Applying to a NETSCC Research Programme

This document is a guide to applying to a NIHR Evaluation Trials and Studies (NETS) research programmes and should be read in conjunction with the general guidance provided on the NETS Coordinating Centre (NETSCC) website.

General Points about the Application Process

Each of the research programmes has a different process for evaluating applications (see Appendix A). Generally speaking, applications are assessed through a two-stage process. An outline application or expression of interest is required by the advertised closing date, following which you may be invited to submit a full proposal. This is usually accompanied by feedback on the application from an evaluation panel and peer reviewers. This must be addressed in the full submission which should be submitted by the date provided in the feedback documentation.

1. Attribution of the costs of Research & Development (AcoRD)

You are advised to read the DH and HSC R&D Division documentation related to the AcoRD guidance before completing attributions.

The costs of undertaking research are divided into three main categories:

Research costs are the costs associated with activities that are entirely related to the research. These would end when the research study ends. For research funded by members of the Association of Medical Research Charities (AMRC), these costs are further separated into Research Part A and Part B costs (eg CTU costs, randomisation, CRF completion, manufacture of study drug, costs related to the evaluation of patients in the clinical study that are not part of the standard care etc.).
Further details are provided in the AcoRD documentation references above.
NHS Support Costs are costs that are associated with additional patient care that is required because the research study is taking place, but that would also form part of the NHS Duty of Care of a patient. These activities would end when the research study ends, and would not continue even if the care being tested continued to be provided as standard care of the patient. Examples include:

- Screening routinely collected data or other processing of patient records in order to identify patients who may be suitable to approach regarding study participation.
- Obtaining informed consent from participants.
- Tests undertaken for the purposes of assessing patient safety, but more closely than would be the case if the intervention was to become standard care e.g. in the research study, a blood test is carried out at Days 0, 7, 14 and 28 to monitor patient safety and provide additional safety measures that will be reported as part of the study. If the intervention was routine care, blood tests would only be carried out on

Days 0 and 28. The tests on Days 7 and 14 are additional safety tests taking place because of the research, and so the cost of these is a NHS Service Support Cost.
- Tests to assess patient safety during follow-up.

Further details of attributing the costs of health and social care R&D can be found on the HSC R&D Division website.

NHS Support Costs are met from the R&D budget of the Departments of Health in the relevant UK nations, ***and are subject to prior agreement and budgetary constraints***. For studies with sites in England, the resources for meeting these costs are mainly met through the NIHR Clinical Research Networks, but agreement may still be required at a Trust level. If your study has sites in devolved administrations, and will incur NHS Service Support Costs, you or a member of your research team should consult with the relevant organisation responsible for the R&D budget in each devolved administration in which study sites are planned.

For Northern Ireland site costs, you should complete the **HSC R&D Division Service Support Costs Application Form** in conjunction with your primary funding application, provide an update at any subsequent application stage, and again if funding is awarded. The application form is available at the HSC R&D Division website.

NHS Treatment Costs are the costs of caring for the patient, regardless of whether that care is experimental or standard. There will therefore be treatment costs associated with all patients taking part in a research study where the research is taking part in the NHS. **Excess Treatment Costs** are the costs that are associated with patient treatments in a research study that are over and above the cost of standard care, and that would continue if the treatment was to become standard care. For some research studies, there could be a treatment cost saving.

Excess treatment costs should be funded by the NHS and so must be discussed with Clinical Directorates and/or Commissioners within the NHS organisations where the research is expected to take place. Early discussions are recommended.

- At outline stage, you will be required to provide figures for the total research, support and treatment costs of your study, which should be estimated as accurately as possible – in most cases, there is at most 10% flexibility between outline and full, unless the outline review indicates that a change in study design or that more significant cost reduction is required. You should ensure that your costs are accurately attributed as research, treatment and support costs and that you speak to the relevant organisations about them.
- Make contact with all relevant organisations as early as possible in your application process, particularly where there are likely to be significant resource implications.
- Work is on-going to adopt an attribution template which will be available in due course. The HRA Schedule of Events and Statement of Activities are useful tools that can be completed and amended at any stage of the application process.
- As well as justifying the costs requested from NIHR, the Justification of Costs section of the full application form should be used to explain the attributions described above. HSC R&D Division can provide support and guidance on completion of this section upon request.

2. Sign-off Process

As part of the NETSCC application process, you will need to confirm support for your funding application from individuals representing organisations that will be involved in its management and delivery. These individuals must "join" the application through the NETSCC Management Information System (MIS), after which they must review the pertinent parts of your application and "approve" it. This confirms agreement to the relevant terms and conditions of their role in supporting or participating in the funding application, which can be found in **Table 1**. Completing the tasks on NETSCC MIS constitutes an electronic signature and indicates that the individual agrees to these terms and conditions.

