale (SCS)]	1	27 April 2015

Membership of the Proportionate Review Sub-Committee

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

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.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

With the Committee's best wishes for the success of this project.

15/WA/0175	**Please quote this number on all correspondence**

Yours sincerely

pp
Roy L. Evans
Chair

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

"After ethical review – guidance for researchers" [SL-AR2]

Copy to: *Ms Sharon Clutterbuck, Royal Holloway University of London*
Dr. Robert Sherwin, The Whittington Hospital NHS Trust

Wales REC 6

Attendance at PRS Sub-Committee of the REC meeting on 06 May 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr John Francis Doran	retired - Consultant Chemical Pathologist	Yes	
Roy L. Evans	Hon Assoc Professor - Chairman	Yes	
Dr Alan Watkins	Senior Lecturer in Statistics	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Penny Beresford	REC Manager

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Wales REC 6
Floor 8
36 Orchard Street
Swansea
SA1 5AQ

Telephone : 01792 607416
Fax : 01792 607533
E-mail : penny.beresford@wales.nhs.uk
Website : www.nres.nhs.uk

16 December 2015

Miss Emily Kenefick
Trainee Clinical Psychologist
Royal Holloway, University of London
Egham Hill
Egham
TW20 0EX

Dear Miss Kenefick

Study title:	**Coping and Adjustment in People with Chronic Obstructive Pulmonary Disease (COPD)**
REC reference:	**15/WA/0175**
Amendment number:	**AM02**
Amendment date:	**30 November 2015**
IRAS project ID:	**178444**

The above amendment was reviewed 15 December 2015 by the Sub-Committee in correspondence.

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*
Notice of Substantial Amendment (non-CTIMP) [changes to study design and protocol]	AM02	30 November 2015
Other [demographic form]	2	14 October 2015
Participant consent form	3	14 October 2015
Participant information sheet (PIS)	3	14 October 2015
Research protocol or project proposal	2	14 October 2015

Membership of the Committee

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

Appendix B

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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 NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

15/WA/0175: Please quote this number on all correspondence

Yours sincerely

pp
Dr John Doran
Alternate Vice Chair

E-mail: penny.beresford@wales.nhs.uk

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

Copy to: *Dr. Robert Sherwin, The Whittington Hospital NHS Trust*
Ms Sharon Clutterbuck

Appendix B

Wales REC 6

Attendance at Sub-Committee of the REC meeting on 15 December 2015 (in correspondence)

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr John Francis Doran	retired - Consultant Chemical Pathologist	Yes	
Dr Alan Watkins	Senior Lecturer in Statistics	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Penny Beresford	REC Manager

Appendix C

Ref: 2015/063 Ethics Form Approved

psychology.it.support@rhul.ac.uk

Thu 04/06/2015 11:09

To: pava068@rhul.ac.uk <pava068@rhul.ac.uk>;
Wroe, Abigail <Abigail.Wroe@rhul.ac.uk>;

Cc: PSY-EthicsAdmin@rhul.ac.uk <PSY-EthicsAdmin@rhul.ac.uk>;
Zagefka, Hanna <Hanna.Zagefka@rhul.ac.uk>;
Lock, Annette <Annette.Lock@rhul.ac.uk>;
uqjt005@rhul.ac.uk <uqjt005@rhul.ac.uk>;

Application Details:

Applicant Name:

Emily Kenefick

Application title:

Coping and Adjustment in People with Chronic Obstructive Pulmonary Disease (COPD)

Comments:

Approved, although we would recommend the following:

1. Replace the university logo on the information sheet with the current one (grey and orange)

Appendix D

Ref: 2015/063R1 Ethics Form Approved

psychology.it.support@rhul.ac.uk

Tue 22/12/2015 16:10

To: pava068@rhul.ac.uk <pava068@rhul.ac.uk>;
Wroe, Abigail <Abigail.Wroe@rhul.ac.uk>;

Cc: PSY-EthicsAdmin@rhul.ac.uk <PSY-EthicsAdmin@rhul.ac.uk>;
Zagefka, Hanna <Hanna.Zagefka@rhul.ac.uk>;
Lock, Annette <Annette.Lock@rhul.ac.uk>;
uqjt005@rhul.ac.uk <uqjt005@rhul.ac.uk>;

Application Details:

View the form click here Revise the form click here

Applicant Name:

Emily Kenefick

Application title:

Coping and Adjustment in People with Chronic
Obstructive Pulmonary Disease (COPD)

Comments:

DEC approves the new protocol, but the applicant is advised
to check carefully if new NHS approval is needed.

