

## Telephone Follow-up Script

This documents provides guidance on how to conduct the telephone follow-up call with ROCSS participants. You can collate the follow-up data on the paper data collection form, or directly into REDCap if you prefer.

Script Text Key:

- **Black bold** - suggested dialog
- *Red italic* – *insert the relative information for the individual participant*
- Blue underline – directions or pointers to explaining if subsequent dialog/questions may be needed

| Guidance & instructions  | Script   |
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|  | <b>Introduction</b>  |
| Follow either Scenario 1 or Scenario 2, whichever applies.   | <p>Hello, my name is <i>&lt;name of person making the call&gt;</i>, I am calling from <i>&lt;insert name of hospital&gt;</i>. Please may I speak to <i>&lt;insert participant's name&gt;</i>.</p> <p><u>Scenario 1: If the participant/carer/next of kin is unavailable or unable to take the call:</u></p> <p><b>When would it be a good time to call back and speak to <i>&lt;insert participant's name&gt;</i> directly?</b></p> <p><u>Await response</u></p> <p><b>Thank you very much, I will call back at that time.</b></p> <p><u>Call the back at the agree time/date and complete the consultation</u></p> <p><u>Scenario 2: If you are speaking directly to the participant:</u></p> <p>I am contacting you from <i>&lt;insert name of hospital/institution&gt;</i> regarding the ROCSS trial which you participated in. Hopefully you have recently received a letter and information sheet asking you to participate in this second part of the ROCSS study called ROCSS-EX.</p> <p>As this letter explained, we would like to expand on the information we got during the first part of the trial by asking a few further questions now participants are a few years from surgery.</p> <p>I would like to ask you a few questions about your stoma closure site and some questions about how you have been since you were discharged from hospital. It should take no longer than 20 minutes.</p> |
| Follow either Scenario 1 Scenario 2 or Scenario 3, whichever applies.  | <p><b>Is it ok to complete this consultation now?</b></p> <p><u>Scenario 1: If the answer is No</u></p> <p><b>Would you be happy to take part, and I can call you at a more convenient time?</b></p> <p><u>If No</u></p> <p><b>That is no problem. Thank you again for your time, I'll record your answer and we won't contact you again.</b></p> <p><u>THIS IS THE END OF THE TELEPHONE CALL</u></p> <p><u>If Yes, arrange a mutually convenient time to call back and complete the consultation</u></p> <p><b>"Thank you very much, I look forward to speaking to you next time".</b></p>  |
| Ensure that the re-confirmation of consent is documented in the participant's medical records (electronic or paper). |  |

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|  | <p><a href="#">Call the back at the agree time/date and complete the consultation</a></p> <p><b>Scenario 2: If the answer is Yes</b><br/> Many thanks. Please can I check that you received the letter and Participant Information Sheet through the post?</p> <p><a href="#">If No</a><br/> The information sheet explains what the ROCSS-EX is and the letter contains an overview of the questions we plan to ask you today, to help jog your memory. We do not need them to continue but as they contain information that you might still find useful, like contact details, we would you like to ensure you have a copy. Please confirm the postal address we should use, or if you prefer provide an email address, and we will send another copy to you.</p> <p><a href="#">If Yes</a><br/> Did you read and understand it and do you have any questions about it? If you have it with you, it may be useful to help you as we talk through the questions.</p> <p><a href="#">Answer any questions</a></p>   |
|  | <b>Participant Blinding</b>   |
|  | <p>Firstly, do you know whether or not a mesh was used when your stoma was reversed? Please do not tell me which group you are in. I only wish to find out if you are aware of your group, therefore can you please answer stating either Yes or No?</p> <p><a href="#">Record response – if applicable, also see “Potential treatment allocation queries” (last section of the script)</a></p>   |
|  | <b>Follow-Up Questions – EQ-5D</b>  |
| <p><i>Ask the participant each of the questions as detailed. Tick one box per question according to the answers provided by the participant, and insert the participant's response on the paper data collection form, or directly into REDCap if you prefer.</i></p> | <p><a href="#">Start with the question:</a><br/> <b>We are trying to find out what you think about your health. I will explain what to do as I go along, but please interrupt me if you do not understand something or if things are not clear to you. There are no right or wrong answers. We are interested only in your personal view.</b></p> <p><b>I am going to read out some questions. Each question has a choice of five answers. Please tell me which answer best describes your health TODAY.</b></p> <p><b>Do not choose more than one answer in each group of questions.</b></p> <ol style="list-style-type: none"> <li><b>1. First, I'd like to ask you about MOBILITY. Would you say you have: No problems walking about, slight problems, moderate problems, severe problems, or are you confined to your chair or bed?</b><br/> <a href="#">Record response</a></li> <li><b>2. Next, I would like to ask you about SELF-CARE. Would you say that you have: No problems washing or dressing yourself, slight problems, moderate problems, severe problems, or are you unable to wash or dress yourself?</b><br/> <a href="#">Record response</a></li> <li><b>3. Next, I would like to ask you about USUAL ACTIVITIES, for example work, study, housework, family or leisure activities. Would you say you have: No problem in performing your usual activities, slight problems, moderate problems, severe problems or are you unable to perform your usual activities?</b><br/> <a href="#">Record response</a></li> </ol> |

