

Research Process at Newcastle



Newcastle Joint
Research Office - NJRO

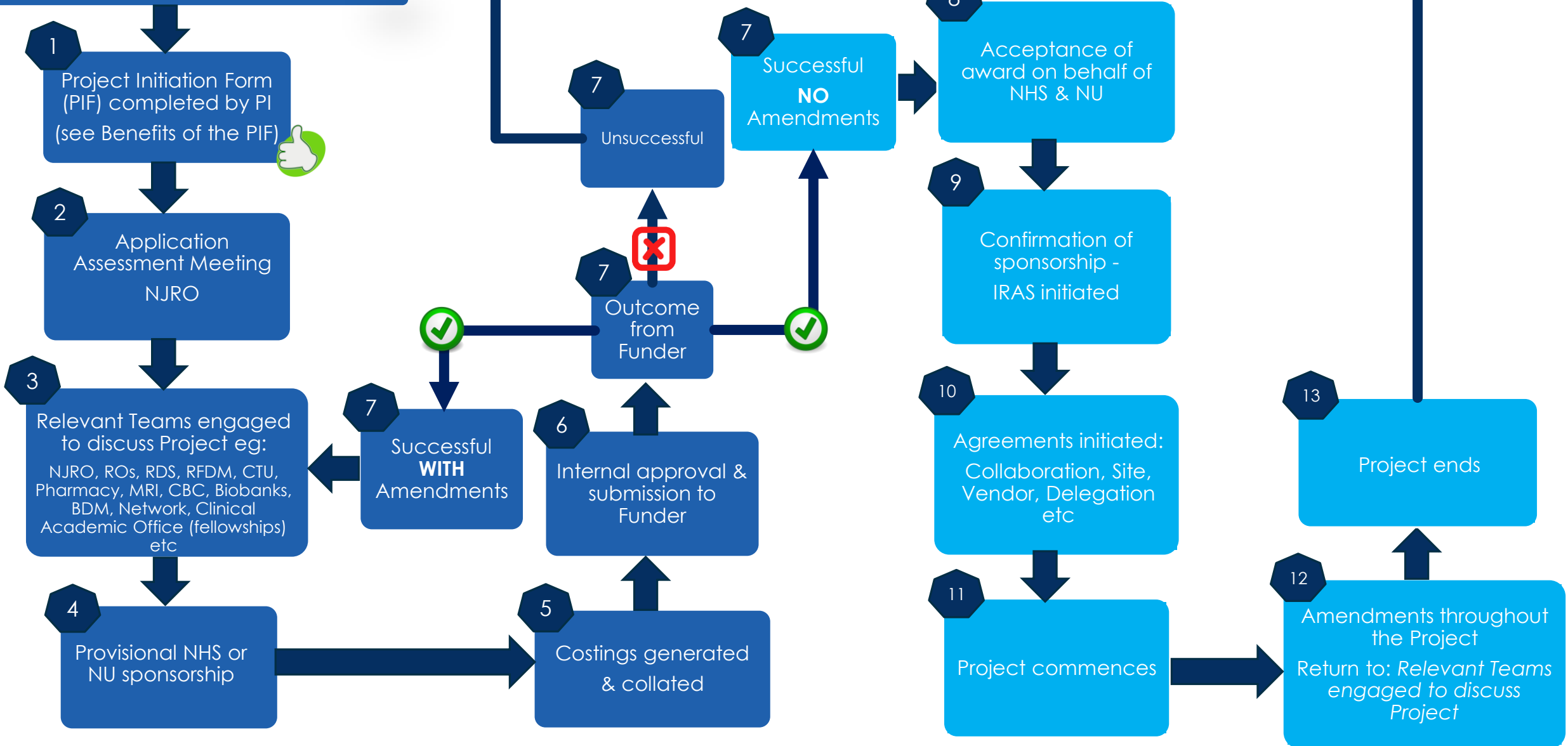


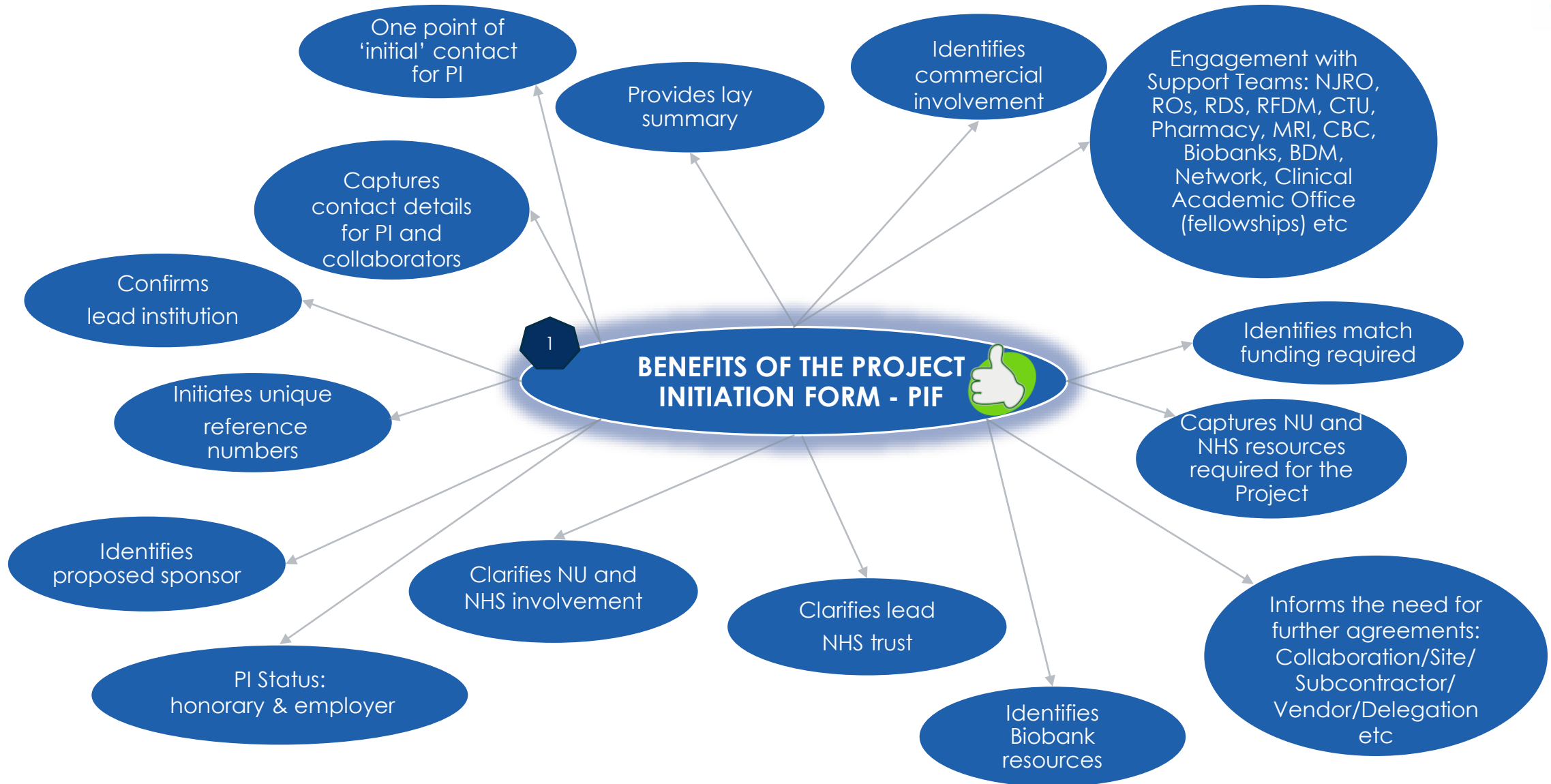
Application Submission & Application Outcome (Non commercially sponsored)

<https://newcastlejro.com/>

Overview for PI: RESEARCH PROCESS

PI RESEARCH IDEA GENERATED







Be Mindful: it can take 2-12 months for the development of an initial idea being ready for submission to Funder – (depending on the type of Project)
Costings can take from 2-8 weeks – NHS & NU
Internal approvals ideally require 5 working days – NHS & NU
Feedback from Funders can take upto 6 months +



1. Project Initiation Form (PIF) completed by PI:

This provides the PI with one initial point of contact to provide project information and triggers the engagement of the relevant teams, initiates the costing process, and provide clarity of which organisations are involved – See Benefits of the PIF.

2. Application Assessment Meeting (AAM) - NJRO:

The PIF, if there is NHS involvement, is reviewed at the weekly AAM meeting held by NJRO – the review involves raising questions about the Project including feasibility, funder, sponsor, costs, relationship of parties, and the need for further engagement - an Application Meetings with the PI and any other Relevant Teams may subsequently be arranged.

3. Relevant Teams engaged - NJRO, ROs, RDS, RFDM, CTU, Pharmacy, MRI, CBC, Biobanks, BDMs, Network etc:

NJRO provides support & advice on:

- Mentor/Supervisor – who and why
- Academic Sponsor – who should this be and can they provide lab space
- Arranging an application meeting for complex, clinical, collaborative projects
- Assistance in writing protocol
- Assistance in completing application form
- Assistance in obtaining Faculty support
- Lay review
- Letters of support from the NU
- Biobanking advice
- Agreements - collaborative and/or site, CDA/MTAs/Data sharing etc
- NHS Costings (via Team Leads)

Research Design Service North East (RDS) provides support & advice on:

- Refinement of research question