Appendix E

1st Floor, Bloomsbury Building
St Pancras Hospital
4 St Pancras Way
NW1 0PE

Tel: 020 3317 3045
Fax: 020 7685 5830/5788
www.noclor.nhs.uk
12 June 2015

Emily Kenefrick
Royal Holloway, University of London
Egham Hill
Surrey
TW20 0EX

Dear Emily Kenefrick,

This NHS Research Governance Approval is based on the REC favourable opinion issued on **8th May 2015.**

I am pleased to confirm that the following study has now received R&D approval, and you may now start your research in **the trust identified below**:

Study Title: **Coping and adjustment in People with Chronic Obstructive Pulmonary Disease (COPD)**

R&D reference: **178444**
REC reference: **15/WA/0175**

Name of the trust	Name of current PI/LC	Date of permission issue(d)
Whittington Hospital NHS Trust	**Mr Anthony Rafferty**	**12th June 2015**

If any information on this document is altered after the date of issue, this document will be deemed INVALID

Specific Conditions of Permission (if applicable)

If any information on this document is altered after the date of issue, this document will be deemed INVALID

Yours sincerely,

Pushpsen Joshi
Research Operations Manager

Cc: Principle Investigator(s)/Local Collaborator(s), Sponsor Contact

Appendix E

1st Floor, Bloomsbury Building
St Pancras Hospital
4 St Pancras Way
NW1 0PE

Tel: 020 3317 3045
Fax: 020 7685 5830/5788
www.noclor.nhs uk

May I take this opportunity to remind you that during the course of your research you will be expected to ensure the following:

- **Patient contact:** only trained or supervised researchers who hold the appropriate Trust/NHS contract (honorary or full) with each Trust are allowed contact with that Trust's patients. If any researcher on the study does not hold a contract please contact the R&D office as soon as possible.

- **Informed consent:** original signed consent forms must be kept on file. A copy of the consent form must also be placed in the patient's notes. Research projects are subject to random audit by a member of the R&D office who will ask to see all original signed consent forms.

- **Data protection:** measures must be taken to ensure that patient data is kept confidential in accordance with the Data Protection Act 1998.

- **Health & safety:** all local health & safety regulations where the research is being conducted must be adhered to.

- **Serious Adverse events:** adverse events or suspected misconduct should be reported to the R&D office and the Research Ethics Committee.

- **Project update:** you will be sent a project update form at regular intervals. Please complete the form and return it to the R&D office.

- **Publications:** it is essential that you inform the R&D office about any publications which result from your research.

- **Ethics:** R&D approval is based on the conditions set out in the favourable opinion letter from the Research Ethics Committee. If during the lifetime of your research project, you wish to make a revision or amendment to your original submission, please contact both the Research Ethics Committee and R&D Office as soon as possible.

- **Monthly / Annually Progress report:** you are required to provide us and the Research Ethics Committee with a progress report and end of project report as part of the research governance guidance.

- **Recruitment data:** if your study is a portfolio study, you are required to upload the recruitment data on a monthly basis in the website: http://www.crn.nihr.ac.uk/can-help/funders-academics/nihrcrn-

- **Amendments:** if your study requires an amendment, you will need to contact the Research Ethics Committee. Once they have responded, and confirmed what kind of amendment it will be defined as, please contact the R&D office and we will arrange R&D approval for the amendment. If your study is Portfolio Adopted, amendments must be submitted for R&D review via the NIHR CRN (CSP), please refer to the Amendments Guidance for Researchers: http://www.crn.nihr.ac.uk/can-help/funders-academics/gaining-nhs-permissions/amendments/
- **Audits:** each year, noclor select 10% of the studies from each service we have approved to be audited. You will be contacted by the R&D office if your study is selected for audit. A member of the governance team will request you complete an audit monitoring form before arranging a meeting to discuss your study.

