PROTOCOL FOR ASSESSING, REPORTING AND MONITORING RISK

1. Policy Statement

GPs are responsible for the ongoing clinical care of COBRA trial participants. Therefore, all trial staff directly involved with research participants have a duty of care to ensure that participants' GPs are aware of any risk to participants or from participants to others, including suicidal thoughts expressed by participants.

Researchers must initiate the risk protocol each time a participant expresses suicidal thoughts, thoughts of self-harm or thoughts of harm to others. This may be as a result of responses to questionnaire items or the participant may disclose information during an interview that leads the researcher to believe that there are thoughts of suicide or harm to self or others. In both instances, the researcher should initiate the risk protocol and notify the site PI (or nominated deputy).

2. Principles

The following principles and procedures govern risk assessment, reporting and monitoring for the COBRA Trial.

The COBRA trial excludes participants at baseline interview who demonstrate any risk to self or others that would require management by specialist mental health or other services. However, included participants might develop such risk during the trial and must be assisted accordingly.

The Chief Investigator has overall responsibility for risk assessment and management for the COBRA trial. The Chief Investigator must ensure that any research personnel involved with the COBRA trial are adequately qualified and trained on risk assessment prior to any patient contact in which risk could be disclosed, and that these personnel receive support and supervision around risk issues during their involvement with the trial.

All cases where significant risk is identified by researchers will be managed according to the COBRA risk protocol and discussed with the Chief Investigator, another designated member of the trial's investigator team and the trial manager. All assessment reports and correspondence relating to risk sent by research staff will be checked by the Chief Investigator or a person from the COBRA team with the designated authority to do so (see delegation of Duties log) before they are sent.

3. Procedures for research personnel

Background training materials are available from the COBRA Trial Team in Exeter. All researchers should attend training in the use of this protocol at least biennially. All researchers will be made familiar with the protocol and new staff who will be involved in assessing/treating patients will be familiarised as part of their induction/training. Risk assessment should therefore be conducted following appropriate training and with appropriate supervision.

The Chief Investigator and Site PIs are responsible for ensuring that appropriate cover is arranged for any risk issues that might arise in their absence when away from research sites. This will entail a person being named as responsible for overseeing risk assessments in their absence and contact details being shared with COBRA trial staff and the trial manager.

Whenever any significant risk is identified (during an interview or through reviewing patient reported outcome measures) a **risk assessment form (appendix A) should be completed and (counter-) signed by the responsible member of staff and site PI or Chief Investigator**. If at all possible this should be done at the time of the assessment, or as soon afterwards as possible. Research staff should seek supervision the same working day that they receive any information regarding risk and ensure management of the information has been handed over to the designated person within the COBRA team.

All contact with patients/GPs and any other professionals around risk should be documented in writing in the participant's Contact and Risk File. Contact with the patient's GP, duty GP or other emergency service should be instigated according to the level of risk identified having followed the COBRA risk policy. As specified in the policy, contact may be by telephone, or if by fax a phone call to the GP Surgery made to ensure receipt of the fax.
Many of the COBRA standardised interviews (e.g., Structured Clinical Interview for DSM-IV – SCID) and questionnaires (e.g. PHQ-9) include questions about suicide risk. COBRA trial staff should always respond to any identified risk (as specified below) via these measures, and a risk assessment in line with this protocol should be completed.

In a SCID interview, reports of suicidal ideation, intent, plans or urges, and any risk of neglect of self or others, or harm to self or others requires further assessment.

A score of more than 0 on the PHQ-9 item 9 requires further assessment.

All personnel working on the COBRA trial should also ensure they ascertain whether participants represent a risk to themselves or others through neglect or active harm and whether participants are themselves at risk of being harmed by others. The same process is to be followed in any instance of risk and **supervision from the designated supervisor should be obtained immediately in the case of significant risk and within the same day for less immediate concerns.**

4. Questions To Ask & Protocol If Risk Has Been Identified For COBRA trial Patients

THOUGHTS

"I see that you've said / you mentioned that…….. These are thoughts / feelings that people suffering from depression often have, but it's important to make sure you are receiving the right kind of support. So if it's OK, I would now like to ask you some more questions that will explore these feelings in a little more depth."