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|   | <p>4. Next, I would like to ask you about PAIN OR DISCOMFORT. Would you say you have: No pain or discomfort, slight pain or discomfort, moderate pain or discomfort, severe pain or discomfort or extreme pain or discomfort?<br/> <a href="#">Record response</a></p> <p>5. Finally, I would like to ask you about ANXIETY OR DEPRESSION. Would you say that you are: Not anxious or depressed, slightly anxious or depressed, moderately anxious or depressed, severely anxious or depressed, or extremely anxious or depressed?<br/> <a href="#">Record response</a></p> <p>Next, I would like to ask you to say how good or bad your health is TODAY. I would like you to picture in your mind a vertical line that is numbered from 0 to 100.</p> <p>100 at the top of the line means the best health you can imagine. 0 at the bottom of the line means the worst health you can imagine.</p> <p>I would now like you to tell me the point on this line where you would put your health TODAY.<br/> <a href="#">Record response</a></p> <p>Also, using a vertical line scale between 0 and 100, where 0 is no pain at all, and 100 is the worst pain you have ever had, what score would you give for your closed stoma site right now?</p> |
| <b>Follow-Up Questions – Medical Advice</b> |   |
|   | <p>Next, we are going to ask some questions about any extra visits to your doctor or hospital because of your stoma closure site.</p> <p>1. Have you seen your GP in a face to face appointment OR telephone appointment because of problems at the site of your original stoma since your operation?"<br/> <a href="#">Record response</a></p> <p><a href="#">If Yes</a><br/> Do you know exactly how many times?<br/> <a href="#">Record response</a></p> <p><a href="#">If YES</a><br/> Could you tell me how many times?<br/> <a href="#">Record response</a></p> <p><a href="#">If NO</a><br/> Could you estimate how many times: Once, 2-5 times, 6-10 times, 11-20 times, or more than 20 times?<br/> <a href="#">Record response</a></p> <p>2. Have you had a hernia truss/support?<br/> <a href="#">Record response</a></p> <p>3. Have you received a prescription for your stoma closure site, or any complications linked to your stoma closure site since your operation?<br/> <a href="#">Record response</a></p>  |

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| <p>Participants may provide medications names - these are to be translated to types when entered in to the ROCSS-EX database.</p> <p>“Don’t know” is an acceptable answer.</p> <p>A date is required and to be calculated accordingly if the participant tells you how long ago they noticed it. Aim to collect at least month and year.</p> | <p><a href="#">If Yes</a><br/> <b>Were you given a prescription for medication?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If YES</a><br/> <b>What was the prescription(s) e.g. painkillers, antibiotics, laxatives?</b><br/> <a href="#">Record ALL responses</a></p> <p><b>4. Have you gone to hospital as a planned visit (NOT as an emergency) for a clinic appointment, regarding your stoma site?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If Yes</a><br/> <b>Do you know exactly how many times?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If YES</a><br/> <b>Could you tell me how many times?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If NO</a><br/> <b>Could you estimate how many times: Once, 2-5 times, 6-10 times, 11-20 times, or more than 20 times?</b><br/> <a href="#">Record response</a></p> <p><b>5. Have you gone to hospital as a planned visit (NOT as an emergency) for hospital procedure or stay, regarding your stoma site?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If Yes</a><br/> <b>Do you know exactly how many times?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If YES</a><br/> <b>Could you tell me how many times?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If NO</a><br/> <b>Could you estimate how many times: Once, 2-5 times, 6-10 times, 11-20 times, or more than 20 times?</b><br/> <a href="#">Record response</a></p> <p><b>6. Have you visited the emergency department at any hospital because of problems at the site of your original stoma, or problems linked to your stoma site since your operation?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If Yes</a><br/> <b>Do you know exactly how many times?</b><br/> <a href="#">Record response</a></p> <p><a href="#">If YES</a><br/> <b>Could you tell me how many times?</b></p> |

