Health Research Authority

West Midlands - Coventry & Warwickshire Research Ethics Committee
2 Redman Place
Stratford
London
E20 1JQ

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

21 July 2025

Prof Claire Henderson
Clinical Professor of Public Mental Health
Health Services and Population Research Department,
David Goldberg Centre,
King's College London
SE5 8AF

Dear Prof Henderson

Study title:	**Advance Choice Document Implementation**
REC reference:	**25/WM/0117**
Protocol number:	**NA**
IRAS project ID:	**346853**

Thank you for your response to the Research Ethics Committee's (REC) request for further information on the above research.

The further information has been considered on behalf of the Committee by the Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised subject to the conditions specified below.

Mental Capacity Act 2005 (England and Wales)

Extract of the minutes relating to the compliance of the Mental Capacity Act:

Relevance of the research to the impairing condition

The Committee agreed the research was connected with an impairing condition affecting persons lacking capacity or with the treatment of the condition. It was discussed that whilst initial consent will be sought for the study, if clients lose consent they will not be removed unless requested. The Committee also noted that the inclusion of Adults Lacking Capacity in the study was to access records rather than involve them in an active trial, so the sections 'Arrangements for appointing consultees', 'Additional safeguards' and 'Information for consultees' were not relevant in this instance.

Justification for including adults lacking capacity to meet the research objectives

The Committee agreed the research could not be carried out as effectively if it was confined to participants able to give consent.

Balance between benefit and risk, burden and intrusion

The Committee agreed that the research has the potential to benefit participants lacking capacity without imposing a disproportionate burden on them.

Good practice principles and responsibilities

The UK Policy Framework for Health and Social Care Research sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of research transparency:

1. registering research studies
2. reporting results
3. informing participants
4. sharing study data and tissue

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

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 management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a public registry before the first participant is recruited and no later than six weeks after. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

A 'public registry' means any registry on the WHO list of primary registries or the ICMJE list of registries provided the registry facilitates public access to information about the UK trial.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: Research registration and research project identifiers).

Where a deferral is agreed we expect the sponsor to publish a minimal record on a publicly accessible registry. When the deferral period ends, the sponsor should publish the full record on the same registry, to fulfil the condition of the REC favourable opinion.

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Where the study is registered on ClinicalTrials.gov, please inform deferrals@hra.nhs.uk and the Research Ethics Committee (REC) which issued the final ethical opinion so that our records can be updated.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter. Where a deferral is agreed, a minimum research summary will still be published in the research summaries database. At the end of the deferral period, we will publish the full research summary.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit: Research summaries - Health Research Authority (hra.nhs.uk)

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).

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, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at Managing your approval - Health Research Authority (hra.nhs.uk)

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Confirmation of any other Regulatory Approvals (e.g. CAG) and all correspondence [ACDI KCL Risk Assessment v1.0 10.07.25 IRAS 346853]	1.0	10 July 2025
Copies of materials calling attention of potential participants to the research [ACDI project summary advert V1.0 18.10.24 IRAS 346853]	1.0	18 October 2024
Copies of materials calling attention of potential participants to the research [ASB Advisory group advert V1.0 14.11.24 IRAS 346853]	1.0	14 November 2024
Copies of materials calling attention of potential participants to the research [ASG Advisory group advert V1.0 14.11.24 IRAS 346853]	1.0	14 November 2024
Copies of materials calling attention of potential participants to the research [Fo Advisory group advert V1.0 14.11.24 IRAS 346853]	1.0	14 November 2024
Copies of materials calling attention of potential participants to the	1.0	13 March 2025

