

OPTIMA Qualitative Sub-Study

Interview Schedule: Research Staff (Principal Investigators, Team Managers, Trial Coordinators)

Version 1.0, 08 March 2012

1. Background

- Was there an invitation for bids or application for funding? Who designed the protocol?
- Why and how you became involved in the trial?
- Why is the trial needed?
- Is there a published systematic review?
- What is your role and do any others have a similar role?
- Date when recruiting started?
- What has it been like so far?

2. Recruiting Recruiters

- How were the recruiters recruited?
- Had the recruiters ever recruited before?
- How did the recruiters start to recruit (i.e. did they receive any training)?

3. Protocol v reality

- In the beginning (i.e. according to the protocol) how did you think patients would be identified and recruited?
- Has it worked out that way? If not, why not? (i.e. recruitment difficulties, is everyone supportive, organisational issues)?

4. Do you recruit, introduce the trial or identify eligible patients?

IF YES:

5. How do you introduce the trial (what do you say, how detailed is it)?

(eg. to doctors, patients, recruiters)

6. Randomisation

- How do you explain to patients how the decision is made in the trial about which treatment they will receive?

- How easy is the concept for patients to understand?

Note: If this seems threatening, we can acknowledge that this is a difficult and confusing concept for everybody

7. Uncertainty

- How do patients feel about/react to the idea of being in a trial when the doctor doesn't know which treatment is best?
- How do you feel about this?

8. Preferences

- What reasons have patients given for not taking part?
- What are the main difficulties patients have with the trial (difficulties with a particular arm)?
- What do you do when a patient gives a reason for not wanting to take part?

Probes:

- If you do explore patient views, how easy/difficult do you find this?
- How successful?
- Specific examples of a 'bad' vs. 'good' recruitment experience

9. Eligibility

- Are the criteria easy to apply?
- Do you ever use criteria that are not really clinical?
- Do you ever feel that a patient should get one treatment rather than another?

Probes:

- Why?
- What do you do?

10. Conflict between roles

- How does your job as researcher compare with your normal clinical practice?
- Is there any conflict between roles?

FOR ALL

11. Improving recruitment

- What might improve recruitment, including the appointments?

Probe: Any training needs?

12. Equipoise

- Do you have a hunch about the outcome of the trial?
- If you were a patient would you have a treatment preference?
- Would you agree to be randomised?
- Are the recruiters in equipoise?

13. View of trial

Have your views changed about the trial since your involvement?