OSAC (Oral Steroids for Acute Cough) Trial **CASE REPORT FORM**	**Section 4 (BLUE CRF):** Symptoms, Signs and Medical History **To be completed for:** all patients confirmed eligible in Sections 1 and 2, for whom the Responsible Clinician has authorised the OSAC trial prescription and who have completed a written consent form. **To be completed by:** Recruiting Clinician **(NB: on paper or online)**

Today's Date: D D M M Y Y Y Y

Patient ID Number: [affix PID label)

OSAC Clinician ID:

4.1 CLINICAL OBSERVATIONS (MUST BE COMPLETED FOR ALL PATIENTS)

NB: Recruiting Clinician to check all clinical observations in Section 2 have been completed before proceeding. Please perform any observations if left blank by Responsible Clinician.

Please measure and record the patient's height and weight on the day of recruitment, UNLESS*:

1. Weight: ☐☐☐ kg
2. Height (record to 2 decimal places): ☐.☐☐ m
3. Patient's **predicted** peak expiratory flow rate: ☐☐☐

***If the patient has been weighed in the last month, the most recent weight can be taken from the electronic record.**

***If the patient's height has been measured in the past 5 years, the most recent height can be taken from the electronic record.**

This information can be taken from the patient's electronic record (enter their weight and height first) or from http://www.peakflow.com/top_nav/normal_values/PEFNorms.html

4. Has the patient been shown how to use the peak flow meter? ☐ Yes ☐ No
5. Patient's **actual** peak expiratory flow rate (best of 3 attempts): ☐☐☐

Please use the EU Scale Adult Standard Mini Wright Peak Flow Meter provided in the Patient Pack only. Do not use any other type of peak flow meter for the OSAC trial.

6. Assessment of patient's peak expiratory flow measurement technique: ☐ Very good ☐ Adequate ☐ Poor

If the patient's actual peak flow rate is <75% of their predicted peak flow rate, the Responsible Clinician should be informed.

4.2 CURRENT SYMPTOMS: PATIENT'S PERSPECTIVE (RECRUITING CLINICIAN TO ASK PATIENT)

1. For how many days (including today) have you been unwell with the cough? ☐☐ (enter number between 1-28)
2. Compared with yesterday, do you feel the same, better or worse? (tick **one** box only) ☐ Same ☐ Better ☐ Worse
3. Please rate your overall impression of your illness in the past 24 hours, on a scale of 0-10: (circle **one** number)

Completely well	0	1	2	3	4	5	6	7	8	9	10	**Extremely unwell**

4. Symptoms	**Has the symptom been present at any time?**		**If yes, is this within the last 24 hours?**	
	Yes	**No**	**Yes**	**No**
a) Phlegm (sputum)	☐	☐	☐	☐
If yes to phlegm, what colour?	☐ Clear ☐ White	☐ Yellow ☐ Green	☐ Blood-stained	☐ Other
b) Shortness of breath	☐	☐	☐	☐
c) Wheeze	☐	☐	☐	☐
d) Blocked / runny nose	☐	☐	☐	☐
e) Fever	☐	☐	☐	☐
f) Chest or shoulder pain	☐	☐	☐	☐
g) Muscle aches	☐	☐	☐	☐
h) Headache	☐	☐	☐	☐
i) Disturbed sleep	☐	☐	☐	☐
j) Feeling generally unwell	☐	☐	☐	☐

Symptoms cont.	**Has the symptom been present at any time?**		**If yes, is this within the last 24 hours?**	
	Yes	**No**	**Yes**	**No**
k) Unable to do normal activities of daily living	☐	☐	☐	☐
l) Confusion / disorientation	☐	☐	☐	☐
m) Diarrhoea	☐	☐	☐	☐

Any other symptoms at any time? ☐ Yes ☐ No

If yes, please describe:

Symptom 1:

Is this within the last 24 hours? ☐ Yes ☐ No

Symptom 2:

Is this within the last 24 hours? ☐ Yes ☐ No

Symptom 3:

Is this within the last 24 hours? ☐ Yes ☐ No

4.3 PAST MEDICAL AND FAMILY HISTORY (NB: Validated questions - wording of questions must be used exactly as written)

Thinking back to the 12 months before your current illness started:

1. Have you had wheezing or whistling in your chest at any time in the last 12 months? ☐ Yes ☐ No
2. Have you been woken up at night by an attack of shortness of breath at any time in the last 12 months? ☐ Yes ☐ No
3. Have you been woken up at night by an attack of coughing at any time in the last 12 months? ☐ Yes ☐ No
4. Have you woken up with a feeling of tightness in your chest at any time in the last 12 months? ☐ Yes ☐ No
5. Have you had an attack of shortness of breath that came on following strenuous activity at any time? ☐ Yes ☐ No
6. Have you had an attack of shortness of breath that came on during the day when you were at rest at any time? ☐ Yes ☐ No
7. If the answer to any of the above is **"Yes"**, do your symptoms occur less frequently or not at all on days away from work and on vacations? ☐ Yes ☐ No
8. Does the weather affect your cough? ☐ Yes ☐ No ☐ No cough
9. Do you ever cough up phlegm (sputum) from your chest when you do not have a cold? ☐ Yes ☐ No
10. Do you usually cough up phlegm (sputum) from your chest first thing in the morning? ☐ Yes ☐ No
11. How frequently do you wheeze? ☐ Occasionally or more often ☐ Never
12. Do you or another member of your family have any history of eczema? ☐ Yes ☐ No ☐ Don't know
    If yes, please tick as many as apply: ☐ You ☐ Parent ☐ Sibling
13. Do you or another member of your family have any history of hay fever? ☐ Yes ☐ No ☐ Don't know
    If yes, please tick as many as apply: ☐ You ☐ Parent ☐ Sibling
14. Do you or another member of your family have any history of asthma? ☐ Yes ☐ No ☐ Don't know
    If yes, please tick as many as apply: ☐ You* ☐ Parent ☐ Sibling

*** If the patient has taken medication for asthma within the past 5 years, they should be excluded from the OSAC trial.**

4.4 MEDICATIONS, INCLUDING PRESCRIBED MEDICATIONS (PLEASE ASK PATIENT AND ALSO CHECK PATIENT'S MEDICAL RECORD)

1. Did you have an influenza vaccination in the **last 12 months**? □ Yes □ No
2. Have you treated this cough with any over-the-counter medications? □ Yes □ No

   If yes, please enter details:

3. Have you taken, in the past 24 hours, any of the following prescribed medication? Tick one box for each question.
   (NB: these are not exclusion criteria)

a) Inhaled bronchodilators, e.g. salbutamol	□ Yes	□ No
b) Oral non-steroidal anti-inflammatories	□ Yes	□ No
c) Topical non-steroidal anti-inflammatories	□ Yes	□ No
d) Antihistamines, e.g. Piriton	□ Yes	□ No
e) Benzodiazepines / antidepressants	□ Yes	□ No
f) Anti-hypertensives	□ Yes	□ No
g) Aspirin	□ Yes	□ No
h) Oral beta-blockers, e.g. atenolol, bisoprolol, propranolol	□ Yes	□ No
i) Beta-blocking glaucoma eye drops	□ Yes	□ No
j) Oral agents for diabetes	□ Yes	□ No
k) Other prescribed medication	□ Yes	□ No

If yes, please enter details:

Paperwork Management

- **When complete, place Section 4 in the recruitment folder. Ensure Sections 1, 2 and 4 are entered on the OSAC clinical database.**
- **On satisfactory completion of recruitment processes, please place the recruitment folder (with all relevant paperwork) securely in a lockable storage location in line with Good Clinical Practice, Data Protection Act guidelines and MHRA requirements.**
- **Return the completed recruitment folders in batches to the Bristol OSAC Trial Centre using the supplied Freepost address labels.**
- **If at any stage the patient becomes ineligible to continue with trial participation or wishes to withdraw do not proceed with recruitment, and if applicable complete the WITHDRAWAL FORM.**
- **Please ensure responsible personnel (as per delegation log) update the patient's medical record to indicate participation in the OSAC trial.**