research [ACDI core slides v1SU&carers v1.0 15.11.24 IRAS 34685]		
Copies of materials calling attention of potential participants to the research [ACDI WP1 TPiR online advert v1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Copies of materials calling attention of potential participants to the research [ACDFacilitator referral flyerV1.1 08Jul25 IRAS 346853]	1.1	08 July 2025
Copies of materials calling attention of potential participants to the research [WP1CAMHS Focus group V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Copies of materials calling attention of potential participants to the research [WP1OA Focus group V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Copies of materials calling attention of potential participants to the research [OA Advisory group advert V1.1 14.07.25 IRAS 346853]	1.1	14 July 2025
Copies of materials calling attention of potential participants to the research [CAMHS Advisory group advert - CarersParentsSupporters V1.1 26.06.25 IRAS 346853]	1.1	26 June 2025
Copies of materials calling attention of potential participants to the research [CAMHS Advisory group advert - YP V1.1 26.06.25 IRAS 346853]	1.1	26 June 2025
Covering letter on headed paper [IRAS 346853 'ACDI V1.0' - Confirmation of Sponsorship]	1.0	12 May 2025
Covering letter on headed paper [Responses to REC review ACDI IRAS 346853 18.07.25]		18 July 2025
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [King's College London - Legal Liability for Human Clinical Trials TWIMC 2024-25]	1.0	24 July 2024
GP/consultant information sheets or letters [ACDI GPletter v1.0 30.06.25 IRAS 346853]	1.0	30 June 2025
Interview schedules or topic guides for participants [ACDI WP1 Staff Topic Guide V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI WP1 SU&Carers FG Topic Guide V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI ACD completion log V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI Service user Non Completion Interview 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI Service user Completion Interview 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI ACD use audit V1.0 23.09.24]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI Expected ACD use carers and supporters V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI Expected ACD use Staff V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI Expected ACD use SU V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI WP2 Facilitator Role Interview Schedule V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Interview schedules or topic guides for participants [ACDI WP2 Staff Focus Groups Topic Guide V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
IRAS Application Form [IRAS_Form_20052025]		20 May 2025

Letter from funder [2946signed.pdf]	1.0	13 February 2024
Letter from sponsor [IRAS 346853 'ACDI V1.0' - Confirmation of Sponsorship]	1.0	12 May 2025
Letters of invitation to participant [ACDI WP1 and WP2 Invitation Emails V1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Non-validated questionnaire [ACDI WP1 focus group staff Employment Questionnaire v1.0 13.13.25 IRAS 346853]	1.0	13 March 2025
Non-validated questionnaire [ACDI WP1 Focus Groups Staff Employment Questionnaire v1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Non-validated questionnaire [ACDI WP1 Focus Groups CAMHS SU Demographic Questionnaire v1.1 10.07.2025 IRAS 346853]	1.1	10 July 2025
Non-validated questionnaire [ACDI WP1 Focus Groups Carer and Supporters Demographic Questionnaire v1.1 10.07.2025 IRAS 346853]	1.1	10 July 2025
Non-validated questionnaire [ACDI WP1 Focus Groups OA SU Demographic Questionnaire v1.1 10.07.2025 IRAS 346853]	1.1	10 July 2025
Non-validated questionnaire [ACDI Baseline questionnaire V1.1 10.07.2025 IRAS 346853]	1.1	10 July 2025
Non-validated questionnaire [ACDI WP2 Expected use Interview Carers & Supporters Demographic Questionnaire V1.1 10.07.2025 IRAS 346853]	1.1	10 July 2025
Other [Shubulade Smith 2pCV]	1.0	19 May 2025
Other [ACDI WP 1 and 2 SOP 03 Protocol for Managing Participant Distress v1.0 13.03.25 IRAS 346853]	1.0	13 March 2025
Other [ACDI WP1 and 2 SOP 07 Protocol for Managing Risk V1.0 16.01.25]	1.0	16 January 2025
Other [ACDI WP 1 and 2 SOP 04 Procedure for Safety Reporting v1.0 19.12.24]	1.0	19 December 2024
Participant consent form [ACDI WP1 focus groups CF - CAMHS carers and supporters V1.1 01.07.2025 IRAS 346853]	1.1	01 July 2025
Participant consent form [ACDI WP1 focus groups CF - CAMHS Staff V1.1 01.07.2025 IRAS 346853]	1.1	01 July 2025
Participant consent form [ACDI WP1 focus groups CF - CAMHS SU V1.1 01.07.2025 IRAS 346853]	1.1	01 July 2025
Participant consent form [ACDI WP1 focus groups CF - OA Carers and supporters V1.1 01.07.2025 IRAS 346853]	1.1	01 July 2025
Participant consent form [ACDI WP1 focus groups CF - OA Staff V1.1 01.07.2025 IRAS 346853]	1.1	01 July 2025
Participant consent form [ACDI WP1 focus groups CF - OA SUs V1.1 01.07.2025 IRAS 346853]	1.1	01 July 2025
Participant consent form [ACDI WP2 CF Expected ACD use - SUs V1.1 07.07.25 IRAS 346853]	1.1	07 July 2025
Participant consent form [ACDI WP2 referral and interviews CF - Carers and supporters V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant consent form [ACDI WP2 referral and interviews CF - Staff V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant consent form [ACDI WP2 Focus groups CF - Staff V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant consent form [ACDI Facilitator Interviews CF V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant consent form [ACDI WP2 referral and interviews CF - Service users V1.1 08.07.2025 IRAS 346853]	1.1	08 July 2025

