

Mechanism for submitting study proposals to the Welsh Paediatric Surveillance Unit

The procedure is as follows:

1. Complete the standard format for project proposals
 2. Design the questionnaire to be used for identified cases (example enclosed)
 3. Complete the WPSU form (part 2) to accompany the proposal
- The proposal, questionnaire and form will be considered for inclusion by the Steering Committee of the WPSU at their meeting in May and October each year. You may be required to provide further information or answer specific questions at this stage. Your attendance at this meeting is important.
 - When approved, arrangements are made for starting the study and including the condition on the WPSU card.

If you have any questions regarding the WPSU please do contact Heather O'Connell on (029) 2074 3946.

WELSH PAEDIATRIC SURVEILLANCE UNIT

FORMAT FOR PROJECT PROPOSALS

The Steering Committee have decided on the following standard format for project proposals:

- Background
- Objectives
- Criteria for inclusion, including the case definition
- Information required on individual cases
- Will patient confidentiality be maintained?
- Duration of study
- Will additional contact with the patient be required?
- Purposes for which the data collected will be used/ Questions the study aims to answer
- References
- Authors

SUBMISSION GUIDELINES

- Each proposal should be submitted on **one sheet of A4 paper** to the Welsh Paediatric Surveillance Unit Steering Committee.
- **The questionnaire** is to accompany the proposal when submitted for approval and for preference should be **one sheet of A4 paper (maximum two sheets)**.
- Please remember to complete **part 2** as fully as possible as these answers may influence acceptance by the WPSU.
- Please read the page on **Useful Information** to ensure that your proposed study is suitable to be conducted under the WPSU parameters.

Please return proposal and questionnaire to:

Closing dates: 1 April and 1 October

Ms Heather O'Connell
WPSU Administrator
Child Health
Cardigan House
University Hospital of Wales
CARDIFF
CF14 4XW

WPSU Proposal form part 2

- All WPSU studies (except audit) must have ethics approval. **Do you have ethics approval?** Please contact your local R&D office first, and then write to the ethics committee (details provided attached). When your project receives ethical approval, WPSU would appreciate a copy of the confirmation letter with the approval number, **or** a letter from R&D **and** Ethics Committee confirming it is not required (see associated documents attached).
- Details of financial/academic support
- Likely number of notifications. WPSU finds that ideal numbers are 50 per year
- Do you have complementary sources of ascertainment to validate the data collected through WPSU?
- Details of other possible sources of data ie consultants working in other specialities to whom WPSU could temporarily mail cards on your behalf to improve case ascertainment.

Useful Information

- WPSU collects only **new** cases of the condition you are studying.
- You will be sent details of the notifying consultants name and address for each notification and **you then send your questionnaire to the notifying consultant.**
- Patient confidentiality must be maintained. Data to be stored electronically must be anonymised:
- WPSU provide a **unique number** per notification for identification purposes, for you to put at the **top of each questionnaire.**
- It is your responsibility to write to notifiers promptly with your data questionnaire and to contact them regularly for incomplete or missing data. Contact the office if a completed questionnaire is outstanding after 3 requests.
- It is a good idea to include another copy of the questionnaire when chasing non-returned questionnaires, and to include a highlighted photocopy of the incomplete questionnaire when you are requesting missing data.
- Address should not be collected but half postcode can be collected for epidemiological analysis.
- If you intend to **follow up** the notifications at a later date you must stress in your questionnaire that this is your intention and request that doctors should record the WPSU number and the patient's details.
- An **Annual Progress Report** will be required.
- A **Report** for the WPSU Annual Report will be required on completion of your study.
- WPSU studies and contact addresses for lead researchers will be listed on the WPSU page of the All Wales Child Health Research Network (LINK) website and on the WPSU page of the WPS website: www.welsh-paediatrics.org

Factors that favour acceptance by the British Paediatric Surveillance Unit (BPSU)

- Scientific importance
- Rarity of the condition, though short-term or geographically limited studies of commoner disorders are considered
- Proposals with outcomes of clear importance to public health
- Uniqueness. Priority will not be given if similar studies have recently been undertaken or if other data sources are readily available (although BPSU encourages the use of alternative data sources for validation and completeness of reporting)
- Attention to detail, in terms of clear achievable objectives, practicability, patient confidentiality and resources
- Practicality and limited workload placed on the reporting paediatrician
- Ethical approval

● **EXAMPLE STUDY QUESTIONNAIRE** WPSU Case number: *(You complete this)*.....

Please keep a record of the child's details and the study number at the top of this form in your WPSU folder. Please ring our office on (your number) if you have any problems with the form. Thank you for your time.

Name of reporting doctor:*(You complete this from WPSU notification slip)*.....

Month/Year of Report:..... *(You complete this from WPSU notification slip)*.....

Date of Birth:	Date of diagnosis:
Sex:	Postcode
Hospital:	

(Information you require here)

Please return this form to (Your name and address)

Factors for Specialist Registrars to consider

- ◆ The WPSU is a very interesting and useful way of collecting project data (and can lead to publications)
- ◆ You will receive support from the Steering Committee but remember:
 - You need to consider carefully your outcomes and whether they are feasible
 - You will need a minimum of 12 months data
 - You will need to collate and process the data you collect
 - A report will be required for the WPSU Annual Report (example attached)
- ◆ Consider joint applications if you rotate posts six monthly, ie with a Consultant colleague and/or one other Specialist Registrar.
- ◆ Consider this to be a long-term project of at least two years

Research Ethics

Using the NRES guidance and NRES leaflet defining research 1 issue 3, it was agreed that WPSU researchers would follow the following procedure -

1. NRES advice is that, "if having considered the published guidance you are unsure whether your project should be classified as research, please seek advice from your R&D office in the first instance." The link is here:

<http://www.nres.npsa.nhs.uk/applications/apply/is-your-project-research/?locale=en>

2. Then either

a) write to Dr Corinne Scott at REC, for "confirmation that the study is not research and therefore does not require ethical review". Template letter to Dr Scott attached.

b) apply for ethical approval if it is research.

Example letter to seek written confirmation from REC for Wales

Dr Corinne Scott
REC for Wales
Fourth Floor
Churchill House
17 Churchill Way
Cardiff
CF10 2TW

[insert date]

Dear Dr Scott,

I am planning to undertake a project using anonymised patient data collected via the Welsh Paediatric Surveillance Unit and would be very grateful for advice on whether a full ethical submission is required for my project.

I am currently working at [insert name] Health Board, and my proposed project would collect data on [insert name of condition]. Please find the full proposal and data collection sheet for this project enclosed.

I have used the National Research Ethics Service tool and sought advice from [insert name] R&D Office, and have concluded that this project would fall under the description of Service Evaluation/Outcome Audit [delete one]. However in order to satisfy Welsh Paediatric Surveillance Unit requirements, I am required to seek a written response from an Ethics Committee before commencing my project.

I hope this is sufficient information to enable you to come to a decision. Please do not hesitate to contact me if you need to know anything further

Yours sincerely,