Royal Free London NHS
NHS Foundation Trust

Research & Development Department
Royal Free Hospital
Pond Street
Ground Floor, Room 649
London
NW3 2QG

www.royalfree.nhs.uk
Switchboard: 020 7794 0500 EXT: 33211
Fax: 020 7830 2468
Direct line: 020 7317 7558

FINAL R&D APPROVAL – NHS PERMISSION **26/01/2016**

Miss Emily Kenefick
Royal Holloway, University of London

Dear Miss Emily Kenefick,

Project ID: 9639 (Please quote in all correspondence)
REC Ref: 15/WA/0175
Title: Adjustment in Chronic Obstructive Pulmonary Disease (COPD) Version 1

Thank you for registering the above study with the Royal Free R&D office. I am pleased to inform you that your study now has local NHS Permission (R&D approval) to proceed and recruit participants at Royal Free London NHS Foundation Trust subject to Sponsor confirmation.

Please note that all documents received have been reviewed and this approval is granted on the basis of the key documents provided which are ethically approved by the Research Ethics Committee:

Document	Date
REC approval and REC approved documents	08 May 2015
REC approval of SubAM2	16 December 2015

As Principal Investigator you are required to ensure that your study is conducted in accordance with the requirements on the attached sheet. These include the conditions of your NHS Permission.

Do not hesitate to contact a member of the team should you have any queries.

Yours sincerely

Dr Adele Fielding
Director of Research and Development
Royal Free London NHS Foundation Trust

Responsibilities of the Researcher

Conditions of NHS permission

Your research has been granted NHS permission by the Research & Development Office (R&D) on behalf of Royal Free London NHS Foundation Trust.

As a condition of the NHS permission you must comply with:

- Applicable Trust's Research & Development Office's Standard Operating Procedures (SOP]
- Department of Health's Research Governance Framework for Health and Social Care
- Research Ethics Committee notice of favourable opinion
- Data Protection Act, Caldicott Principles and Trust Information Governance Policy.
- All other relevant legislation and regulatory approvals including the following *if applicable*
    - Medicines and Healthcare products Regulatory Agency
        - notice of acceptance of a clinical trial of investigational medicinal product (CTIMP)
        - notice of no objection of a clinical investigation for a medical device
    - Human Tissue Act 2004 and the Codes of Practice with special relevance to Code 9 Research
    - Human Tissue (Quality and Safety for Human Application) Regulations 2007

Responsibilities for Research Teams

As Principal Investigator you are required to ensure that:

- The roles and responsibilities of all members of the research team are documented in a delegation log and that all team members are made aware of these.

- All researchers conducting the study have applicable (up-to-date) honorary contracts.

- All researchers are suitably trained, qualified and experienced to carry out duties delegated to them and if conducting a clinical trial, have up-to-date Good Clinical Practice (GCP) training (updated every 2 years).

Responsibilities for the Principal Investigator in relation to Tissue and Data in the absence of a study agreement:

- After Ethics approval for the study has expired, you shall ensure that tissues are disposed of in accordance with the protocol and Human Tissue Act 2004, transferred to a licensed Tissue Bank or used under a new ethically approved research project.

- Ensure that all necessary arrangements are in place for appropriate transfer, storage, handling, retention (archiving) and, if applicable, destruction of study data. The Sponsor will act as the custodian of such data.

Reporting on Recruitment

Please ensure that you notify the R&D office with:

- Confirmation of **recruiting your first patient** by emailing rf.randd@nhs.net

- There is also a requirement to report accrual on a regular basis. If your study has been adopted onto the NIHR portfolio you will be contacted directly by the NIHR Clinical Research Network Coordinating Centre. For all other studies you are required to provide an update to the R&D Office on recruitment every 6 months.