During both the outline and full application process, the Lead Applicant will need to "assign tasks" and request the participation in the application of appropriate individuals. Contact details for appropriate individuals within Northern Ireland are provided in **Table 2**.

Applications led from Northern Ireland

When a study is led from Northern Ireland the following signatories are **required**:

- Lead Applicant
- Head of Department Contracting Organisation (normally the employing organisation of the Chief Investigator)
- Sponsor
- Finance Director Administrative Authority/Contracting Organisation
- NHS Costs Nominated Signatory – **a signature from the lead NHS organisation is sufficient; you do not need signatures from each proposed NHS organisation or each devolved administration**
- Representative of the R&D function of the Devolved Administration – **a signature is required from the relevant organisation in EACH Devolved Administration:**
    - Northern Ireland: HSC R&D Division, Public Health Agency: Janice.bailie@hscni.net or Julie.mccarroll@hscni.net
    - Wales: Health and Care Research Wales: research-fundingsupport@wales.nhs.uk
    - Scotland: NHS Research Scotland: Gordon.Watt@scotland.gsi.gov.uk

The following **may** also be required:

- NHS Facilities and Staff nominated signatory
- Partner Organisations facilities and staff (if applicable) – where non-NHS organisations will be involved in the delivery of the research

Sign-off of Electronic Application

<u>Lead Applicant</u>/Chief Investigator actions: Inviting participants on MIS

- Add the representative to your online application and select the role and task that they should complete
- The representative will receive an email notifying them of their involvement and inviting them to log on to the NETS MIS to complete their task
- If this is the first request received by them, the participant will need to register on the system, and create a username and password
- Once registered, the participant will be able to log in and view all **Projects** and action **Tasks** in which they are involved
- Once you have completed all the sections and uploaded the electronic form, a separate task will be generated prompting you to request that the signatories review their relevant sections in the application, and confirm they accept the application's content
- This replaces the need for wet or ink signatures on the paper copy. Submitting this task constitutes an electronic signature of the supporting role
- It is your responsibility to ensure these 'signatures' have been completed **within two weeks of submission**, after which time it will close.
- You can monitor these acceptances via the 'Research Team' tab. Once all signatories are completed the lead applicant should email a screen shot of the completed page to the relevant funding team

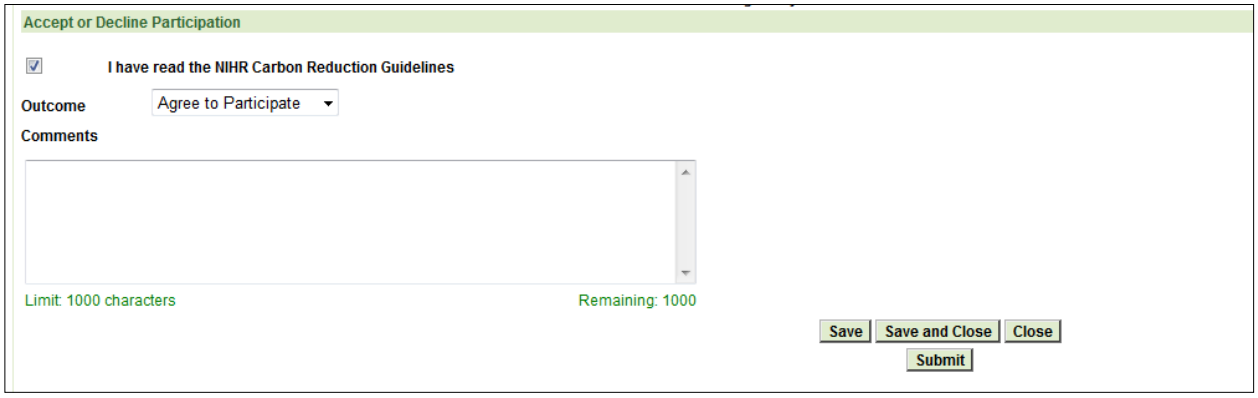
<u>Invited Signatory</u> actions: joining and reviewing applications

