1. Policy Statement

GPs are responsible for the ongoing clinical care of CADENCE study participants. Therefore, all study 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.

Generally, contact with the GP will be made following discussion and with full consent from the study participant. However, if the participant refuses permission for the cardiac rehabilitation nurses to inform the GP then the nurse should consult the site **Supervisory Clinician** (nominated by the Chief Investigator / site principal investigator). This consultation should take places immediately if risk is considered imminent and within 2 working days if risk is not considered imminent. If it is concluded that there is a significant risk (i.e. the patient has thought how they would kill themselves, has made plans to kill themselves, has made preparations to harm self, or has a history of self harm), the patient's GP will be notified **with or without** the patient's consent. In cases in which GPs are contacted without the patients consent, the decision to do this should be explained to the patient as soon as possible.

Cardiac rehabilitation nurse must initiate the risk protocol each time a participant is perceived to exhibit suicide risk, i.e. expresses suicidal thoughts / ideas, thoughts of self-harm, or thoughts of harm to others. Risk may come to light as a result of responses to questionnaire items or the participant may disclose information during an interview that leads the nurse to believe that there are thoughts of suicide or harm to self or others.

2. Principles

The following principles and procedures govern risk assessment, reporting and monitoring for the CADENCE Study.

The CADENCE Study excludes at baseline interview participants who are actively suicidal. For the purposes of this study "actively suicidal" is defined as someone who has suicidal thoughts, who shows evidence of planning / preparation to harm/ kill themselves AND i) reports there is nothing preventing them from harming / killing themselves or ii) feels at immediate risk that they might harm / kill themselves. Actively suicidal equates with scoring yes to at least one of questions 1 to 4, in the risk protocol (page 6 of this document) plus Scoring 'no' to Q5 or 'yes' to Q6. . Since suicidal intent can fluctuate considerably from day-to-day, we will also exclude patients who have harmed themselves / attempted suicide in the 4 weeks prior to the recruitment interview.

However, included participants who are not suicidal at the time of recruitment might develop such risk during the study and must be assisted accordingly. Study nurses should receive adequate training/supervision to respond appropriately to this risk, working within their competence. If a participant discloses any potentially significant thoughts of suicide or self-harm, study nurses must initiate the risk protocol.

The Chief Investigator has overall responsibility for ensuring that the processes and standards for risk assessment and management are maintained for the duration of the CADENCE Study. Responsibility for these processes and standards for risk assessment and management will be delegated to the local Principal Investigators, for sites other than Exeter.

Specifically, the Chief Investigator and Site Principal Investigators are responsible for:

i) ensuring that any research personnel involved with the CADENCE Study are adequately qualified and trained on risk assessment prior to any patient contact in which risk could be disclosed
ii) ensuring that supervision for risk issues is accessible and readily available
iii) ensuring that study nurses are aware of who can provide supervision (i.e. the Supervisory Clinicians) and how supervisors can be contacted, and
iv) 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 CADENCE Study staff and the Project Manager/Academic Lead.

3. Procedures for study nurses

Background training materials are available from the CADENCE Study team in Exeter. All study nurses will attend training in the use of the risk protocol and new staff who will be involved in assessing/treating patients will be familiarised as part of their induction/training. All study nurses should attend such training at least biennially. Risk assessment should therefore be conducted only following appropriate training and with appropriate supervision.

Definition of suicide risk

The Patient Health Questionnaire/PHQ-9 include questions about suicide risk. CADENCE Study staff should always respond to any risk identified via the PHQ-9 (as specified below), and a risk assessment in line with this protocol should be completed. Patients may also disclose suicidal thoughts during any other face to face or telephone contact.

In the CADENCE study, suicide risk is identified by:

1) A score of 1 or more on the **PHQ-9** item 9, i.e. see items **in bold** below Q9.
   Over the last two weeks, how often have you been bothered by thoughts that you would be better off dead, or of hurting yourself in some way?:
   0. Not at all
   1. Several days
   2. More than half the days
   3. Nearly every day
2) Patients who disclose information during other interviews (face-to-face or telephone) with the study nurse, indicating that they have attempted

suicide or that they have been thinking of ways to commit suicide, will be considered to be at risk of suicide.

All personnel working on the CADENCE Study 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 imminent risk and within 2 working days for less immediate concerns.**

Actions to be taken

Before interviewing a participant (either telephone or face-to-face), the study nurses should review all previous data on suicide ideation and ensure that contact details for the Supervisory Clinicians are current. When suicide risk is suspected, study nurses must initiate the risk protocol each time a study participant expresses thoughts of suicide (during an interview or through reviewing patient reported outcome measures).