PLANS

1 Do you know how you would kill yourself? Yes / No

If **yes –** details

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2 Have you made any actual plans to end your life? Yes / No

If **yes –** details

ACTIONS

3 Have you made any actual preparations to kill yourself? Yes / No

If **yes –** details

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4 Have you ever attempted suicide in the past? Yes / No

If **yes –** details

PREVENTION

5 Is there anything stopping you killing or harming yourself at the moment? Yes / No

If **yes –** details

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6 Do you feel that there is any immediate danger that you will harm or kill yourself? Yes / No

If **yes -** details:

FOLLOW-UP FROM PREVIOUS CONTACT

7 **If Action B was enacted at previous assessment and level B risk is identified at current assessment**: Last time we met I suggested that you spoke to your GP about these thoughts, and I also wrote to your GP about this. Have you been able to speak with your GP about these thoughts since we last met? Yes / No

To be used following any indication of risk from questionnaire items, responses to interview questions or any other sources. Look at answers from the sheet to determine level of risk, A B or C:

Actions by COBRA trial Staff Member	***Tell Participant***
All answers 'no' apart from Q5 'yes':	
A	*I can see that things have been very difficult for you, but it seems to me these thoughts about death are not ones you would act on – would this be how you see things? (if they say yes) I would advise you to make an appointment to see your GP to talk about these feelings.*
'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6	
B1	*Things seem to be very hard for you right now and I think it would help if you were to speak to your GP about these feelings. I will be writing to your GP to tell them that you have been here today and have been having some troubling thoughts. I would also advise you to make an appointment to see your GP to talk about these feelings.*
'Yes' for any **one** of Qs 1-4; plus 'yes' for Q5 and 'no' for Q6 **and** 'no' to Q7	
B2	*I think it's important that your GP knows how difficult things are for you right now. I will be telephoning your GP to speak with him/her and suggest that you meet with one another. I also advise that you make an appointment to see your GP to talk about these feelings. N.B: telephone call to GP to be followed up by letter. The letter should include the statement "*the clinical management of this patient remains your responsibility, but it is part of our protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your care plan.*"*
Scoring 'no' to Q5 or 'yes' to Q6	
C Actively Suicidal	*I am very concerned about your safety at this moment, I am going to make some telephone calls to your GP/ Care Co-ordinator / Crisis Management team/the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.*

Action to take in the case of immediate risk:

Participant needs immediate help – **do not leave them alone, or if on telephone, do not hang up**. Follow your chain of supervisory contact in order to involve supervisory clinician right away. Then (with supervisor if possible) follow the chain of contact below:

1. **GP/out-of-hours GP**; if not
2. **Crisis team;** if not
3. **Clinician accompanies to A&E**; if not (or interview is over telephone)
4. **Call ambulance.**

Date risk protocol enacted: Participant ID:		
Time Point: Telephone screen / Baseline / 6 month / 12 month / 18 month / other, please specify:		
Risk protocol has identified level of risk as: A B1 B2 C		
Suicide Risk Information: Report which questionnaire and the score that gave cause for concern and attach copy of risk assessment. Include whether the participant has reported any of the following: • Current suicidal ideation • Suicide plans • Active preparations to commit suicide • Protective factors or lack of them • Regular contact with GP?		
Clinical supervisor contacted: Y / N Date: Name of supervisor:		
Actions taken:		
Additional relevant information:		
Researcher Name:	Date:	Signature:
Clinical Supervisor Name:	Date:	Signature:

Supervisory Clinicians and Emergency Contact Numbers - Exeter Site

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding COBRA risk protocol"

Supervisory Clinicians

The MDC Operational Manager holds diaries for most University of Exeter staff and can help locate them.

1. Chief Investigator (Exeter): Prof Dave Richards –

2. Co-Investigators (Exeter):
Prof Willem Kuyken –
Prof Ed Watkins –
Dr Paul Farrand –
Dr Kimberly Wright –
Dr Heather O'Mahen –
3. Principle Investigators:
Dr Dean McMillan (York) –
Dr Dave Ekers (Durham) –

4. Trial Manager (Exeter): Shelley Rhodes –

Emergency Contact Numbers

1. The **Mental Wellbeing & Access Networks** are the first points of contact for crisis intervention during normal working hours**:**

- Exeter: Exeter team; 8am – 6pm; Newton Abbot: Teignbridge team; 8am-6pm;
- Barnstaple: Tawside team; 8am-6pm;

2. Out of hours or in an emergency where you cannot get hold of the MWb&A team contact the **Crisis Resolution Home Treatment Team:**

- Exeter: Exeter, East & Mid Devon team;
- Newton Abbot: Teignbridge team;
- Barnstaple: North Devon team;

Please note that these numbers are to make an urgent referral to the Crisis Team and should not be given out to participant /members of the public under any circumstances. The participant's GP can also make an urgent referral to the Crisis Team and should be the first port of call.