- Once the Lead Applicant enters your details against the selected role, you will receive an email to notify you of your involvement and invite you to log on to the NETS MIS and complete your Tasks
- If you have not already done so, you will need to register on the system, and create a username and password
- Once logged in to MIS, a new request will appear in the **My Tasks** list
- Complete the check box regarding Carbon Reduction Guidelines and select "**Agree to Participate**" in the Outcome box drop-down menu (see **Image 1**)
- Once the Lead Applicant has completed and uploaded their application, a new Task will appear in their **My Tasks** list prompting them to notify the signatories that they need to review the completed application, confirm their acceptance of the terms and the conditions of their role in the completed application
- You will receive an email notifying you of another pending Task
- You should then select the new task in your **My Tasks** list and review the pdf application before selecting "**Review and Submit**"
- Submitting this task constitutes an electronic signature of the supporting role
- The Lead Applicant is responsible for ensuring that this is completed within **2 weeks** of the closing date for the application, after which time the online application will close

Requested Tasks may include:

✓ Accept full application participation (*Role Name)*
✓ Full Application
✓ Revised Application
✓ Accept Revised Application Participation (*Role Name*)
✓ Provide Full Application Signature (*Role Name*)
✓ Provide Revised Application Signature (*Role Name*)

Image 1: Accepting participation in the application on MIS



Further guidance on the Supporting Role Signatory Process can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0008/96515/MIS-brief-for-Supporting-Role-Signatories.pdf.

A guide for Chief Investigators can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0010/67762/MIS-Brief-Chief-Investigators.pdf.

Guidance notes for completing full proposal can be found at http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0005/79664/FullGuidanceNotesSAF-V1_22.pdf

Table 1: NETSCC Applications Role and Responsibilities (also available here)

Role	Guidance statement
Lead Applicant (Outline application)	In confirming your role as Lead Applicant (CI) in this application you confirm that the information given in this form is complete and correct and that you take full responsibility for the accuracy of this submission. You shall be actively engaged in, and in day to day control of, the project. You confirm that you understand that progress reports will be required by the funding programme and that no substantive variation in the scheme as outlined in the application will be permitted without prior reference to the funding programme.
Lead Applicant (Full application)	In confirming your role as Lead Applicant (CI) in this application you confirm that the information given in this form is complete and correct and that you take full responsibility for the accuracy of this submission. You confirm that all co-applicants mentioned on this application have been given access to the application and accepted their role in this submission. You shall be actively engaged in, and in day to day control of, the project. You confirm that you understand that progress reports will be required by the funding programme and that no substantive variation in the scheme as outlined in the application will be permitted without prior reference to the funding programme.
Head of Department Contracting Organisation	In confirming your role in this application you are agreeing that the work, if funded will be accommodated and administered in the department/institution and that applicants for whom you are responsible will undertake this work. We would normally expect the person who signs this to be the person who is responsible for the department where the bulk of the research will take place.
Sponsor	In confirming your role as sponsor you are agreeing that if funded, your institution is prepared to become the sponsor for this study and will take on all responsibilities as per the Research Governance Framework for Health and Social Care.
Finance Director Administrative Authority / Contracting Organisation	In confirming your role in this application you are stating that you have checked the financial details of this research application and read the terms of the standard contract, and that your institution is prepared to enter into such a contract and administer the award if made. You also confirm that the staff grades and salaries quoted are correct and in accordance with the normal practice of your institution
NHS Facilities and Staff nominated signatory's declaration	In confirming your role in this application you agree to the use of NHS facilities and staff for this work. Also that you are satisfied by the arrangements made for indemnity.
Partner Organisations facilities and staff	In confirming your role in this application you agree to the use of the Partner Organisation facilities and staff for this work.
NHS Costs Nominated Signatory	In confirming your role in this application you are agreeing to the NHS costs being funded by your organisation for patients recruited to this trial within the sites covered by your organisation, Further assurance will be sought in relation to NHS costs at other sites.

Role	Guidance statement
Representative of the R&D Function of the Devolved Country	For research projects originating in Scotland, Wales or Northern Ireland, you will need to provide evidence of support with regards to NHS support and treatment costs. For research projects originating in Northern Ireland (NI), or likely to recruit mainly in NI, the NETSCC programme will need you to provide evidence that the Public Health Agency in Northern Ireland are aware of and approve your NHS Support costs before any funding can be approved. For proposals originating outside NI but using NI as one of many recruitment areas, you will need to contact the Public Health Agency in Northern Ireland before approval, and they will take the final decision as to whether they will support recruitment there.

