Rheoli a Llywodraethu Ymchwil Gofal Sylfaenol Cymru Gyfan

All Wales Primary Care Research Management & Governance

All Wales Primary Care Research Management & Governance Office

Streamlined NHS Permissions Approach to Research – Cymru (SPARC)

System Process - Overview

Bwrdd Iechyd Lleol(a) (t)Local Health Board Powys

ALL WALES PRIMARY CARE RESEARCH MANAGEMENT
& GOVERNANCE OFFICE

Streamlined NHS Permissions Approach to Research – Cymru (SPARC)

System Process – Overview

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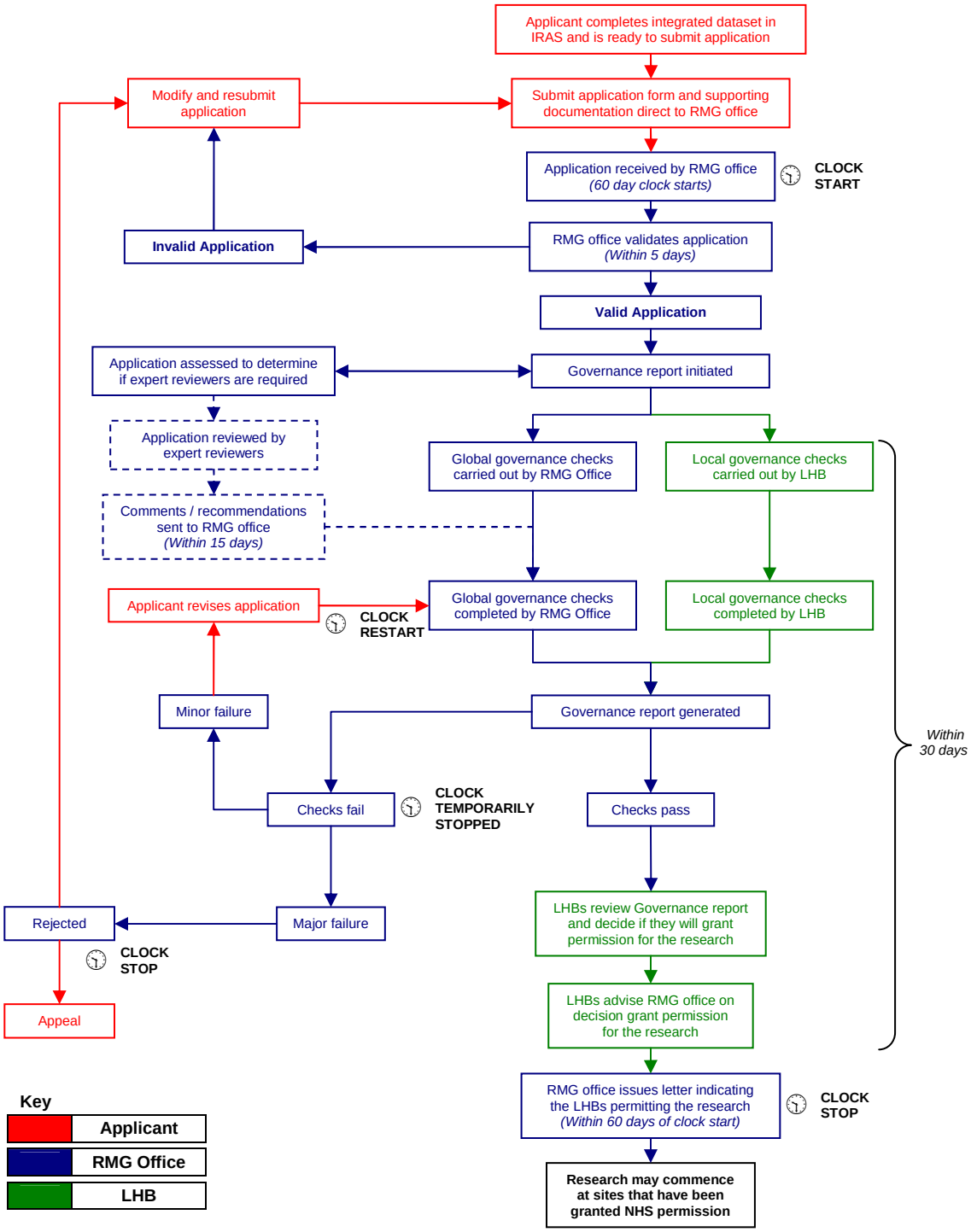
Streamlined NHS Permissions Approach to Research

The process of obtaining NHS permission for primary care research studies in Wales is described on the following pages.

