

## OPEN STUDY

### QUALITATIVE SUB-STUDY

#### **Draft Qualitative Interview Topic Guide – Declined to take part in trial**

*The interview schedule is developmental. The questions will need to be tailored to the specific answers of each interviewee. As analysis proceeds and findings need to be further explored, question areas may be modified or new ones introduced. The interview schedule given here is therefore a general topic guide for the one-to-one qualitative interviews.*

#### **Introduction**

**Interviewee consent** – discuss participant’s consent to be interviewed:

- Check participant is happy to go ahead with the interview
- Go through the consent form (emphasize confidentiality)
- Check participant is happy with audio recording of the interview
- Ask if there are any questions or concerns

**Purpose of the study** – You were approached about taking part in a trial about surgery for a urethral stricture. This interview is part of an additional study. We don’t know much about why people do or do not want to be involved in randomised controlled trials.

**Aim of the interview** – We don’t want to change your mind about not taking part in the trial but we are interested in hearing your opinions about a number of things such as your understanding of research, why you didn’t want to take part and how you have felt about the process so far.

#### **Core Questions**

##### **Q1 Introduction to the trial**

- How did you first hear about the trial?
  - Who first told you about it?
  - Had you meet them before?
  - What did you think about them?
  - What did they say?
  - What questions did you have?
  - What was your initial reaction?
  - What concerns did you have (if any)?

##### **Q2 Recruitment information**

- What did you think about the written information they gave you about the trial?
  - Is there any additional information you would have liked to have?
- Did you talk to anyone about taking part in the trial?
  - Partner? Family? Friends? Other Health Professionals?
  - What did you say to them?
  - What advice did they offer you?
- What concerns did you have (if any)?
  - What concerns did anyone else have (if any)?

### **Q3 Consent Meeting & Discussing Randomization Process**

- What happened when you went to the follow-up meeting about taking part in the trial?
  - Did you go alone?
  - Who did you meet?
  - Had you meet them before?
  - What did you think about them?
  - What did they say?
- What questions did you ask?
  - What answers were you given?
- How was the randomization process explained to you?
  - How well do you feel you understood what the randomization process is?
  - Did you have any concerns about this?
  - What concerns did anyone else have (if any)?
- Did you feel that you had enough time to consider taking part in the trial?

### **Q4 Decision**

- Why did you decline to take part in the trial?
  - What were/are your key concerns (if any)?
  - What were/are others key concerns (if any)?

### **Q5 Closing questions**

- Have there been any aspects that you have found difficult so far?
- What could they do to improve your experience of taking part so far?
- What changes would you like to see made?
- What advice would you give to other people thinking about taking part in the trial?
- Is there anything else you would like to add?

**Thank you for taking part in this interview**