

OSAC TRIAL PATIENT WITHDRAWAL FORM

To be completed by a member of the OSAC research team or by a recruiting site clinician on behalf of any participant who chooses to withdraw from the trial after the completion of the recruitment process. The form should also be completed if a participant has to be withdrawn for safety reasons. **Please complete this form using black ink and BLOCK CAPITALS. Fax the completed form to the OSAC Trial Manager on 0117 928 7341.**

PATIENT DETAILS

Participant ID:

Participant D.O.B.: / /

GP Practice Site ID:

GP Practice Name:

WITHDRAWAL DETAILS

Date of withdrawal: / / Time (24 hrs): Hrs Hrs Min Min

| Type of withdrawal (please tick any or all boxes) | Additional instructions to Bristol centre trial team: |
|--|--|
| A. Taking the trial medication <input type="checkbox"/> | 1. Update clinical database to record that the patient has stopped taking (or has decided not to take) the trial medication. |
| B. Receiving weekly telephone calls <input type="checkbox"/> | 1. Update clinical database to foreclose the weekly telephone queries 2. Update trial management database to block further telephone follow-up. |
| C. Symptom diary <input type="checkbox"/> | 1. Update clinical database to foreclose any further symptom diary data collection 2. Update trial management database to close further symptom diary data collection |
| D. Primary Care Notes Review <input type="checkbox"/> | 1. Update clinical database to foreclose the primary care notes review. 2. Update the trial management database to block primary care notes review data collection. 3. Inform the GP site that they will be required not to complete the primary care notes review for this patient. |
| E. Use of data collected so far <input type="checkbox"/> | 1. Instruct GP site to shred all CRFs 2. Update clinical database to archive all data collected so far 3. Update trial management database to archive all data collected so far |
| F. Not known <input type="checkbox"/> | 1. Research Nurse to contact patient by telephone to establish reason for withdrawal |

Further information about the reason for withdrawal (if known):

DETAILS OF PERSON COMPLETING THE FORM

Print name:

Signature:

Date completed: / /

Paperwork Management: Fax the completed form to the Bristol trial centre on the above number. Take a copy and file in your GP site file. Place the original in one of the prepaid return envelopes provided in your site file and send to the Bristol trial centre. Bristol centre to follow the instructions which apply to the type of withdrawal, and file this form in the TMF.