Reporting Study Events

Unexpected events and incidents

Please ensure that your study team reports the following **to the Sponsor** as required by the protocol, Sponsor SOPs or RFL Trust's SOPs:

- For **CTIMPs**
  - All suspected unexpected serious adverse events (SUSARs),
  - Protocol violations, serious breaches of protocol and of GCP
  - Urgent safety measures
- For **all other studies**
  - All unexpected serious adverse events (SAE) related to the research protocol

Please ensure that your study team reports the following :

- For **all research**
  - All complaints from NHS patients from Royal Free should be reported in the first instance to the Royal Free London NHS Complaints Manager.
  - All research related incidents occurring at the Royal Free should be reported through DATIX, the Trust Incident Reporting System (available on Freenet).
- For **CTIMPs**
  - Please report all SUSARs and Serious Breaches of Protocol and GCP occurring at Royal Free through DATIX.
- For **all other studies**
  - Please report unexpected SAEs related to the research protocol, serious breaches of protocol and GCP if applicable through DATIX.

Study progress and changes

Please ensure that your study team reports the following to the R&D Office:

- Amendments (including a request to extend the study)
- Monitoring activity information:
  - for non-commercially Sponsored clinical trials provide a summary of corrective and preventive actions from monitoring reports, as agreed with the Sponsor
  - for Industry Sponsored Clinical Trials provide a copy of the monitoring log on an annual basis, as agreed with the Sponsor
  - Annual Progress Reports submitted to REC (for Royal Free Sponsored research)
- Audit activity information:

  - Notification of audits or inspections
  - Audit reports (where possible, and in agreement with the sponsor, to provide a copy of the corrective and preventive actions arising from an audit)
- Notification of end of study or suspension of study
- Publications

Study documentation

Research teams are required to:

- Prepare and maintain a site file to ensure that data and documentation associated with the study are available for audit. Please refer to the SOP for Investigator Site File SOP 019 Investigator File available at: http://rf.royalfree.org.uk/research/

- Contact the R&D Office by email (rf.randd@nhs.net) as soon as the study has been suspended or ended in order to arrange for archiving.

If you require any further information on the above please see the Trust's Research Office website http://rf.royalfree.org.uk/research/

Royal Free Research Office Standard Operating Procedures are available at:
http://rf.royalfree.org.uk/research/

Healthcare from the heart of your community

Berkshire Healthcare NHS
NHS Foundation Trust

Miss Emily Kenefick
Doctorate in Clinical Psychology
Royal Holloway, University of London,
Egham Hill, Egham, Surrey
Post Code TW20 0EX

date: 4th January 2016

Research & Development
Fitzwilliam House · Skimped Hill Lane
Bracknell · Berkshire · RG12 1BQ

t: **01344 415825**
f: **01344 415666**
e: **research@berkshire.nhs.uk**

Our Ref: 2016/01 REC Ref: 15/WA/0175

Study title: Coping and Adjustment in People with Chronic Obstructive Pulmonary Disease (COPD)

Start date: 04/01/2016 End date: 31/03/2016

Dear Emily Kenefick

Confirmation of Trust Management Approval

On behalf of Berkshire Healthcare NHS Foundation Trust, I am pleased to confirm Trust Management Approval for the above research on the basis described in the application, protocol and other supporting documents. The Approval is conditional on you informing the R&D Department when you recruit the first patient so that we can monitor our performance against the NIHR high level metric. Please let us know the number of participants you will recruit in BHFT.

If there are any changes to the study protocol, the R&D Department must be informed immediately and supplied with any amended documentation as necessary, including confirmation that the amendments have been favourably reviewed by the Sponsor and the Ethics Committee. If the end date changes from that shown above, then please inform BHFT R&D Manager. Trust approval will cease on the end date above. Please contact the R&D Manager to discuss and request any extension.

