

**ASSIST study**  
**Enrolment Instructions**

Procedure (See flowchart in Figure 1)

1. Decide how you will identify patients attending each clinic because you will need to enter patients according to a fixed schedule (i.e. every K<sup>th</sup> patient). When you have decided how you are going to do this, please use the same system all the time. Whoever administers the appointments and patient checking-in may be able to help with this.

Possible ways of counting patients are:

- *Count each patient attending the clinic in chronological order of when they present at the day's clinic*
  - *Use an alphabetical list of the patients scheduled to attend the clinic and count from that (i.e. 1<sup>st</sup> on the list alphabetically at Clinic 1 would be Patient 1)*
  - *If there is only one participating physician at a site, then they could count patients as they see them*
2. At the beginning of the study you will be given a **Random starting number** ( **R** ) by the Study Statistician (CWS), and a number **K**
  3. At your **first** clinic, invite the patient numbered **R** (see Point 2) on the list for the clinic session to enter the study
  4. You need to continue to count patients attending clinics, accumulating the total. For example:
    - If you see 8 patients at your first clinic, then the cumulative total is 8
    - If you see 7 patients at the next clinic, these will be patients 9 to 15, so the cumulative total is 15
    - If you see 9 patients at the next clinic, they will be patients 16 to 24, so the cumulative total is 24
    - Etc.
  5. After the first patient (patient **R**), you will invite every **K<sup>th</sup>** (see point 2) patient to participate
  6. Complete Section A of the CRF to record whether the patient consents to enter the study (Question 3=Yes) and whether they are eligible (**all** of Questions 1 to 5 must be **Yes**, and Question 6 must be **No**)

7. If they consent and are eligible, do the other study assessments and complete the CRF. If they do not consent or are not eligible, do not proceed with the patient.
8. Invite the next **Kth** patient
9. When you have entered 20 patients **STOP**.

#### **EXAMPLE**

- Random starting number: **R=4**
- **K=11**

The 4<sup>th</sup> patient counted (as per section **Error! Reference source not found.**) will be the first patient who is invited to participate. If they agree, allocate them number 001 in your site.

- 1 Log the patient as entering the study
- 2 Confirm their eligibility (Questions 1 to 6 of the CRF)
- 3 If Questions 1 to 5 are all "YES" and Question 6="NO" then the patient is eligible- GO to Step 4. Otherwise STOP
- 4 Conduct all study procedures as set out in the protocol and complete the CRF

Then invite the 11th patient after this one (i.e. patient no. 15) to participate and repeat the procedure above but allocating them study number 002. Then repeat for the 26<sup>th</sup> patient, and so on until 20 patients have entered the study.

If all patients agree to take part, then this site would actually study patients 4, 15, 26, 37 etc..

If the 2<sup>nd</sup> patient invited (i.e. the 15<sup>th</sup> patient in this example) does not agree to take part, but the rest do agree and are eligible, then the site would study patients 4, 26, 37, 48 etc.

**Figure 1: PROCEDURE FLOWCHART**

