Report Supplementary Material 3: Risk protocol and letter of notification

Researcher Risk Escalation Protocol:

Disclosure of self-harm/suicide risk and other potential risks

NHS National Institute for Health Research

The following principles and procedures govern the assessment, reporting and monitoring of risk of self-harm/suicide or other potential risks for the RESPECT study

- All researchers should follow this protocol when conducting all participant assessments.
- All researchers will be given risk training specific to this study.
- When clinical leads are away they should ensure appropriate cover is arranged for any risk issues that may arise.

This study specific procedure includes the following:

1. **Preparation for sessions**
2. **Exploring risk questions & level of risk**
3. **Reporting risk to clinical lead**
4. **Documenting the procedure and storage**
5. **Exploring other risk issues**

Appendix 1: Clinical lead contact details

Appendix 2: Self-harm/suicide risk disclosed during questionnaire/interview session: flow chart 1

Appendix 3: Exploring risk questions

Appendix 4: Exploring risk questions - Guidance

Appendix 5: Self-harm/suicide risk form

Appendix 6: Non-suicide risk form

1. Preparation for assessments

The researcher **must** ensure that they have the following documents with them when conducting questionnaire/interview sessions with participants to ensure risk protocols can be implemented as quickly and as accurately as possible:

- A copy of the 'researcher protocol: Disclosure of self-harm/suicide risk and other potential risks'
- Contact details for clinical lead(s)
- Copies of the risk of self-harm/suicide flowchart
- A blank copy of the 'exploring risk questions'
- A copy of the 'exploring risk questions' Guidance
- A copy of the 'self-harm/suicide risk form'
- A copy of the 'non-suicide risk form'
- Access to a mobile phone

- Contact details for: participant's care co-ordinator/duty worker, out of hours/crisis team/local taxi number- in case of risk emergencies.

Disclosure of risk during questionnaire/interview session:

- This protocol must be enacted if the participant discloses risk of suicidal thoughts/intent/plans, or expresses risk of self-harm to the researcher during a questionnaire/interview session.
- This protocol must also be enacted if the participant discloses other potential risks (see section 5).

2. Exploring Risk Questions & Level of Risk

- If risk of self-harm/suicide is disclosed during the questionnaire/interview session, the six 'exploring risk questions' should be asked.

Actions to take following disclosure of risk of self-harm/suicide:

- Explain to the participant that you need to ask them some further questions, using the following phrase:
  "You have mentioned <repeat participant's words used in interview>. I'm sorry that you're feeling this way right now. I would like to ask you a few more questions that will explore these thoughts and feelings further. Some of the questions are sensitive but they are very important in making sure you receive the right kind of support"
- Ask the participant the six 'exploring risk questions' (**Appendix 3**) make sure you document **verbatim** the participant's responses to the probing question **and** each of the six exploring risk questions to aid in establishing level of risk.
- Use the 'exploring risk questions guidance' (**Appendix 4**) to determine the possible level of risk & advise the participant of the outcome:

- **Level A:** advise the participant to make an appointment to see a member of their care team to talk about their thoughts and feelings. **Contact the** clinical lead listed in **Appendix 1 by telephone immediately following the session.**

- **Level B:** advise the participant that you will be writing to their care coordinator/duty worker to tell them they have been experiencing these thoughts and feelings, and advise them to make appointment to see a member of their care team to talk about their thoughts and feelings. **Contact** clinical lead **by telephone immediately following the assessment.**

- **Level C:** advise the participant that you are going to contact your clinical contact and their care coordinator/duty worker/the emergency services to let them know they have been experiencing these thoughts and feelings and to arrange for them to receive immediate help. **Contact the** clinical lead **by telephone IMMEDIATELY.** If they do not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… Level C risk'. The clinical lead will then respond when available. The researcher should then **follow the 'Actions to take in the case of immediate risk' below.**

- The researcher should then contact the Clinical lead by telephone to advise them of the risk of self-harm/suicide, the participant's responses to the exploring risk questions and your response following the exploring risk questions guidance.

- If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… risk'. The clinical lead will then respond when available.