Please note that Berkshire Healthcare NHS Foundation Trust is the site name when uploading recruitment data.

If you have any questions about the above, or you require any other assistance, then please contact the R&D Department.

I wish you every success with the study.

Yours sincerely

Stephen Zingwe
Research and Development Manager (BHFT)

Department of Psychology

Royal Holloway, University of London, Egham, Surrey TW20 0EX, UK

Information Sheet
Coping and adjustment in people with Chronic Obstructive Pulmonary Disease (COPD).

My name is Emily Kenefick and I am a trainee Clinical Psychologist at Royal Holloway, University of London. I am carrying out research into the factors that influence how people with COPD cope with and adjust to their illness. The study is part of my training in clinical psychology and is being supervised by Dr Abigail Wroe, Clinical Psychologist.

What Is The Purpose Of The Study?
This study is important for helping us understand more about how people with long-term illnesses can adjust to their diagnosis and maintain a good quality of life- physically and psychologically.

Why Have I Been Asked To Take Part?
We are looking for people with a diagnosis of COPD who are participating in pulmonary rehabilitation. I would like to invite you to take part in the study by completing some questionnaires.

What Will The Study Involve?
If you choose to participate, I will ask you to complete a set of simple questionnaires. The questions are about the way in which you think, feel and behave in relation to your COPD, and they take a maximum of 20-30 minutes to complete- though people usually complete them much quicker than that.

Who Will See My Information?

Only my supervisor and I will have access to your responses to the questionnaires that you complete. Your responses will be coded with a number. This will be linked with your name and contact details and stored separately so that all information is confidential. Everything you report is confidential unless you tell me something that indicates that you or someone else is at risk of harm. I would discuss this with you before telling anyone else.

You can decide not to answer some questions if you wish. The study will be written up as a university project as part of my doctoral degree and potentially published in a scientific journal. No personal information is included in the final report, and your information will not be identifiable to you when the project is written up and/or published.

Who Has Reviewed This Study?
The Wales Research Ethics Committee (REC) 6 Proportionate Review Sub-Committee has reviewed and approved this study. This study has also been reviewed and approved by the Psychology Department internal ethical procedure at Royal Holloway, University of London.

Do I Have To Take Part?
You do not have to take part in this study if you don't want to. If you decide to take part, you may then withdraw at any time without having to give a reason and we can remove your responses from the data if you ask us to. You do not need to answer every item. Taking part, or choosing not to take part in this study, will not affect your access to services now or in the future.

What Should I Do If I have any questions?
Please call 01784 414012 and ensure you ask for Emily Kenefick, or email emily.kenefick.2013@live.rhul.ac.uk. If you would like to discuss any aspect of the research with my supervisor, you can contact Dr. Abigail Wroe by email at Abigail.wroe@rhul.ac.uk.

I would like to take part, what happens next?

If you would like to take part, I will give you a consent form to sign and a pack of questionnaires to complete at home. I will also give you a pre-paid envelope so that should you decide to participate, you can return the completed questionnaires to me directly, or you can bring them back into your next group rehabilitation session for me to collect. Take your time to complete them and feel free to contact me with any questions as you consider your participation.

To thank you for your participation, you will be entered into a prize draw for the chance to win a cash prize!

Please keep this information sheet yourself for reference.

Department of Psychology, Royal Holloway, University of London, Egham, Surrey TW20 0EX, UK

CONSENT FORM ID number……

Coping and adjustment in people with Chronic Obstructive Pulmonary Disease (COPD).

You have been asked to participate in a study about the factors that influence the extent to which people with COPD cope with and adjust to their illness, which is being carried out by Emily Kenefick.

Have you (please circle yes or no):

- Read or understood the information sheet about the study? yes no
- Had an opportunity to ask questions? yes no
- Got satisfactory answers to your questions? yes no
- Understood that you're free to withdraw from the study at any time, without giving a reason and without it affecting your care? yes no

Do you agree to take part in the study? yes no

Would you be interested in helping Emily to write a report of the study's results in a way that is accessible to COPD patients? yes no

(If so, please leave your contact number or email address and Emily will contact you again after the study in this regard).

