

## **Pre Consent Agreement - Fasting**

Where it is a requirement that subjects present for screening whilst fasting, the ethics committee must be aware of and approve the offer to subjects to provide fasting samples upon screening. It may be inappropriate to do this with vulnerable groups such as the elderly.

If subjects do take up the offer of arriving fasted, then they should be warned about the possible consequences (dizziness etc. and in the case of diabetics the potential for low/high blood sugars).

The subject should be aware that they can take longer to think about the study and come back for a further visit should they not wish to undergo the consent process whilst fasting. Therefore failure to arrive for the screening visit in a fasting state would not preclude them from entering the study.

When these safeguards are in place then the risk to the subject is low. It is the subject's choice to decide whether or not to arrive for the screening visit having met the conditions.

Consideration should be given when writing protocols to ensure that they do not exclude subjects from screening simply because the testing conditions were not met at the initial visit. Processes should permit the required tests to be done at a later date, perhaps within a window defined as the screening visit, or at a subsequent visit.

At no time should it be suggested to a subject to begin a wash-out period, change a medication, or do anything that could affect his or her medical condition, safety or well-being, prior to having the full study explained and obtaining their written informed consent.

## LETTER OF INVITATION

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*Reply slip. Please cut/tear off and return to the address above.*

Study Title: XXXXXXXXXXXXXXXXXXXX

- I have read the Patient Information Sheet Version XX Dated XX XX XXXX and am interested in taking part in the above study and agree to be contacted by the study team. I understand that I am under no obligation to take part in this study.

Please delete as appropriate:

- I agree to attend the screening visit in a fasting state as described in the above Patient Information Sheet.
- I would prefer to attend the screening non-fasting and understand that this may require a further visit to complete screening requirements.

Name: .....

Address: .....

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Telephone No: .....

Signature .....

Date: .....