OPTIMA QRS

Interview Schedule for staff
Version 2.0, 1 June 2013

(* indicates question added as data collection proceeded)

1. **Background (some questions may not be relevant, depending on participant's role)**

Can we start of by you telling me a little bit about the history of the study, and your involvement?

- Invitation for bids or application for funding?
- Who designed the protocol?
- Why and how you became involved in the trial? *Involved in trials before this?*
- Why is the trial needed?
- What is your role and do any others have a similar role? *How do you identify yourself then- clinician or investigator? How have you found your role- any challenges specific to it?*
- Date when recruiting started?
- **What has it been like so far?**

2. **Recruiters**
   - **Who recruits? Who are primary recruiters?**
   - Had the recruiters in OPTIMA ever recruited before? Are they experienced with trials?
   - How did the recruiters start to recruit (i.e. did they receive any training)? Any info?

3. **Recruitment pathway (this section also used in 'structured interviews')**
   - How are patients referred to your centre?
     - Where do eligible patients come from (GP referrals...)
   - Can you talk me through what happens from the time a patient is referred to your centre to the time a decision is made about whether or not they want to participate in the trial?
     - Who first sees the patient when referred?
     - Who gives the diagnosis to the patient? When?
     - How are potentially eligible patients identified? When? (MDTs…)

- *Who is responsible for identifying eligible patients?
- Who introduces trial to the patient? (* Are research nurses involved at this point?)
- Who gives the PIS to the patient?
- Who follows up the patient after trial introduction? (other means through which patient may hear about the trial prior to the formal trial introduction and thereafter?)
- *How/when is the patient's decision about trial participation communicated (in person or over the phone? After how long?)?
- Who takes consent?
- When, how and by whom is randomisation done after the patient consents?

4. **Protocol v reality**
   - At the start of the study, what was the thought process on how patients would be:
     a) identified
     b) recruited?
   - Has it worked out that way? If not, why not?

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

IF YES go to 6, IF NO go to 13:

6. **How do you tend to introduce the trial** (what do you say, how detailed is it)? Stage of pathway?
   (e.g. to doctors, patients, recruiters)

7. **Randomisation**
   - How do you explain to patients how the decision is made in the trial about which treatment they will receive?
   - How easy is it for patients to understand the concept of randomisation? How have they reacted? How have you responded to that? Do you ever have doubts over whether patient understands or not?

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

8. Uncertainty

- How do patients feel about/react to the idea of being in a trial where the doctor doesn't know which treatment is best?
- How do you respond to those reactions?
- How does the uncertainty element make you feel? *Difference between your investigator hat or clinician hat?*

9. Reasons for declining OPTIMA

- What reasons have patients given for not taking part?
- What would you say 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 do you do this and), how easy/difficult do you find this?
- Do you have any *specific examples of 'bad' vs. 'good' recruitment experiences?*

10. *Reasons for accepting OPTIMA

- *Do you explore patients' reasons for accepting the trial?
- * What types of reasons have you encountered to date?

11. Eligibility

- Are the eligibility criteria clear to you, and do they work in reality? *Have you found they've been easy to apply?*
- Do you ever use any other criteria (e.g. non clinical)?
- Do you ever feel that a patient should get one treatment rather than another (Why? What do you do in these instances?)?
- * Do you use online prediction tools such as Adjuvant online or Predict?

12. Conflict between roles

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

FOR ALL

13. Improving recruitment

- What might improve recruitment, including the appointments?

Probe: Any training needs?

14. Equipoise

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

15. View of trial

Have your views changed about the trial since your involvement?

16. What would you say are the main difficulties OPTIMA is experiencing?

- How does this compare to other trials you have been involved with?
- Any OPTIMA specific challenges?