Table 2: Northern Ireland NHS organisation signatories

Role	Organisation	Contact Name	Department	Email and telephone	Comments
Sponsor and/or NHS Facilities and Staff Nominated Signatory	BHSCT	**Primary:** Alison Murphy	BHSCT Research Office	Alison.Murphy@belfasttrust.hscni.net T: 028 9063 6366	
		Secondary: TBC			
	NHSCT	**Primary:** Frances Johnston	NHSCT Research Office	frances.johnston@northerntrust.hscni.net 028 9442 4653	
		Secondary: Des Rooney		Des.rooney@northerntrust.hscni.net 028 9442 4176	
	SHSCT	**Primary:** Irene Knox	SHSCT Research Office	Irene.Knox@southerntrust.hscni.net 028 3861 4274	
		Secondary: Peter Sharpe		Peter.sharpe@southerntrust.hscni.net 028 3836 0696	
	SEHSCT	**Primary:** Paul Carlin	SEHSCT Research Office	Paul.Carlin@setrust.hscni.net 028 9055 3101	
		Secondary: David Hill		David.Hill@setrust.hscni.net 028 4483 8309`	
	WHSCT	**Primary:** Sally Doherty	WHSCT Research Office	Sally.Doherty@westerntrust.hscni.net 028 7161 1156	
		Secondary: TBC			
Sponsor	Queen's University Belfast	**Primary:** Louise Dunlop	QUB Research & Enterprise (Research Governance)	l.h.dunlop@qub.ac.uk 028 9097 2572	
		Secondary: Paula Tighe		p.tighe@qub.ac.uk 028 9097 3861	
	Ulster University	**Primary:** Nick Curry	Ulster University Research & Impact (Research Governance)	n.curry@ulster.ac.uk 028 903 66629	
		Secondary: Elaine McCormick		e.mccormick@ulster.ac.uk 028 903 66518	

Role	Organisation	Contact Name	Department	Email and telephone	Comments
Administrative Authority of Finance Office AND NHS Costs Nominated Signatory	BHSCT	**Primary:** Kate O'Brien	BHSCT	kate.obrien@belfasttrust.hscni.net 028 95 046928	
		Secondary:			
	NHSCT	**Primary:** Kim Ferguson	NHSCT	kim.ferguson@northerntrust.hscni.net 028 9086 5181	
		Secondary: Ramsey Mewha		ramsey.mewha@northerntrust.hscni.net 028 2563 5333	
	SHSCT	**Primary:** Dean Faloon	SHSCT	dean.faloon@southerntrust.hscni.net 028 3861 3060	
		Secondary:			
	SEHSCT	**Primary:** Claire Crudden	SEHSCT	claire.crudden@setrust.hscni.net	
		Secondary:			
	WHSCT	**Primary:** Kieran Anderson	WHSCT	kieran.anderson@westerntrust.hscni.net 02871345171 Ext 214957	
		Secondary: Wendy Gourley		Wendy.Gourley@westerntrust.hscni.net 028 7186 0616 Ext 218250	
Administrative Authority of Finance Office	Queen's University Belfast	**Primary:** Colleen Spence	QUB Research Support Office	Colleen.Spence@qub.ac.uk 028 9097 5183	
		Secondary: Siobhan McGlinchey /Alison Mahon		s.mcglinchey@qub.ac.uk alison.mahon@qub.ac.uk 028 9097 1160/3167	
	Ulster University	**Primary:** Nigel McFarland	Ulster University Research & Impact (Research Governance)	ulster-submission@ulster.ac.uk 028 701 24378	
		Secondary: Diana Ridley Chris Klavinskis		dl.ridley@ulster.ac.uk 028 701 24752 c.klavinskis@ulster.ac.uk 02870124685	

Role	Organisation	Contact Name	Department	Email and telephone	Comments
Representative of the R&D function of the Devolved Country	Public Health Agency	**Primary:** Janice Bailie **Secondary:** Julie McCarroll	HSC R&D Division	Janice.bailie@hscni.net 028 9536 3490 Julie.mccarroll@hscni.net 028 9536 3490	
Head of Department Contracting Organisation	Chief Investigator's Centre Director/Service Lead				

Studies Involving Research Infrastructure

It is essential that costs included in applications clearly reflect the use of research infrastructure and expertise. It is therefore advised that appropriate contact is made as early as possible in the application process so that resources can be managed effectively and costs can be as accurate as possible.

NI Clinical Trials Unit

The involvement of a Clinical Trials Unit is strongly encouraged and is likely to increase the chances of a successful application. If appropriate expertise is not included within the application/team, and a CTU is not involved, you will be required to explain why this is the case within your application.

If you would like to request **NICTU support**, please complete the NICTU Collaboration Request Form (available at http://www.nictu.hscni.net) and send this to info@nictu.hscni.net, copied to Lynn Murphy (Lynn.murphy@belfasttrust.hscni.net). For additional information see http://www.nictu.hscni.net.