Procedural steps for the permission process

Step	Action	Responsibility
1	Complete dataset in Integrated Research Application System (IRAS) and collate supporting information and documentation.	Applicant
2	Submit application to All Wales Primary Care Research Management & Governance (RMG) Office. • NHS REC submission checklist. • NHS REC Form. • NHS/HSC R&D submission checklist. • NHS/HSC R&D Form (project information). • NHS SSI submission checklist • NHS/HSC R&D Form (SSI) [also known as the Site Specific Information (SSI) form]. • IRAS exported project data xml file (project information). • IRAS exported project data xml file (sites information). • Study documentation listed in the submission checklists, as portable document format (pdf) files. • Wales / Welsh specific information.	Applicant
3	Application received by RMG office **(60 day clock starts)**.	
4	Application validated according to RMG office checklist within 5 days of receipt clock start **(within 5 days from clock start)**. If application is valid, go to step 6. If application is invalid, go to step 5.	RMG office
5	An invalid application notification is sent to the applicant. A re-submission is required in order for the application to progress further.	RMG office
6	A valid application notification is sent to the applicant.	RMG office
7	Initiate Governance report. Assess application to determine if expert reviewers are required. If expert reviewers are not required, go to step 10. If expert reviewers are required, go to step 8.	RMG office

Step	Action	Responsibility
8	Send application to reviewers selected from a pool of expert reviewers for review.	RMG office
9	Assess application according to assessment criteria. Send review with comments / recommendations to RMG office within 15 days of receipt **(within 20 days from clock start)**.	Reviewer
10	Identify named participating research sites within the R&D form and corresponding Local Health Board.	RMG office
	Steps 11 to 14 should be completed within 30 days target (within 35 days from clock start).	
11	Undertake governance checks using information from the R&D form, SSI form and associated documentation. Global governance checks will be undertaken by RMG office. Local governance checks will be undertaken by the Local Health Boards.	RMG office & LHB
12	Governance checks completed and a governance report is generated, check status confirmed from the governance report. If checks “pass” go to step 13. If checks “fail” go to step 16.	
13	Use governance report to decide whether or not to grant permission for the research.	LHB
14	Advise RMG office of decision to grant permission for the research. If permission is granted, the LHB issue a signed letter indicating their permission for the research to commence. If permission is not granted, the LHB issue a signed letter indicating their refusal including justification for not granting permission.	LHB
15	Issue applicant with letter indicating the LHBs granting permission for the research to commence and those where permission is not granted **(within 60 days from clock start)**. Include LHB letters as attachments.	RMG office
	Research may commence at sites that have been granted NHS permission.	
16	If checks fail, temporarily stop the clock.	RMG office
17	Confirm if it is a minor or major failure. If “minor checks fail” go to step 18. If “major checks fail” go to step 22.	

Step	Action	Responsibility
18	Detail the “minor checks fail” conditions (i.e. minor revisions; additional information required).	RMG office
19	Notify applicant of “minor checks fail” and detail the minor revisions or additional information required in the notification.	RMG office
20	Revise application or provide additional information as requested and re-submit to the RMG office.	Applicant
21	Consider revisions or additional information If revisions or additional information are acceptable go to step 12. If revisions or additional information are not acceptable go to step 17.	RMG office
22	Detail the “major checks fail” conditions.	RMG office
23	Notify applicant of the application rejection due to “major checks fail” and detail the reasons of “major checks fail” in the notification.	RMG office
24	Revise and submit a new application; or Appeal against the decision.	Applicant

Flowchart of the permission process