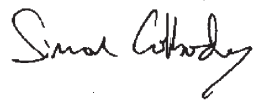
Study Specific Procedure 2
Researcher guide to reporting risk

Study Specific Procedure Version no.	Date Approved	Clinical supervisor Signature
V1.8	02/12/13	

The following principals and procedures govern risk assessment and reporting in the CASPER study:

- All researchers will have received the CASPER risk training.
- Whenever any risk is identified a risk assessment should be completed and (counter-) signed by the local clinical lead / principal investigator and researcher who identified risk as soon after the assessment as possible.
- When site clinical leads are away they should ensure appropriate cover is arranged for any risk issues that might arise in their absence.

2.1 When to report risk of self-harm / suicide

The procedure must be enacted if:

On any questionnaire returned through the post,

- A participant scores 1 (*several days*) or 2 (*more than half the days*) on Question 9 of the PHQ-9 '*Thoughts that you would be better off dead, or of hurting yourself in some way*' **AND** has a total score of 20 or above on the PHQ9 questions.

  OR

- A participant scores 3 (nearly every day) on question 9 of the PHQ-9 *'Thoughts you would be better off dead or of hurting yourself in some way'*

During the diagnostic interview,

- A participant scores 1 (*several days*) or 2 (*more than half the days*) or 3 (nearly every day) on Question 9 of the PHQ-9 '*Thoughts that you would be better off dead, or of hurting yourself in some way*'.

  OR
- A participant answers '*Yes'* to Question 3g of the MINI during the diagnostic interview '*Did you repeatedly consider hurting yourself, feel suicidal, or wish that you were dead? Did you attempt suicide or plan a suicide?*' **N.B.** If the participant scores '*Yes'* to a past episode but **not** to the past 2 weeks on Question 3g then the procedure does not have to be enacted.

(See appendix 1 and 2 for flow charts illustrating when and how to enact risk procedure)

2.2 Exploring level of risk

There are six Exploring Risk questions and a PHQ-9 probing question (see page 3) to be used following indication of risk from Question 9 of the PHQ-9 or during the diagnostic interview where a participant responds 'Yes' to Question 3g of the MINI.

Exploring risk procedure for questionnaires

- If a participant scores 1 or 2 on any of the questionnaires for PHQ-9 Question 9 AND has a total PHQ-9 of 20 or above OR a participant scores a 3 on the PHQ-9 Question 9. Try to telephone the participant first. If unable to reach participant to explore level of intent, contact clinical lead / principal investigator for advice.
- Explain to the participant that you are calling because you are concerned about their wellbeing as they have answered having '*Thoughts that you would be better off dead, or of hurting yourself in some way'* for ('*several days'*/ '*more than half the days'* / '*nearly every day*') in the last 2 weeks.
- Ask the Exploring Risk questions. First, ask the PHQ-9 probing question to document disclosed thoughts about their answer to the Q9 of the PHQ-9. Then ask the 6 risk questions. *As far as is possible, please record the participant's own thoughts/words to assist in establishing active or passive ideation.*
- Explain that you have to inform the CASPER research team clinical supervisor and may need to inform their GP.
- Advise participant to seek advice/help from GP if the participant feels they need it.

Exploring risk procedure during diagnostic interview

- During a diagnostic interview, if the participant scores *anything* other than 0 (*not at all*) on the PHQ-9 Question 9 **or** the participant answers '*Yes'* to Question 3g of the MINI *in the past 2 weeks* explain that you are concerned about their wellbeing.
- Ask the Exploring Risk questions. First, ask the PHQ-9 probing question to document disclosed thoughts about their answer to Question 9 of the PHQ-9. Then ask the 6 risk questions. *As far as is possible, please record the participant's own thoughts/words to assist in establishing active or passive ideation.*
- Explain that you have to inform the CASPER research team clinical supervisor and may need to inform their GP.
- Advise participant to seek advice/help from GP if the participant feels they need it.

Informing the participant of potential GP contact

- During telephone contact, indicate we may need to inform their GP, but even if the participant does not agree, you ***must*** still speak to clinical lead who will decide how/if the GP needs informing. **N.B.** Remember all participants have already consented to us contacting their GP if we are concerned about their wellbeing as they have initialled box No. 4 *I agree to my GP being informed of my participation in the study and of any health concerns the CASPER study team may become aware of during my participation.* Reassure the participant that their current situation does not necessarily prevent them from participating in the study and will not affect the care they receive from their GP.

Once telephone call to participant has ended

- Contact the site clinical lead / principal investigator to report participant's responses to Exploring Risk questions (see section 2.3). Clinical lead / Principal investigator will decide if/how to report to participant's GP.