Clinical Research Network/Cancer Trials Network/Public Health Research Network

You are encouraged to consider if your study could be supported/adopted by a Northern Ireland research network infrastructure organisation, as this can often strengthen applications. If you wish to utilise one of these resources, you should initiate discussions with the relevant organisation as early as possible. Initial enquiries should be to:

- Northern Ireland Clinical Research Network: Paul Biagioni, NICRN manager: Paul.Biagioni@belfasttrust.hscni.net
- Northern Ireland Cancer Trials Network/Centre: Melanie Morris, NICTN Operational Director: melanie.morris@belfasttrust.hscni.net
- Northern Ireland Public Health Research Network: Mark Tully, NIPHRN Clinical Director: m.tully@qub.ac.uk

When preparing to complete the finance sections of your application, you should also include Julie McCarroll, Programme Manager, HSC R&D Division, (Julie.McCarroll@hscni.net) to ensure costs for activities are allocated accurately and network support is agreed where appropriate. Any discussion regarding costs, rates and attributions is ***advisory*** and does not replace the need for sign-off from the NHS Costs Nominated Signatory and Representative of the R&D Function of the Devolved Country.

Northern Ireland Biobank

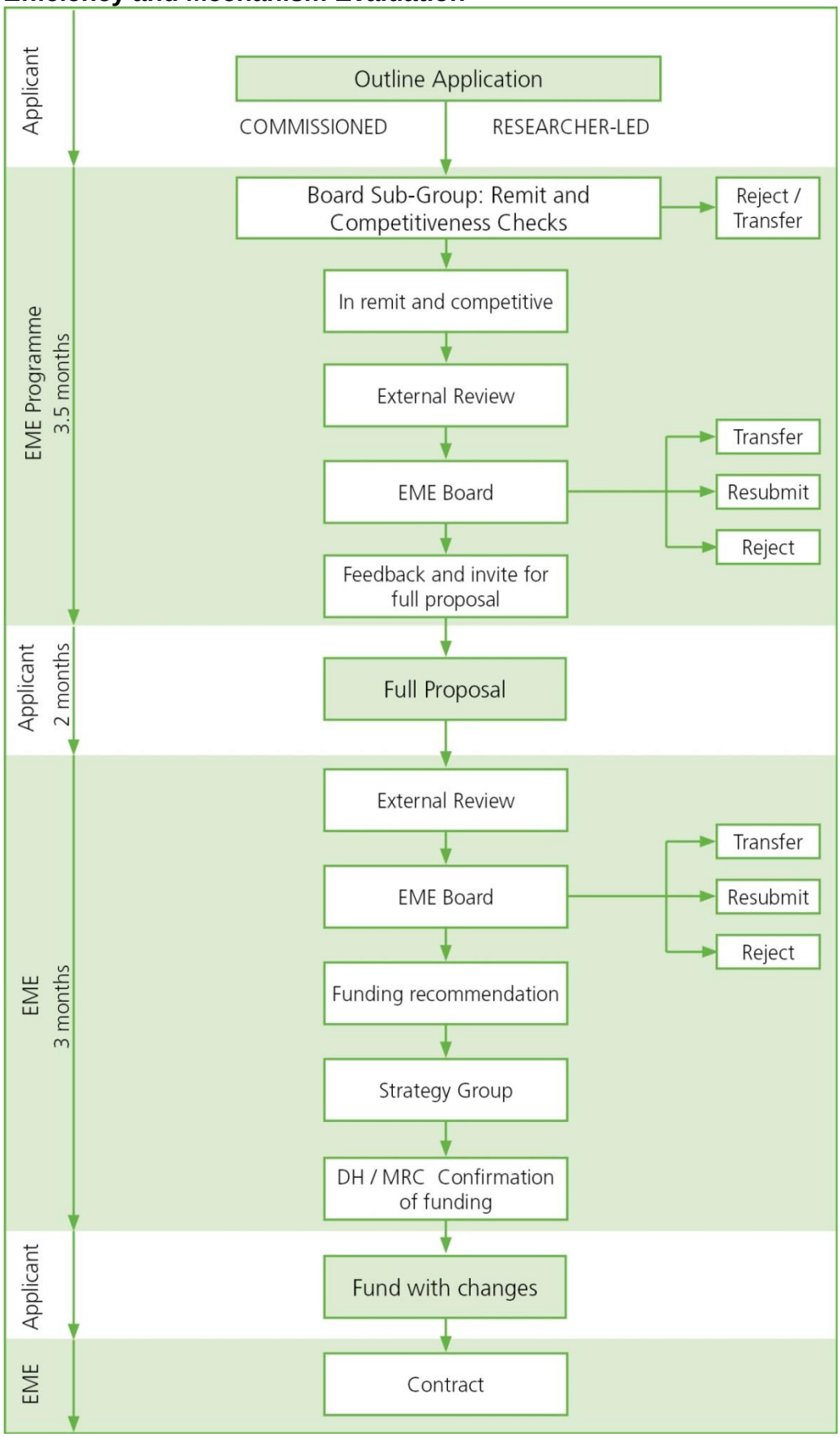
If your proposal includes the use of samples from, or the collection of samples by the Northern Ireland Biobank, **it is recommended you discuss your proposal with the biobank in the first instance for advice on the feasibility of acquiring samples within specific timeframes and whether it will fall within the remit of NIB ethics approval.** You must then register with NIB **to complete a preliminary application**. The costs related to sample collection, processing, storage, handling and maintenance **must** be properly calculated and claimed in the NETS research application. Advice on costs **and, if appropriate, letters of support** can be provided by NIB; please contact the **NIB Administrator** at nibiobank@qub.ac.uk in the first instance.

