

## OSAC (Oral Steroids for Acute Cough) Trial GP SITE DELEGATION LOG

<b>Practice Name:</b>		<b>OSAC Site ID:</b>	
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### Instructions

Against each task delegated by the research lead, write the name of the responsible member of staff. The responsible member of staff should sign the log. When complete, the Research Lead (PI) should sign and date this log and fax it to the trial team.

### Changes in staff member responsibilities

If the member of staff performing any of the trial duties changes, please use the continuation rows at the end of the form, and write the number of the trial task in the first column. The Research Lead (PI) should sign off any staff changes, and the relevant page of this form should be faxed to the Bristol trial centre.

Trial tasks:	Frequency	
1. Complete CRF 1 on paper (face-to-face eligibility assessment)	Per patient	GCP-trained GP, GCP-trained NP or GCP-trained PN where this is part of normal role
2. Complete CRF2 on paper (clinical examination)	Per patient	GCP-trained GP or GCP- trained NP where this is part of normal role
3. Authorise the trial prescription	Per patient	GCP-trained GP
4. Consent the patient	Per patient	The GP, NP or PN who has assessed the patient's eligibility, or the GCP-trained NP or the GCP-trained PN who will complete the rest of the recruitment procedure and administer the patient pack
5. Complete CRF 3 on paper (patient registration)	Per patient	The GCP-trained clinician who consented the patient
6. Complete CRF4 on paper (symptoms and medical history)	Per patient	The GCP-trained clinician who consented the patient
7. Administer the contents of the patient pack to the patient, including the IMP	Per patient	The GCP-trained clinician who consented the patient
8. Enter CRF1, CRF2 and CRF4 data onto the online web database within 24 hours of recruitment	Per patient	Appropriately trained member of practice team who will take responsibility for resolving any queries with the person originally collecting the data
9. Fax CRF3 to the Bristol trial centre (0117 928 7341) by the end of the same working day	Per patient	Appropriately trained Member of practice team
10. Postal return of consent and CRF3 to Bristol trial centre	Per patient	Appropriately trained Member of practice team
11. Maintain the trial site file	Updated weekly, per patient and in response to updates from the trial team	Appropriately trained member of practice team
12. Order and store patient packs and recruitment folders	To ensure that the practice has a two week supply of patient packs and recruitment folders in store	Appropriately trained member of practice team
13. Monitor storage temperature and complete OSAC temperature log	Weekly	Appropriately trained member of practice team
14. Complete screening log and fax weekly to the OSAC trial centre	Weekly	Appropriately trained member of practice team
15. Arranging the recruitment consultation for eligible patients	Per patient	Appropriately trained member of practice team
16. Adverse events: check the patient list weekly and report any Serious Adverse Events to the trial team	Weekly	GCP-trained GP, NP or PN where this is part of normal role

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<b>Responsible member(s) of staff</b>					
<b>Name</b>	<b>Role</b>	<b>Tasks performed (refer to list 1-16 above)</b>	<b>Signature</b>	<b>Start date (dd/mm/yyyy)</b>	<b>End date (dd/mm/yyyy)</b>

<b>Signature of Research Lead (PI):</b>		<b>Date (dd/mm/yyyy):</b>	
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**Please fax this log to the OSAC trial team on 0117 928 7341**