Exploring Risk in Research Interviews

Participant ID code: | **PHQ-9 Score:**

PHQ-9 probing question*:* "Can you tell me more about why you answered (several days* / more than half the days* / nearly every day*delete) to 'Thoughts that you would be better off dead, or of hurting yourself in some way'?" 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:**

2.3 Reporting risk to clinical lead / principal investigator

- Researcher must **immediately** report risk of self-harm / suicide to their local Clinical lead / Risk contact/ Principal investigator who will decide if/how the case needs reporting to participant's GP.
- Researcher ***must complete and document*** the first part of the Suicide Intention form stating how the risk was identified and the Exploring risk questions ***prior*** to contacting the clinical lead.
- First, try to phone the clinical lead on their mobile. If there is no answer send a text message to that mobile **immediately**. In the text include participant ID code, suicide risk and your name / contact number. If the participant has been randomised include whether they are sub threshold or above threshold.
- When speaking to the clinical lead inform them of how the risk was identified (questionnaire or diagnostic), the overall score on the PHQ-9, the participant's thoughts/words from the PHQ-9 probing question and exploring risk questions.
- Try local site no.1 contact first followed by local site no.2 contact. If neither available, try one of other site leads. Leeds, Newcastle and Durham to try York clinical lead / principal investigator as second port of call before either each other.

York	1. Clinical Lead	[redacted]	[redacted]
	2. Principal Investigator (Chief Investigator)	[redacted]	[redacted]
Leeds	1. Principal Investigator	[redacted]	[redacted]
	2. Clinical Lead	[redacted]	[redacted]
Durham	1. Clinical Lead / Principal Investigator	[redacted]	[redacted]
Newcastle	1. Case Manager Supervisor 2. Risk contact	[redacted] [redacted]	[redacted] [redacted]

Active risk

- If participant appears actively suicidal, clinical lead / principal investigator may wish to speak directly to participant themselves.
- If case is urgent and risk seems high but no clinician available, 'err on the side of caution' and contact GP immediately without clinical advice, no expectation for you to try all clinicians. Try no. 1 and if no response, call GP direct.
- If participant appears actively suicidal and at <u>immediate risk</u>, if possible try to keep the participant on the telephone whilst contacting their GP. If unable to keep participant on the

telephone, contact the GP straightaway following conversation with the participant to inform them of the immediate risk. IMPORTANT If your are ringing a mobile ensure you know location of the participant. If unable to contact GP, researcher must speak with Clinical Lead and consider contacting emergency services**.**

Passive risk

- If participant's risk seems passive and clinical lead / principal investigator advises you not to phone GP directly, then follow Clinical Lead instructions (see 2.6 Documenting the procedure).

There are no hard and fast rules: if it is clear from the Exploring Risk questions that a participant's ideation is passive, there is no immediate risk and their scores are low, or that they do not have any suicidal thoughts, the clinical lead / principal investigator may advise you to write a letter to their GP or advise that there is no need to inform the GP. However, if any of their responses to Exploring Risk questions indicate that they have made plans / preparations and are actively suicidal, then clinical lead / principal investigator will typically advise you to contact GP immediately by phone to inform them of urgent risk.

2.4 Informing participant's GP

- Typically participant's GP will be aware of risk but in some circumstances it will alert new, unknown risk.
- Researcher should call GP practice and ask to speak to participant's named GP.
- If named GP available, researcher to introduce themselves as part of the CASPER study team and explain their role. To say they are calling regarding one of their (GP's) participants giving participant name / DoB etc.
- **For suicide risk:** Explain that the participant has disclosed that they are having significant suicidal thoughts (give details such as whether this was identified on the PHQ-9 / MINI and any information about plans and preparations).
- **For other risk factors:** Pass on details of issues given by the participant.
- Inform the GP that CASPER protocol states that we need to make them aware of any risk issues, and that it is now their decision as how to proceed with the participant's care.

2.5 If named GP not available

- Ask to speak to another GP. If another GP is available then researcher to introduce themselves as part of CASPER study team, explaining that they have already tried to contact the participant's (give their name, DoB etc) GP but that they are not available.
- If no GP available, ask to speak to the practice manager and ask him / her to pass on the message to a GP as soon as possible. Also ask them to call you back to confirm they have passed on the message.
- If practice manager not available, leave message with receptionist asking for GP or practice manager to ring back as soon as possible. Keep trying to contact the practice until contact with a GP or practice manager has been made.

2.6 Documenting the procedure

- Researcher to inform the clinical lead / principal investigator who advised them to contact GP that GP is aware of risk of self-harm / suicide.
- Researcher to clearly document all contacts, decisions, actions / lack of action and rationales on the YTU database. These should be initialled and dated.
- Researcher must complete Suicide Intention form (page 8) and exploring risk questions, a copy of which must be stored securely (with participant data at York site) once it has been counter signed by Clinical Lead/PI.
- If a GP letter is sent, then a hard copy should be produced and stored securely at relevant site (with the participants documentation at York site) and an anonymous copy with participant ID kept in the 'GP Letters' folder on the 'I' drive for York researchers, and stored on secure server in other centres.

2.7 Exploring other risk areas

Risk from others

- Risk from others includes abuse of elders and can take many forms including physical, psychological, emotional, sexual or financial.
- If risk from others is detected follow procedure 4 Safeguarding Older Adults.

Self neglect

- Self neglect does occur sometimes in older adults. Examples include not eating or caring for one's physical needs. If concerned about self neglect contact local site clinical lead / principal investigator.

Cognitive impairment

- Cognitive impairment does occur in older adults and typically presents as loss of memory. If concerned about cognitive impairment contact local site clinical lead / principal investigator.