Northern Ireland Clinical Research Facility

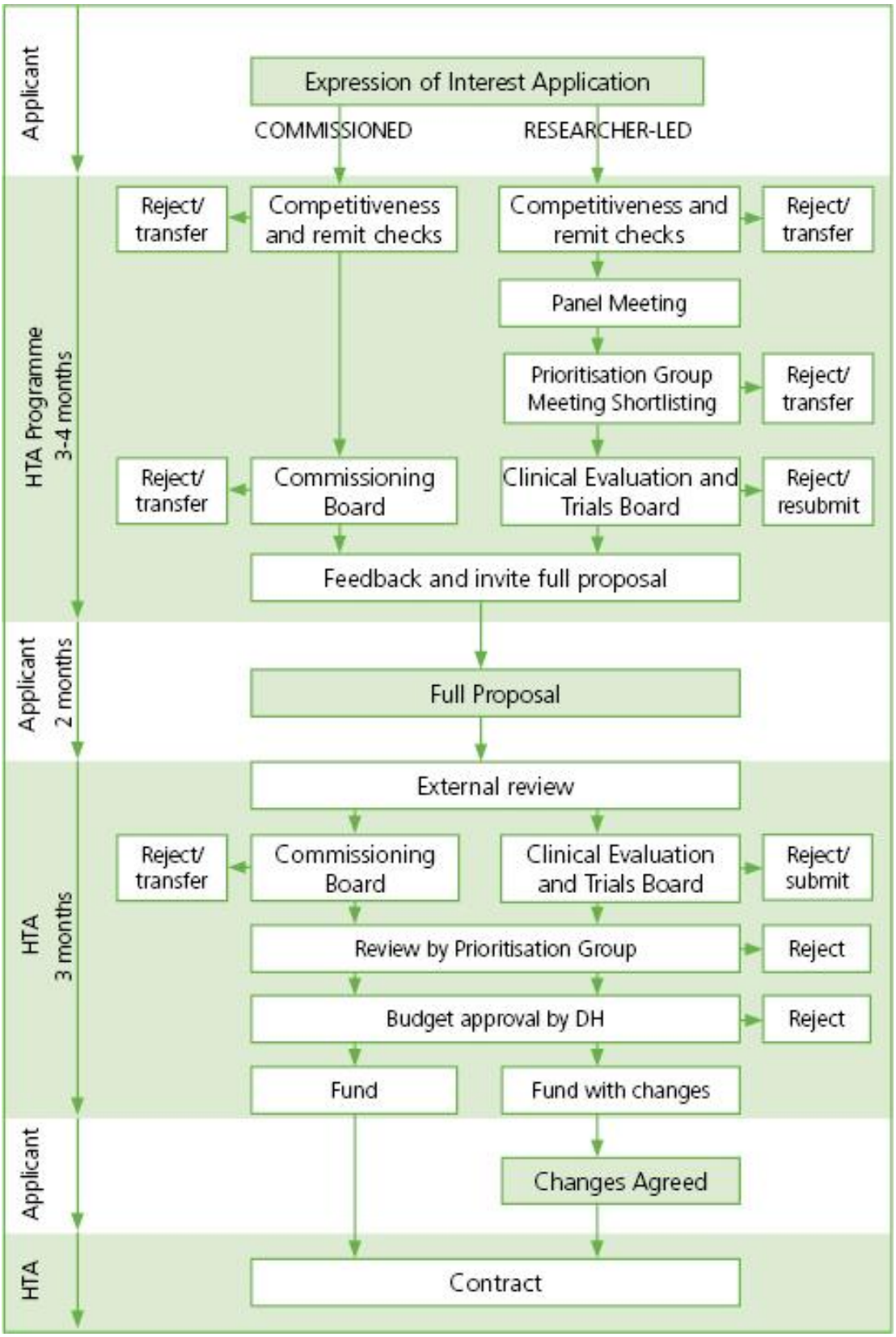
If your study could utilise the Northern Ireland Clinical Research Facility, early contact with the NICRF is advisable. An application pack which provides clear instruction on how to apply for access to the NICRF and / or include NICRF costs into your grant application is available. Your application to use the facility will be considered by the Access Committee and is subject to ethical and governance approvals. Specific advice can also be provided on appropriate costing of NICRF-related activities for inclusion in your application for funding. Please email NICRF@belfasttrust.hscni.net in the first instance.