The risk protocol includes:

1) Asking appropriate questions to clarify exact thoughts / plans held by the subject. Suggested scripts to clarify patients thoughts / plans about self-harm suicide can be found in Figure 1.
2) Taking the appropriate action to inform the GP and ensure responsibility for managing the risk is passed-on to the correct person / agency as appriopriate, by telephone / fax / letter, as indicated in the protocol. If contact is made by fax, a telephone call to the GP Surgery should be made to ensure receipt of the fax. Record details of any telephone conversation (time of call, who discussed with, decisions on actions taken) and always follow-up telephone call with a completed GP risk letter (see below). A schematic of the actions to be taken should risk be suspected, in light of the patient responses, can be found on Page 7 of this document.
3) Discussing the case with one of the nominated Supervisory Clinicians.
    a. For the majority of cases where risk is non-urgent (level A, B1 and B2 risk according to the risk protocol on page 7), appropriate actions can be taken according to the risk protocol and discussions with supervisor can take place within 2 working days, ideally at the time when the supervisor is signing off the risk assessment form, so that any details can be clarified.
    b. For cases of immediate risk (i.e. actively suicidal – level C risk according to the protocol on page 7), supervision needs to be sought immediately. Please note, however, that the risk training and the risk protocol have been designed to clarify the most appropriate course of action in the event of immediate suicide risk. Safeguarding the well-being of the patient, by following the risk protocol, is the immediate priority and, providing the appropriate course of action is clear, the nurses should feel empowered to act in line with the risk protocol to ensure risk is managed quickly and appropriately. Nurses who have been appropriately trained should

not feel constrained to delay appropriate actions until supervision has been sought, in cases where the appropriate course of action is clear. In such cases clinical supervision should be sought immediately after appropriate responses to risks have been enacted.

c. In cases of immediate risk where the appropriate course of action is not clear to the nurse, it may be necessary to seek clinical supervision immediately, before any clinical response is enacted.

4) Completing the risk assessment form (Appendix A), recording any decisions made during supervision with Supervisory Clinician on the risk assessment form.
5) Send the risk assessment form to the study manager / administrator at each site for recording in the patient contact files, along with a copy of the letters / faxes to the GP / other healthcare professionals. This should be done at the time of the assessment, or within 2 working days. This report should not contain any information that could identify the patient.
6) Record any subsequent contact with healthcare practitioners in writing, discuss with a supervisory Clinician. Details of contact should be send to the study manager / administrator.
7) All assessment reports and correspondence relating to risk sent by nurses will be checked by one of the Supervisory Clinicians (see delegation of Duties log) before they are sent to GPs / other healthcare professional or filed in the patient contact and risk file.

Patients consent to contacting the GP

Whenever a study nurse becomes aware that a participant has thoughts of suicide / self-harm, the study nurse should reinforce the importance of maintaining a dialogue with his/her GP and ask for permission to pass the information to his/her GP.

If the participant agrees to this communication, the study nurse should write / telephone the participant's GP within 48 hours to pass on the information obtained (as detailed in the schematic on page 7). On telephoning, if the participant's GP is not available then the study nurse should ask to speak to the duty doctor. The study nurse should make it clear to the GP that that they are not able to provide specialist mental health support and that clinical responsibility for the management of suicide risk among study participants remains with the GP. If the participant does not agree to their GP being informed, the study nurse should contact the Supervisory Clinician to discuss.

4. 'Questions To Ask' and Protocol If Risk Has Been Identified For CADENCE Study 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** (i.e. nurse writing to the GP to inform of risk and suggesting that patient makes appointment to see GP) **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 to be taken by CADENCE Study Staff	***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. My study protocol guidance means that I must write 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. My study protocol guidance means that I must telephone 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. Please make sure that you are familiarised with your phone system, and know how to put callers on hold/mute while you contact the supervisory clinician. This might involve using conference facilitites on networked phones or accessing a second phone line/mobile to request assistance.**

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.**

Appendix A: CADENCE Study Risk Assessment Form

Date risk protocol enacted:			**Participant ID:**	
Time Point: Telephone screen / Baseline / 5 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:

Study nurse Name:	Date:	Signature:
Clinical Supervisor Name:	Date:	Signature:

Appendix B: GP Risk Letter

Surgery Address

Date

Dear Dr xxxxxxxxxx

POTENTIAL RISK TO PATIENT

Re: Study Participant Name_____
DOB_____

As you know, PATIENT NAME, is taking part in the CADENCE Study which is developing and testing an enhanced psychological care intervention (consisting of behavioural activation and/or care coordination) for patients who experience depressive symptoms after an acute cardiac event.

As part of the study, a study nurse from the CADENCE team interviews patients on a number of occasions to assess their health. During these assessments, we assess risk, including risk to self and others and suicide risk.

During the interview we conducted on DATE, PATIENT NAME reported …….. (DETAILS OF PARTICIPANT'S THOUGHTS, PLANS ACTIONS).

As a consequence of this we instigated the CADENCE Study risk policy. We ……
(DETAILS OF ACTIONS TAKEN).

The CADENCE Study's clinical and research procedures do not provide participants with services to manage significant risk to self or others, including suicidal intentions. Clinical management of all patients in the CADENCE Study remains the responsibility of their GP. Of course, as part of our study protocol we have a duty to inform you of these disclosures and our actions in response to them so that you can take account of them in your clinical management of this patient. We trust that the above information will be of value to you in doing so.

Yours sincerely,

Site Study nurse Supervised by Site Clinical Lead

Cc: Participant