GIG CYMRU NHS WALES | Bwrdd Iechyd Prifysgol Betsi Cadwaladr University Health Board

Research & Development Approval
Guidelines to the application process

All research activity must be registered with the Research & Development Office and approved by the R&D Internal Review Panel. Conducting research in the absence of R&D approval is in breach of Good Clinical Practice.

The R&D approval process is co-ordinated on an All Wales basis by Health and Care Research Wales Permission Co-ordinating Unit (PCU).

R&D approval is granted by the Internal Review Panel across Betsi Cadwaladr University Health Board.

The application form for R&D approval can be found on the Integrated Research Application System *(IRAS)* website at **https://www.myresearchproject.org.uk** - the web based integrated application system through which you can apply for all permissions needed for research in the UK.

Integrated Research Application System (IRAS)

- Is a single system for applying for permissions and approvals for health and social care / community care research in the UK.
- Enables you to enter the information about your project once instead of duplicating information in separate application forms.
- Uses filters to ensure the data collected and collated is appropriate to the type of study, and consequently the permissions and approvals required.
- Helps you meet regulatory and governance requirements.
- Retains familiar aspects of the online ethics application system.

IRAS captures the information required for the relevant approvals from the following review bodies:

- NRES / NHS / HSC Research Ethics Committees
- NHS / HSC Research and Development offices
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Administration of Radioactive Substances Advisory Committee (ARSAC)
- Confidentiality Advisory Group (CAG)
- Gene Therapy Advisory Committee (GTAC)
- Ministry of Justice

Application for R&D review must be made using the form found on this site. You must first answer the filter questions, it is very important that these questions are answered correctly as your answers will determine which questions are enabled on the forms. You should then fill in the 'Full Set of Project Data' – this will then migrate information automatically into the other forms. Finally you should check the R&D form and Site Specific Information (SSI) form thoroughly before submission.

When using IRAS it is recommended that you read the question specific advice as it gives relevant advice on each individual question in IRAS. Please refer to the question specific advice when preparing your application as it will answer many queries you might have about what will be looked for from the responses you provide.

All research projects requiring review by the R&D Internal Review Panel must be sent to Health and Care Research Wales - Permissions Co-ordinating Unit (PCU) for Wales. Electronic versions of the documents listed below must be sent via e-mail to:

Research-Permissions@wales.nhs.uk

Submissions should include *(bold are mandatory documents – without them an application cannot be accepted)*:

1. **The Checklist** – this is generated in IRAS from the Checklist tab, all documents included in the submission need to be listed on this form.

2. ***Signed* NHS R&D Application Form -** you can find the online application form at **https://www.myresearchproject.org.uk** (this must be sent in pdf[1] and xml[2] format)

3. ***Signed* NHS Site Specific Information form** from the same website (this must be sent in pdf[3] and xml[4] format)

4. **Research Proposal** (protocol)

5. **Supporting documents** as appropriate (lay summary, Investigator's Brochure or Summary of Product Characteristics, copies of questionnaires, treatment schedule, diary cards, interview schedule, invitation letter, poster, etc.)

6. Participant Information Sheet (PIS)

7. Informed Consent Form (ICF)

8. Letter to the Consultant/GP (if appropriate)

9. **Investigators' CV** and where relevant the **academic supervisor's CV.**

10. **Evidence of Insurance/Indemnity (if the study sponsor is non-NHS)**

11. Any other supporting document you may have been asked to complete (Costing form/funding details, pharmacy, haematology, as well as any agreements and signatures such as Chief of Staff)

12. **Risk Assessment form** – for all research submissions (a template can be provided on request)

N.B. All documents must have a version number and date

Question 23 on the SSI form needs to be ticked and details of the R&D person you spoke to (at BCUHB) entered. You will be asked to obtain certain signatures on a different signature page which you will be given, please make sure you do contact the R&D office to obtain advice on this.

On receipt of the application, the PCU office will check that the application is valid. This is an administrative check that the application is complete, including supporting documentation.

[1] Once you have completed all the questions ensure that the R&D form is highlighted on the left hand side within the navigate page of your project. Click on the 'Submission' tab and click on 'Proceed to Submission', you should then follow the instructions which will download a pdf file for you to save. You must send an electronic copy of this form, together with a scanned copy of the signature pages – if they have not been electronically authorised – to PCU. Clicking the submission button DOES NOT automatically send your project to any review body.

[2] Ensure that the R&D form is highlighted on the left hand side. Click on the 'Submission' tab, click on 'save completed form as xml' do not open this file, save a copy and send in electronic format to PCU

[3] As above but ensure that the SSI form is highlighted on the left hand side.

[4] As above but ensure that the SSI form is highlighted on the left hand side.

Validation of an application shall be undertaken within five days of receipt of the application and the Chief Investigator shall be notified of a valid or an invalid application.

Once a complete application is received by PCU, they will notify the relevant NHS Organisation

We are here to help

Research & Development

R&D Office – (Research and Development submissions/and Ethics - Wales REC 5)

BCUHB - Clinical Academic Office
Clinical School
Ysbyty Gwynedd
Bangor
LL57 2PW

Tel/Fax: 01248 384877

Dr Rossela Roberts
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Ms Lisa Hother
Research & Development Assistant — lisa.hother@wales.nhs.uk

Ms Melissa Van Der Bijl
Research Facilitator — Melissa.vanderbijl@wales.nhs.uk

Tel. 01248 388327

R&D Office – (Research and Development Monitoring/Audit)

BCUHB - R&D Office (1st Floor)
Holywell Community Hospital
Holywell
CH8 7TZ

Tel: 01352 718382

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Ms Wendy Scrase
Primary Care Research Facilitator **wendy.scrase2@wales.nhs.uk**

Tel. 01248 388180

Additional help can be obtained from the online SOP eLearning site - The health research SOP toolkit has been developed to help guide your research project through each stage of the research pathway according to the principles of 'Good Clinical Practice', from the planning stage through to site closure and final reporting. You can access it using the following link:

http://learning.wales.nhs.uk

Other links:

HRA web-site: http://www.hra.nhs.uk/
R&D Intranet pages: http://howis.wales.nhs.uk/sitesplus/861/page/42140