Appendix A: NETS Research Programme application processes

Efficiency and Mechanism Evaluation

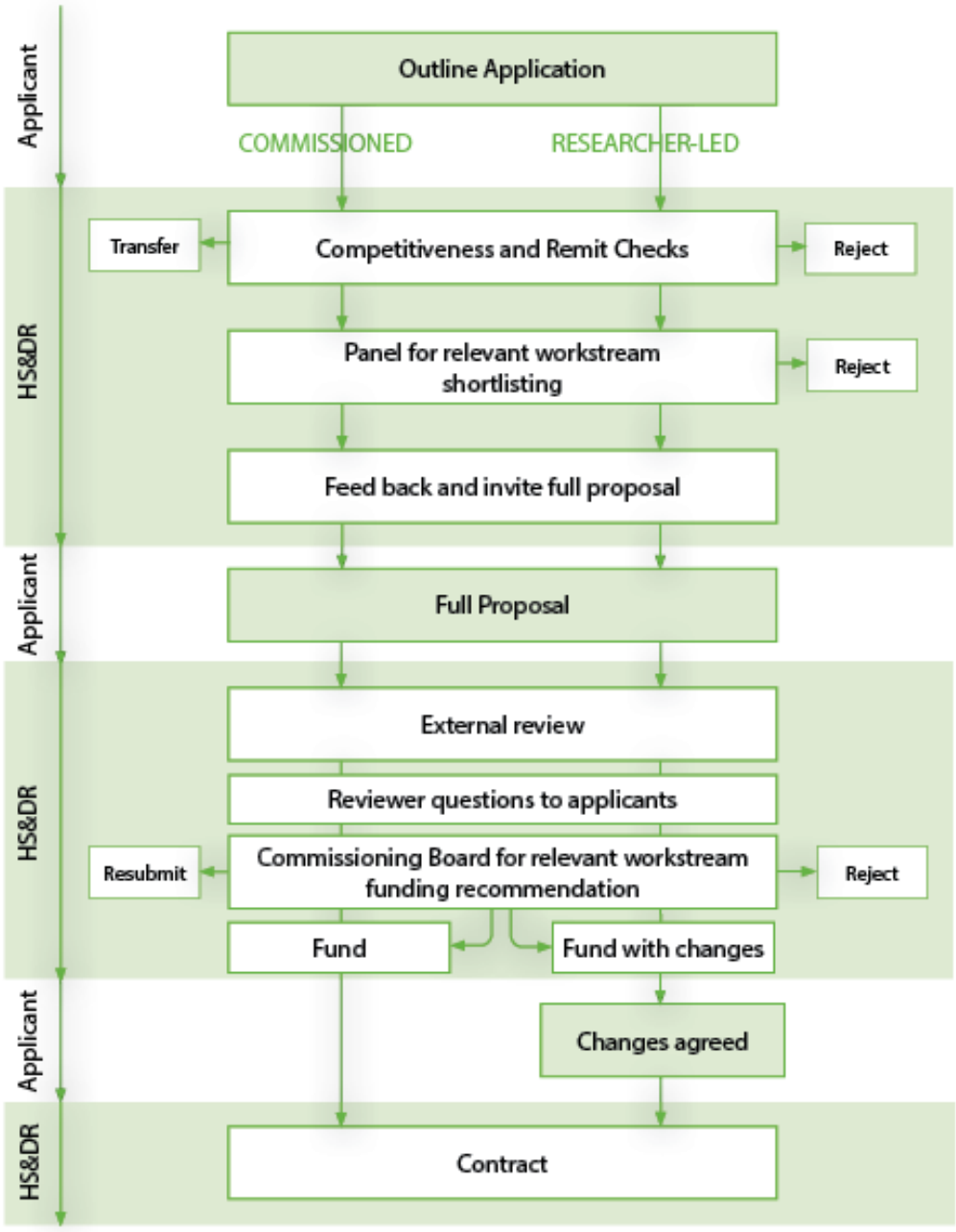


Health Technology Assessment



Application Process

Applications are usually assessed using the two stage process outlined below.