- If the clinical lead advises/confirms that a letter needs to be sent to the participant's care co-ordinator/duty worker, a brief narrative summary of the participant's response to the exploring risk questions should be completed. The letter should be signed by the researcher and countersigned by the clinical lead and sent to the participant's care team.

- The researcher should sign and date the exploring risk questions form.

- The researcher should then complete the 'self-harm/suicide risk form' (Appendix 4). This needs to be signed and dated by the researcher and countersigned and dated by the clinical lead.

Actions to take in the case of immediate risk:

- If the level of risk has been identified as **Level C** then the participant requires immediate help – **do not leave the participant alone.**
- Contact the clinical lead by telephone **IMMEDIATELY.** They will discuss with the researcher the necessary actions to take, which are likely to include one or more of those listed below.
- If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating 'STUDY… IMMEDIATE risk'. If the clinical lead does not respond immediately, the researcher should take one of the actions listed below.
- Contact care coordinator/duty worker.
- Accompany the participant to A&E if the participant is on hospital premises – do not leave the participant until a clinician has taken responsibility for their care.
- Call a taxi to take the participant to A&E if participant is not on hospital premises. The researcher should accompany the participant to A&E and should not leave the participant until a clinician has taken responsibility for their care.
- Call an ambulance.

Telephone Numbers for care co-ordinator/ duty worker: <insert relevant number>

3. Reporting risk to clinical lead

- If a participant has been disclosed being at risk of self-harm/suicide, the researcher must contact the clinical lead by telephone via the contact details list.

- If the clinical lead does not answer the phone, the researcher should leave a voice message and then immediately send a text stating ‘STUDY… risk’. The clinical lead will then respond when available.
- The researcher will need to report how the risk was identified/disclosed and the participant’s verbatim responses to the exploring risk questions.
- The clinical lead and researcher will decide whether or not the participant’s care coordinator/duty worker should be contacted, and if so whether to contact them by letter or by telephone, depending on the level of risk:
- The clinical lead may advise the researcher not to call or send a letter to the participant’s care team (i.e. Level A risk).
- The clinical lead may advise the researcher to send a letter to the participant’s care team (‘Letter: Notification of Risk’) detailing a brief narrative summary of the participant’s response to the exploring risk questions. The letter must be signed by the researcher and countersigned by the clinical lead.
- The clinical lead may advise the researcher to contact the participant’s care coordinator/duty worker by telephone to advise them of the participant’s risk of self-harm/suicide.
- The researcher is to inform the clinical lead when the participant’s care coordinator/duty worker has been informed (by telephone or by letter) of the risk of self-harm/suicide.
- The researcher should sign and date the exploring risk questions form.
- The clinical lead should countersign and date the ‘self-harm/suicide risk form’ once completed and signed and dated by the researcher.

4. Documenting the procedure and storage

- The researcher must ensure they have signed and dated the exploring risk questions form.
- Researcher must ensure the self-harm/suicide risk form (**Appendix 5**) has been completed accurately, signed and dated, and has been countersigned and dated by the clinical lead
- Researcher to clearly document all contacts, decisions, actions/lack of actions and rationales on the self-harm/suicide risk form. The form should be signed and dated by the researcher, and countersigned and dated by the clinical lead
- Researcher to document on the study spreadsheet that the risk protocol has been enacted and that letter has been sent to participants care coordinator/duty worker
- Researcher must ensure the completed self-harm/suicide risk form and exploring risk questions form have been filed away in the participant’s personal non-data file.
- Researcher must ensure that a copy of the ‘Letter: Notification of Risk’ letter is stored in the participant’s personal non-data file.

There may be instances where a different course of action needs to be implemented from those detailed here, where this is deemed clinically appropriate following consultation with a clinician. Any such instances will be documented appropriately on the self-harm/suicide form.