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|   | <p><a href="#">Record response</a></p> <p><a href="#">If NO</a></p> <p>Could you estimate how many times: Once, 2-5 times, 6-10 times, 11-20 times, or more than 20 times?</p> <p><a href="#">Record response</a></p> <p>7. Do you think that you have or have had a hernia at the site of your stoma closure?</p> <p><a href="#">Record response</a></p> <p><a href="#">If Yes</a></p> <p>Roughly when did you first notice it?</p> <p><a href="#">Record response</a></p>  |
| <b>Follow-up Questions - HerQLes tool</b> |  |
|   | <p>Now we are moving onto the final section. Here we want to find out about your abdominal wall function at the site of your old stoma.</p> <p>I will read a statement to you and I would like you to tell me if you agree or disagree with the statement and how much by answering with a number from 1 – 6. 1 is you strongly disagree, 6 is you strongly agree.</p> <ol style="list-style-type: none"> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall has a huge impact on my health.</li> </ul> <a href="#">Record response</a> </li> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall causes me physical pain.</li> </ul> <a href="#">Record response</a> </li> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall interferes when I perform strenuous activities e.g. heavy lifting.</li> </ul> <a href="#">Record response</a> </li> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall interferes when I perform moderate activities e.g. bowling / bending over.</li> </ul> <a href="#">Record response</a> </li> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall interferes when I walk or climb stairs.</li> </ul> <a href="#">Record response</a> </li> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall interferes when I dress myself, take showers and cook.</li> </ul> <a href="#">Record response</a> </li> <li>Answering with a number from 1-6. 1 is strongly disagree and 6 is strongly agree <ul style="list-style-type: none"> <li>My abdominal wall interferes with my sexual activity.</li> </ul> <a href="#">Record response</a> </li> </ol> |

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|   | <p>8. Answering with a number 1-6. 1 is strongly disagree and 6 is strongly agree</p> <ul style="list-style-type: none"> <li>• I often stay at home because of my abdominal wall.</li> </ul> <p><a href="#">Record response</a></p> <p>9. Answering with a number 1-6. 1 is strongly disagree and 6 is strongly agree</p> <ul style="list-style-type: none"> <li>• I accomplish less at home because of my abdominal wall.</li> </ul> <p><a href="#">Record response</a></p> <p>10. Answering with a number 1-6. 1 is strongly disagree and 6 is strongly agree</p> <ul style="list-style-type: none"> <li>• I accomplish less at work because of my abdominal wall.</li> </ul> <p><a href="#">Record response</a></p> <p>11. Answering with a number 1-6. 1 is strongly disagree and 6 is strongly agree</p> <ul style="list-style-type: none"> <li>• My abdominal wall affects how I feel every day.</li> </ul> <p><a href="#">Record response</a></p> <p>12. Answering with a number 1-6. 1 is strongly disagree and 6 is strongly agree</p> <ul style="list-style-type: none"> <li>• I often feel blue because of my abdominal wall.</li> </ul> <p><a href="#">Record response</a></p> |
|   | <p><b>Ending the call</b></p> <p>That is the end of the questions I had for you today.<br/> <a href="#">See final section below if the participant asks about their treatment allocation.</a></p> <p>Thank you so much for taking the time to speak with me today, we very much appreciate it. Thank you and goodbye.</p>  |
| <p>If the participant asks about their trial treatment (whether or not they received a mesh during their stoma closure operation)</p> | <p><b>Potential treatment allocation queries</b></p> <p>I do not know whether or not a mesh was used when your stoma was reversed.</p> <p>If you would like to find out, I can note your request and you will be sent a letter to tell you when we have completed ROCSS-EX. This will be sent to you by the central ROCSS team at the University of Birmingham. For them to do this, I will need to provided them with your contact details. This can be a postal address or an email address, whichever you prefer, and they will only use this information for this purpose. If you happy for the central ROCSS team to have your contact details, please tell me your preferred contact details.<br/> <a href="#">If participant is willing for their contact information, record the preferred details.</a></p>  |