OSAC TRIAL:
SAE Weekly Checking Log

- **A weekly check of each trial participant's primary care notes for any SAEs/SUSARs must be done by a designated staff member (OSAC research team or GP practice teams) and this log completed.**
- **The check must be done weekly for the first four weeks after the patient has entered the trial.**
- **Please keep this log in your site file.**
- **If a SAE is identified in any week please fax a copy of the log to the Bristol trial centre – fax: 0117 928 7341.**

An adverse event, reaction or unexpected adverse reaction is serious if it:

a) results in death,
b) is life-threatening,
c) requires hospitalisation or prolongs a current hospitalisation,
d) results in persistent or significant disability/incapacity,
e) results in a congenital anomaly or birth defect,
f) other: an adverse event the nature or severity of which is not consistent with the known information about the drug provided in the SPC (summarised in the trial protocol and the Patient Information Booklet)

OSAC Site Enrolment Date:	_____ / _____ / 20_____ (dd/mm/yyyy)
Name of recruiting site:	

Date (dd/mm/yy)	OSAC patients' notes checked (tick)	SAEs identified (0, 1, 2…)	SAEs reported to UH Bristol within 24 hours (Yes/No)	Name of delegated staff member	Signature

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