5. Exploring other risk issues

Instances may arise when other non-suicide risk issues need to be explored. Such instances may include, but are not restricted to:

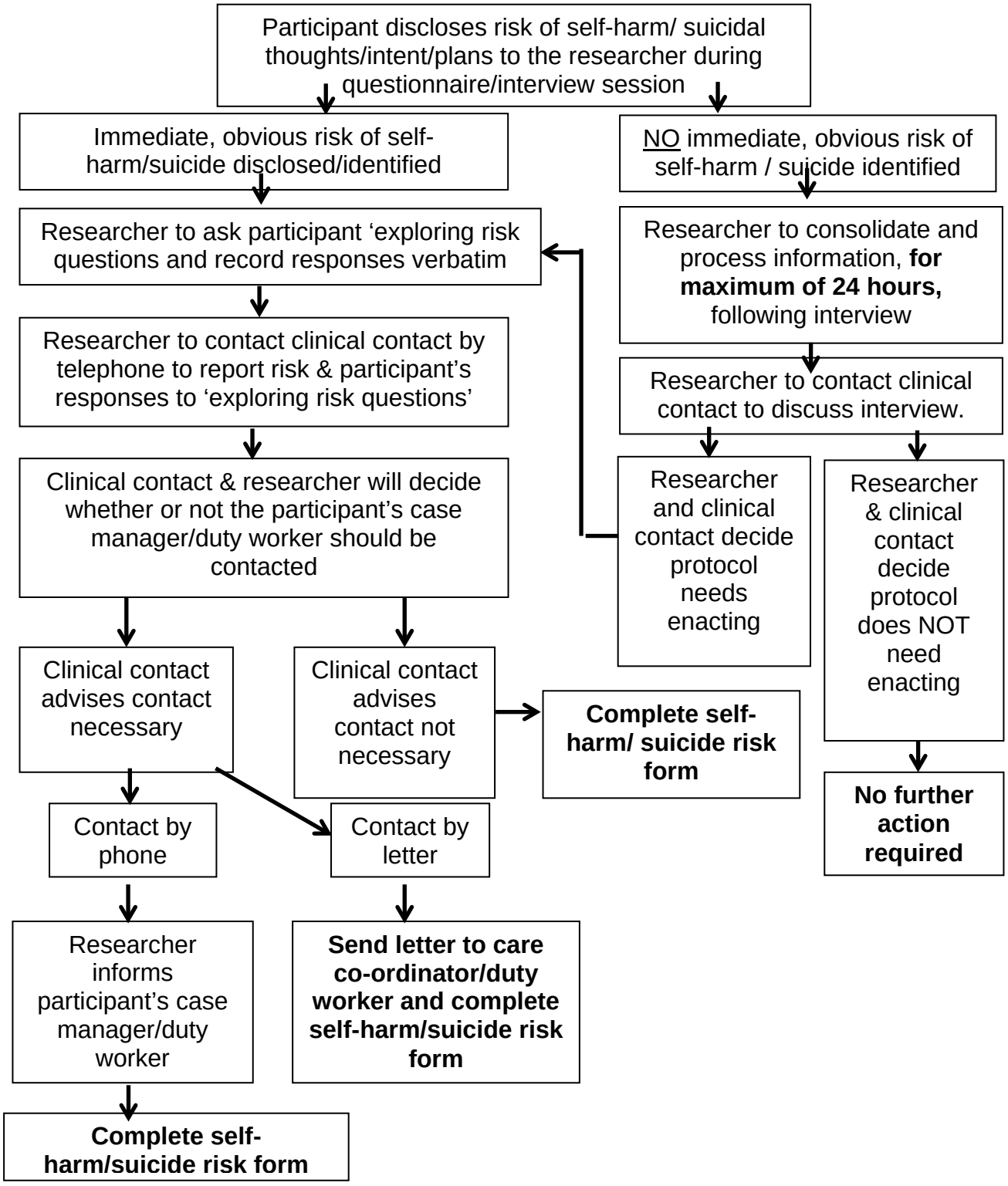
- Risk to others
- Risk from others - this includes events such as domestic violence

- The researcher should contact the clinical lead by telephone to discuss their concerns.
- Researcher must ensure the non-suicide risk form (**Appendix 6**) has been completed accurately, signed and dated, and has been countersigned and dated by the clinical lead
- Researcher to clearly document all contacts, decisions, actions/lack of actions and rationales on the non-suicide risk form. The form should be signed and dated by the researcher, and countersigned and dated by the clinical lead
- Researcher to document on the study spreadsheet that a non-suicide risk form has been completed.
- Researcher must ensure the completed non-suicide risk form has been filed away in the participant's personal non-data file.
- If any letters are sent regarding a non-suicide risk, the researcher must ensure that a copy of the letter is stored in the participant's personal non-data file.

