



# Australian Paediatric Surveillance Unit

A Unit of the Royal Australasian College of Physicians, Division of Paediatrics and Child Health  
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## Australian Paediatric Surveillance Unit INVESTIGATOR AGREEMENT

As Chief Investigator of the study of <<insert study name>> to be conducted through the APSU from <<insert date>> to <<insert date>>

I certify that I:

1. Have obtained ethics clearance from a Human Research Ethics Committee that is properly constituted according to NHMRC guidelines, and that I
  - a. will notify the relevant ethical committee of any subsequent changes to the approved proposal;
  - b. will provide evidence of ethical approval to the APSU;
  - c. will notify the APSU of any planned changes to the study protocol as these will require approval by the Scientific Review Panel.
2. Will maintain patient confidentiality at all times.
3. Will not divulge the contact details of reporting clinicians, supplied by the APSU, to persons outside this study.
4. Will make no attempt to contact patients directly.
5. Will ensure data confidentiality, making the study database accessible only to study investigators specified on the protocol sheets.
6. Will convene meetings or teleconferences involving all co-investigators, at least every six months during the duration of the surveillance study, to discuss study progress and to review data.
7. Will undertake to publish and disseminate the findings arising from this study within 2 years of completion of data collection. For ongoing long terms studies an update must be published at least every 4 years. If these time limits for publication are not met, the APSU reserves the right to analyse and publish the data.
8. Will seek the agreement of study co-investigators for any publications and presentations produced from this study.
9. Will notify the APSU of any presentations, publications or publicity arising from the study.
10. Will, in any publications or presentations:
  - a. acknowledge the APSU for facilitating this study.
  - b. acknowledge the major funders of the APSU during the period of the study, currently, the NHMRC, Australian Government Department of Health and Ageing, Faculty of Medicine, The University of Sydney and the Royal Australasian College of Physicians
  - c. acknowledge by including in the author list, "contributors to the APSU" (please see also the Vancouver Protocol and the INoPSU statement on acknowledgment).
  - d. consider acknowledging by name, individual clinicians who notify cases to this study
11. Will provide a brief summary of the study for inclusion in the APSU Annual Report, detailing final outcome of notifications received (i.e. will categorise cases as definite, probable, duplicate, error, misdiagnosis, or unknown) and any highlights or impacts that have resulted from this study.
12. Will complete every three months, a brief survey checking the number of cases notified, numbers of confirmed cases and questionnaire response rates.
13. Will pay to the APSU, the agreed annual fee of \$11,000 (inc GST) for the listing the study on the APSU report card from January 2006 to December 2006.
14. For an additional fee of \$22,000 (inc GST) the APSU will run the study including questionnaire data collection, database development, data entry and analysis.

**Name and Position:**

**SIGNATURE:** ..... **DATE:** .....