1. **Accident and Emergency Department**

- Exeter: Royal Devon & Exeter Hospital, Barrack Road, Exeter, EX2 5DW
- Newton Abbot: Torbay Hospital, Newton Road, Torquay, Devon, TQ2 7AA
- Barnstaple: North Devon District Hospital, Raleigh Park, Barnstaple, Devon, EX31 4JB

Supervisory Clinicians and Emergency Contact Numbers - York Site

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding COBRA risk protocol"

Supervisory Clinicians

1. Principle Investigator (York): Dr Dean McMillan –

Faye Plummer), Kerry Cipriano (– work days Monday, Tuesday, Wednesday and Friday) and Alice North (– work days 09:30am to 2pm Monday to Thursday) have access to Dean's diary and can be contacted if he is unavailable.

2. Chief Investigator (Exeter): Prof Dave Richards –

3. Co-Investigators (Exeter):
Prof Willem Kuyken –
Prof Ed Watkins –
Dr Paul Farrand –
Dr Kimberly Wright –
Dr Heather O'Mahen –

4. Principle Investigators:
Dr Dean McMillan (York) –
Dr Dave Ekers (Durham) –

5. Trial Manager (Exeter): Shelley Rhodes –

Emergency Contact Numbers

- Out of Hours GP
    a. Contact West Yorkshire Urgent Care Service: 0345 605 99 99

- Crisis team
    a. Working hours
        Crisis resolution team (referrals line) -
        OR Single Point of Access phoneline for psychiatric and secondary care mental health services -

    b. Out of hours
        Crisis resolution team (referrals line) -
        OR Connect Helpline (Leeds survivor led crisis service); 6pm – 10:30pm;

- Accident and Emergency Departments
    a. Leeds General Infirmary, Great George Street, Leeds, West Yorkshire, LS1 3EX
    b. St James's Hospital, Beckett Street, Beckett Street, Leeds, West Yorkshire, LS9 7TF

Supervisory Clinicians and Emergency Contact Numbers – Durham Site

When contacting staff by mobile if you are unable to reach them please text "URGENT please contact regarding COBRA risk protocol"

Supervisory Clinicians

1. Principle Investigator (Durham): Dr Dave Ekers –
BA supervisor Mark Dawson –

2. Principle Investigator (York): Dr Dean McMillan -

3. Chief Investigator (Exeter): Prof Dave Richards –

4. Co-Investigators (Exeter):
Prof Willem Kuyken –
Prof Ed Watkins –
Dr Paul Farrand –
Dr Kimberly Wright –
Dr Heather O'Mahen –

5. Principle Investigators:
Dr Dean McMillan (York) –
Dr Dave Ekers (Durham) –

6. Trial Manager (Exeter): Shelley Rhodes –

Emergency Contact Numbers
Out of hours GP on 111 NHS Direct 0845 46 47

Helplines;
Mental Health Matters 0800 085 7027 SANEline 0845 767 8000
Samaritans 08457 90 90 90 National Domestic Violence Freephone Helpline 0808 2000 247

Crisis Team- 24 hours
- North Durham
- South Durham and Darlington

Accident and Emergency Department / Urgent Care Centre

North Durham
- Durham: University Hospital Of North Durham, North Road, Durham, County Durham, DH1 5TW. Tel: Urgent Care Centre (Peterlee), Peterlee Hospital, O'Neill Drive, Peterlee, County Durham, SR8 5UQ
- Sunderland Royal Hospital, Kayll Road, Sunderland, SR4 7TP

South Durham
- Darlington Memorial Hospital, Hollyhurst Road, Darlington, County Durham, DL3 6HX.
- Darlington Walk-In Centre, Dr Piper House, King Street, Darlington, County Durham, DL3 6JL,

Teesside A&E Departments (some in south may find this is closer than Darlington)
- University Hospital Of North Tees, Hardwick Road, Stockton-on-Tees, Cleveland TS19 8PE.
- The James Cook University Hospital. Marton Road, Middlesbrough, Cleveland, TS4 3BW.