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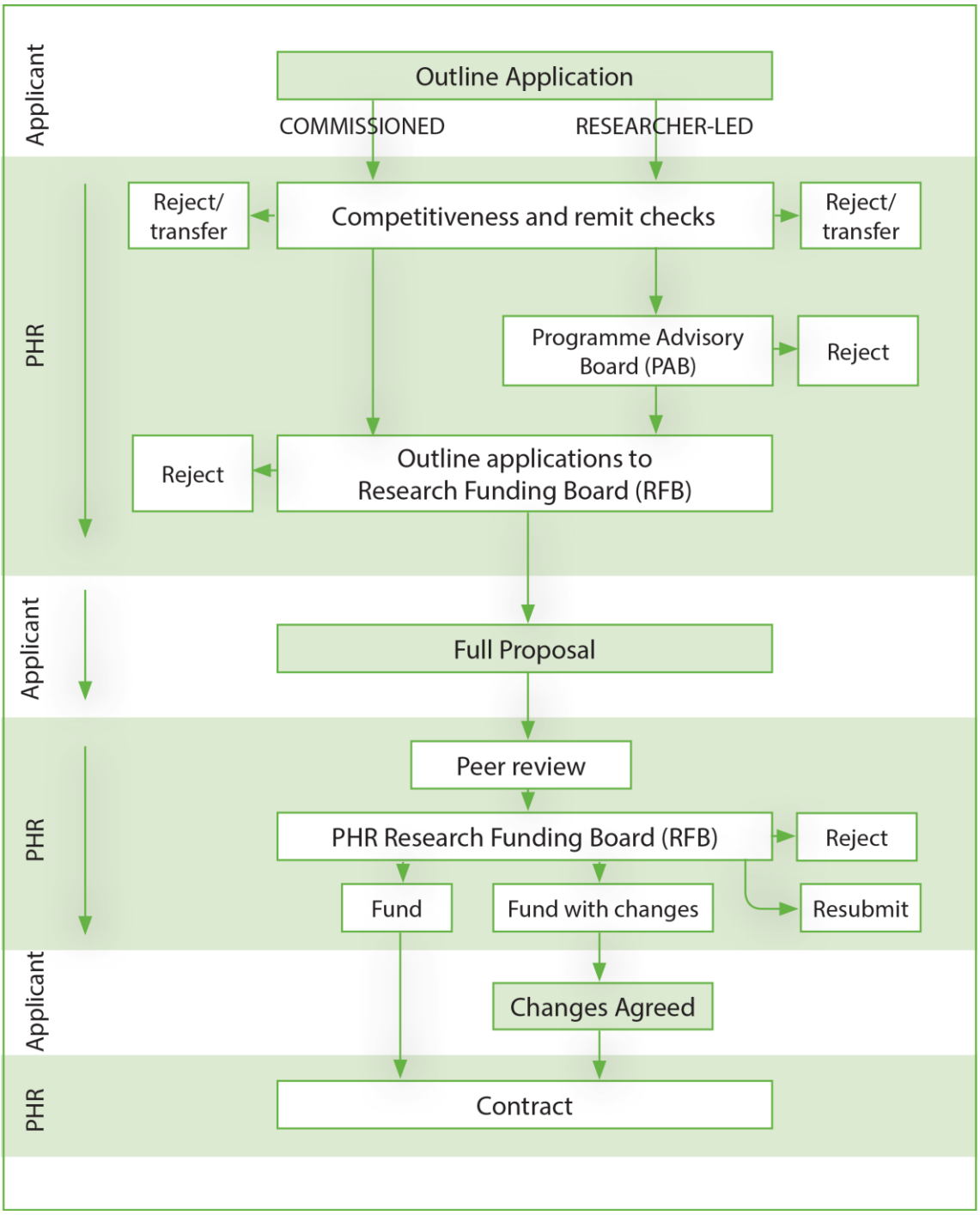
Applicant
Outline Application
COMMISSIONED
RESEARCHER-LED
PHR
Reject/ transfer
Competitiveness and remit checks
Reject/ transfer
Programme Advisory Board (PAB)
Reject
Reject
Outline applications to Research Funding Board (RFB)
Applicant
Full Proposal
PHR
Peer review
PHR Research Funding Board (RFB)
Reject
Fund
Fund with changes
Resubmit
Applicant
Changes Agreed
PHR
Contract