Tel number: _____ **email address:** _____

Would you like to receive a copy of the completed project report? yes no
(If so, you will be contacted in order to discuss how you would like to receive it).

Do you give permission to Emily to retain your contact details until the end of the study? yes no

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

NB: This consent form will be stored separately from the anonymous information you provide.

Department of Psychology

Royal Holloway, University of London, Egham, Surrey TW20 0EX, UK

Coping and adjustment in people with Chronic Obstructive Pulmonary Disease (COPD).

Participant Demographic Form

Study ID number ……

Gender (Please circle)	MALE FEMALE
What is your age?	
Ethnicity (Please tick relevant category)	White – British White – Irish White - other White background Mixed - other Mixed background Black/Black British – Caribbean Black/ Black British – African Black/Black British - Any other Black backgrou Asian/Asian British – Indian Asian/Asian British – Pakistani Asian/Asian British – Bangladeshi Asian/Asian British - Any other Asian backgrou Any other ethnic group
How long have you had your COPD/lung condition?	
Do you currently have any *other* physical health conditions? **If so, please state the condition(s).**	YES/NO
Are you currently experiencing any mental health difficulties for which you are receiving professional support (medication, therapy)? **If so, please state the difficulty.**	YES / NO

In the past, have you experienced any mental health difficulties for which you have received professional support (medication, therapy)? **If so, please state the difficulty.**	YES / NO

Whittington Health NHS

Department of Psychology

Royal Holloway, University of London, Egham, Surrey TW20 0EX, UK

Information Sheet
Coping and adjustment in people with Chronic Obstructive Pulmonary Disease (COPD).

My name is Emily Kenefick and I am a trainee Clinical Psychologist at Royal Holloway, University of London. I am carrying out research into the factors that influence how people with COPD cope with and adjust to their illness. The study is part of my training in clinical psychology and is being supervised by Dr Abigail Wroe.

What Is The Purpose Of The Study?
This study is important for helping us understand more about how people with long-term illnesses can adjust to their diagnosis and maintain a good quality of life-physically and psychologically.

Why Have I Been Asked To Take Part?
We are looking for people with a diagnosis of COPD who are about to participate in pulmonary rehabilitation. I would like to invite you to take part in the study by completing some questionnaires at the beginning and end of your pulmonary rehabilitation programme. We are looking for around 50 participants.

What Will The Study Involve?
If you are interested in taking part, please let the pulmonary rehabilitation staff know today that you are happy to hear from me. I will then telephone you to discuss the study and answer any questions you may have. If you are happy to participate, I will ask you to complete the consent form at the end of this information sheet and return to me in the pre-paid envelope provided.

Next, I will ask you to complete a set of questionnaires over the telephone. The questions are about the way in which you think, feel and behave in relation to your COPD, and they take up to 15 minutes to complete. If you prefer, I can post you the questionnaires to complete at home and send back in a freepost envelope.

You will be asked to complete some questionnaires at the end of the pulmonary rehabilitation programme. This can be done by telephone or by post.

We would also like to have access to your responses on the questionnaires that you complete with the pulmonary rehabilitation staff before and after the programme starts. We will also be asking the pulmonary rehabilitation staff for access to your score on the MRC Breathlessness Scale, which was provided by your GP/respiratory specialist when you were referred to pulmonary rehabilitation.

Who Will See My Information?

Only my supervisor and I will have access to your responses to the questionnaires that you complete with me. The pulmonary rehabilitation team will share with only my supervisor and me your responses to the questionnaires you complete with them, as well as your MRC Breathlessness Scale score. Your responses will be coded with a number. This will be linked with your name and contact details and stored separately so that all information is confidential. Everything you say/report is confidential unless you tell us something that indicates that you or someone else is at risk of harm. We would discuss this with you before telling anyone else.