Durham Police 0345 60 60 365 Emergency & Non-Emergency (**In emergencies, if no answer call 999)**

Adverse Event Reporting

Adverse Event

An **Adverse Event (AE)** is any untoward or unintended medical occurrence or response, whether it is causally related to the trial treatments or not.

Serious Adverse Event

An adverse event can be further classified as a **Serious Adverse Event (SAE)** if the event is:

- Fatal
- Life threatening
- Requires hospitalisation or prolongs existing hospitalisation
- Results in significant or persistent disability or incapacity
- Results in congenital abnormality or birth defect
- Leads to any other condition, judged significant by a clinician.

Immediate Action for Reporting an SAE

If you are alerted to an **SAE** please contact your site PI. An immediate report (within 24 hours of a **SAE** coming to light) must be made orally or in writing to the research sponsor (University of Exeter) Therefore, telephone the Chief Investigator (or the Trial Manager (at the Exeter site immediately. If you are unable to speak to either the CI or the TM and have left answer phone messages, it is important that you also text the Chief Investigator.

Please complete an **Adverse & Serious Adverse Event Recording Form** and fax a copy to the Exeter site immediately ().The immediate report must be followed by a detailed written report of the event. This report must also be sent to the main Research Ethics Committee (South West REC) and the COBRA DMC within 15 days of the CI becoming aware of the event. This will be handled by the lead site (Exeter).

At 6, 12 and 18 month follow-up assessments AE & SAE that might have occurred since the previous visit should be elicited from the participant. If a participant (or their GP or next of kin) discloses an AE or SAE please document it using the Adverse & Serious Adverse Event Recording Form. As COBRA is a non-CTIMP we are not required to log all non-serious AE's, however the Adverse Event & Serious Adverse Event Recording Form allows researchers to record AE's when it is not immediately clear if it falls into the SAE category.

General completion guidelines

Ask the participant the start and end date/time of the event. If they cannot remember then enter as accurate an estimate as possible. Document the outcome of the event and any actions taken. Confirm it with your site PI and ask them to countersign it.

Please note that ALL instances where the risk protocol is enacted must be recorded in the usual manner on the Risk Form and countersigned by the site lead or a nominated deputy.

Adverse & Serious Adverse Event Recording Form

Date of incident:	Participant ID:		
Details of incident: Outcome:			
Please indicate type (tick all that apply): Fatality: ☐ Persistent or significant disability or incapacity: ☐ Life-threatening: ☐ Congenital anomaly or birth defect: ☐ Hospitalisation or prolongation of hospitalisation: ☐ Other: ☐			
Additional relevant information:			
Action taken by research team (if any):			
Name of Researcher (BLOCK CAPITALS):	Date:	Signature:	
Name of site PI (BLOCK CAPITALS):	Date:	Signature:	

Serious Adverse Event (SAE) Report Form

The Chief Investigator should report any SAE to the sponsor within 24 hours, orally or in writing. The immediate report must be followed by a detailed written report on the event, using the form below. A copy of this form must also be sent to the main Research Ethics Committee and DMC within 15 days of the CI becoming aware of the event.

1. Details of Chief Investigator

Name:	Prof David A Richards
Address:	XXXX
Telephone:	
Email:	XXXX
Fax:	

2. Details of Study

Full title of study:	COBRA (Cost and Outcome of BehaviouRal Activation): A randomised controlled trial of behavioural activation versus cognitive behavioural therapy for depression
Name of main REC:	South West Research Ethics Committee
REC reference:	12/SW/0029
Research sponsor:	University of Exeter
Sponsor's reference for this report (if applicable):	

3. Type of Event

Please categorise this event, ticking all appropriate options:

Fatality: ☐	Life threatening: ☐	Hospitalisation or prolongation of hospitalisation: ☐
Persistent or significant disability or incapacity: ☐	Congenital anomaly or birth defect: ☐	Other: ☐

4. Circumstances of the Event

Date of event:	
Location of event:	
Describe the circumstances of the event (attach further details if required):	
What is your assessment of the implications, if any, for the safety of study participants and how will these be addressed?	

5. Declaration

Name of Chief Investigator: (BLOCK CAPITALS)	
Date of submission:	
Signature:	

6. Acknowledgement of Receipt by REC

The South West Research Ethics Committee acknowledges receipt of the above.

Name: (BLOCK CAPITALS)	
Position on REC:	
Date:	
Signature:	

Signed original to be sent back to the Chief Investigator; copy to be kept for information by main REC.