Participant consent form [ACD creation - Recording agreement V1.1 08.07.25 IRAS 346853]	1.1	08 July 2025
Participant consent form [ACDI CF Implementation Group Meetings V1.1 08.07.25 IRAS 346853]	1.1	08 July 2025
Participant information sheet (PIS) [ACDI WP1 focus groups PIS - CAMHS Carers and supporters V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Participant information sheet (PIS) [ACDI WP1 focus groups PIS - CAMHS Staff V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Participant information sheet (PIS) [ACDI WP1 focus groups PIS - CAMHS Carers and supporters V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Participant information sheet (PIS) [CDI WP1 focus groups PIS - OA Carers and supporters V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Participant information sheet (PIS) [ACDI WP1 focus groups PIS - OA Service users V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Participant information sheet (PIS) [ACDI WP1 focus groups PIS - OA Staff V1.1 03.07.2025 IRAS 346853]	1.1	03 July 2025
Participant information sheet (PIS) [ACDI PIS ACD referral and interviews CAMHS carers and supporters V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews - CAMHS Service users V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews CAMHS staff V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews Forensic Carers and supporters V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews Forensic Service users V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews Forensic Staff V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews - GA service users V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews GA carers V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews GA staff V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews - OA service users V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews OA carers V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS ACD referral and interviews OA Staff V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS Expected ACD use - CAMHS SUs V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS Expected ACD use - Forensic SUs V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS Expected ACD use - GA SUs V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 PIS Expected ACD use - OA SUs V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Participant information sheet (PIS) [ACDI WP2 focus groups PIS - Staff V1.1 08.07.25 IRAS 346853]	1.1	08 July 2025

Participant information sheet (PIS) [ACDI WP2 PIS Implementation Group Meetings V1.1 01.07.25 IRAS 346853]	1.1	01 July 2025
Participant information sheet (PIS) [ACDI Facilitator Interviews PIS V1.1 30.06.25 IRAS 346853]	1.1	30 June 2025
Research protocol or project proposal [ACDI Protocol V1.1 16.07.25 IRAS 346853]	1.1	16 July 2025
Summary CV for Chief Investigator (CI) [Claire Henderson 2pCV]	1.0	01 January 2025

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.

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: Quality assurance - Health Research Authority (hra.nhs.uk)

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: Learning - Health Research Authority (hra.nhs.uk)

IRAS project ID: 346853	**Please quote this number on all correspondence**

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

Yours sincerely

pp. Owen Foulkes, Approvals Administrator

Miss Stephanie Ellis, BEM

Chair

Email:coventryandwarwick.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: Prof Bashir Al-Hashimi

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