You can decide not to answer some questions if you wish. The study will be written up as a university project as part of my degree and potentially published in a scientific journal. No personal information is included in the final report, and your information will not be identifiable to you when the project is written up and/or published.

Who Has Reviewed This Study?
The Wales Research Ethics Committee (REC) 6 Proportionate Review Sub-Committee has reviewed and approved this study.

Do I Have To Take Part?
You do not have to take part in this study if you don't want to. If you decide to take part you may withdraw at any time without having to give a reason. You do not need to answer every item. Taking part, or choosing not to take part in this study, will not affect your access to services now or in the future.

What If I Am Unable To Complete Pulmonary Rehabilitation?
If you are unable to complete pulmonary rehabilitation for any reason and you do not complete the questionnaires at the end of the programme, we will still include in the study the questionnaires you completed at the beginning of the programme. We will not do this if you contact us and ask us not to.

What Should I Do If I Would Like To Find Out More?
Please call 01784 414012 and ensure you ask for Emily Kenefick, or email emily.kenefick.2013@live.rhul.ac.uk. If you would like to discuss any aspect of the research with my supervisor, you can contact Dr. Abigail Wroe by email at Abigail.wroe@rhul.ac.uk.

To thank you for your participation, you will be entered into a prize draw for the chance to win a cash prize!

Please keep this part of the sheet yourself for reference. Please feel free to ask any questions before you complete the consent form below. The consent form will be stored separately from the anonymous information you provide for this research. This study has been reviewed and approved by the Psychology Department internal ethical procedure at Royal Holloway, University of London and by the NHS.

Psychology Department Ethics Committee, Royal Holloway, University of London, 201

Whittington Health NHS

Department of Psychology

Royal Holloway, University of London, Egham, Surrey TW20 0EX, UK

CONSENT FORM

ID number…….

Coping and adjustment in people with Chronic Obstructive Pulmonary Disease (COPD).

You have been asked to participate in a study about the factors that influence the extent to which people with COPD cope with and adjust to their illness, which is being carried out by Emily Kenefick.

Have you (please circle yes or no):

- Read or understood the information sheet about the study? yes no
- Had an opportunity to ask questions? yes no
- Got satisfactory answers to your questions? yes no
- Understood that you're free to withdraw from the study at any time, without giving a reason and without it affecting your care? yes no

Do you agree to take part in the study? yes no

Do you give permission to the rehabilitation staff to share with Emily your responses to the questionnaires you complete with them? yes no

Do you give permission to Emily to retain your contact details until the end of the study, until it is no longer necessary to contact you? yes no

Would you be interested in helping Emily to write a report of the study's results in a way that is accessible to COPD patients? yes no
(If so, Emily will contact you again after the study in this regard).

Would you like to receive a copy of the completed project report? yes no
(If so, you will be contacted in order to discuss how you would like to receive it).

Name of Participant	Date	Signature
Name of Person taking consent.	Date	Signature

NB: This consent form will be stored separately from the anonymous information you provide.

Whittington Health NHS

Department of Psychology

Royal Holloway, University of London, Egham, Surrey TW20 0EX, UK

Coping and adjustment in people with Chronic Obstructive Pulmonary Disease (COPD).

Participant Demographic Form

Study ID number ……

Gender (Please circle)	MALE FEMALE
What is your age?	
Ethnicity (Please tick relevant category)	White – British White – Irish White - other White background Mixed - other Mixed background Black/Black British – Caribbean Black/ Black British – African Black/Black British - Any other Black background Asian/Asian British – Indian Asian/Asian British – Pakistani Asian/Asian British – Bangladeshi Asian/Asian British - Any other Asian background

	Any other ethnic group
How long have you had your COPD/ lung condition?	
Do you currently have any *other* physical health conditions? **If so, please state the condition(s).**	YES/NO
Are you currently experiencing any mental health difficulties for which you are receiving professional support (medication, therapy)? **If so, please state the difficulty.**	YES / NO
In the past, have you experienced any mental health difficulties for which you have received professional support (medication, therapy)? **If so, please state the difficulty.**	YES / NO