Appendix 1 Clinical Lead Contact Details

	Contact 1: **Professor Elizabeth Hughes**	**Contact 2:** **Professor Fiona Nolan**
Role	Chief Investigator / Clinical contact	Clinical contact
Mobile		
Email	E.C.Hughes@hud.ac.uk	fiona.nolan@candi.nhs.uk

Appendix 2 Self-harm/suicide risk flowchart 1: Disclosed via questionnaire/interview session



Appendix 3 Exploring risk questions

Probing question: "Can you tell me more about why you expressed suicidal thoughts/intent/plans? Details of disclosed thoughts (please record verbatim as far as possible)	
Plans	
1. Do you know how you would kill yourself? If **Yes** – details	Yes / No
2. Have you made any actual plans to end your life? If **Yes** – details	Yes / No
Actions	
3. Have you made any actual preparations to kill yourself? If **Yes** – details	Yes / No
4. Have you ever attempted suicide in the past? If **Yes** – details	Yes / No
Prevention	
5. Is there anything stopping you killing or harming yourself at the moment? If **Yes** – details	Yes / No
6. Do you feel that there is any immediate danger that you will harm or kill yourself? If **Yes** – details	Yes / No

Researcher name:

Researcher signature: **Date:**

Appendix 4 Exploring risk questions guidance

This guidance is to be used to determine the level of risk, A B or C, based on the participant's responses to the six Exploring Risk Questions.

Participant's responses to Exploring Risk Questions	**Advise the 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 a member of your mental health team 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 a member of your mental health team about these feelings. I will be writing to your care co-ordinator 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 a member of your mental health team to talk about these feelings.*
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/ the emergency services to let them know how you are feeling and to arrange for you to receive immediate help.*

Appendix 5 Self-harm/suicide risk form

The participant below has disclosed/identified as having thoughts of suicidal intent/self-harm during the questionnaire/interview session.

Participant ID Code: ☐ ☐ ☐

Date of questionnaire/interview session:

Has the participant been advised to contact their care co-ordinator/ duty worker?: Yes ☐ No ☐

Has the care team been sent the notification of risk letter? Yes ☐ No ☐

Summary of how suicide risk protocol was implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact care co-ordinator/duty worker within mental health team, name of person spoken to, date of contact)

Researcher name:

Research signature: **Date:**

Name of clinical contact:

Clinical contact **signature:** **Date:**

Appendix 6 Non-suicide risk form

The participant below has disclosed/identified as being at risk other than self-harm/suicide during a questionnaire/interview session.

Participant ID Code: ☐ ☐ ☐

Assessment date:

Risk identified and how:

Summary of how risk protocol implemented:

(Which clinician gave advice, what advice was given, was risk judged as passive or active? If advised to contact care co-ordinator/duty worker within mental health team- name of person spoken to, date of contact)

Researcher name:

Research signature: **Date: ……..**

Name of clinical contact:

Clinical contact **signature:** **Date: ……..**

[Name of Care Coordinator
Name of Team
Address 1
Address 2
Address 3
Address 4
Postcode
Insert Date]

Dear [Name of Care Coordinator]

Re: NOTIFICATION OF RISK –[*Forename Surname; DOB; NHS Number*]

RESPECT: Randomised Evaluation of Sexual health Promotion Effectiveness informing Care and Treatment: a feasibility study of an intervention aimed at improving the Sexual Health of People with Severe Mental Illness

As you know, your patient, [*Forename Surname]*, is taking part in the above study. As part of this study we explore issues relating to sexual risk.

I am writing to let you know that [*Forename Surname*, *insert brief narrative summary of identified risk]*

I have recommended that they make an appointment to come and see you and discuss this further.

As ever, the clinical management of this patient remains your responsibility, but it is part of our study protocol to inform you of any risks disclosed to ourselves so that you can take account of them in your clinical management of this patient.

Yours sincerely

[Print Researcher Name]

RESPECT study

[Print Clinical Lead Name]

RESPECT Study