- Sources of funding
- Trial design
- Sampling strategies and sample size calculations
- Planning for successful trial conduct

Newcastle Clinical Trials Unit (NCTU) provides support & advice on:

- Trial development (in conjunction with RDS)
- Trial set-up
- Trial conduct, management and monitoring
- Trial analysis, reporting and close-down

Business Development & Enterprise:

- Intellectual Property (IP) – evaluating/protection/exploiting
- Commercialisation strategies

Institute provides support & advice on:

- Peer Review
- Initiating costing within NUProjects (NUP) via information from the PIF

Clinical Academic Office (CAO):

Discuss Clinical Fellowship Proposals with CAO who will provide fellowship specific documentation, which should be read in conjunction with this document. (Examples of Fellowships: NIHR ICA, NIHR Post Doctoral, NIHR Clinician Scientist, Wellcome Pre Doctoral, MRC Doctoral)

4. Provisional NHS & NU Sponsorship:

From information provided on the PIF - discussions take place with Sponsorship Teams to agree 'in principle' which organisation should undertake this role.

5. Costings generated and collated:

Research Officer (RO) will assist the PI with:

- Costing the Research Project in NUP
- Coordinating collaborator costs
- Preparing Collaborators Budget Breakdown (CBB)
- Assist in completing the Funder Application Form

NJRO (NuTH Research Funding Development Manager) will assist the PI with:

- NHS costings via Team Leads
- Coordinating collaborator costs
- Preparing Collaborators Budget Breakdown (CBB)
- Assist in completing the Funder Application Form

6. Internal approval & submission to Funder

- PI starts internal approval via NUP – all documents uploaded (Application Form, case for support, costings, CBB, CVs any other supporting documents)

Institute:

- Academic Unit approval is obtained in NUP

NJRO:

- Check application and all supporting documents are uploaded to NUP
- Approve application in NUP
- Sign paper version of application if NU led
- Submit electronic applications along with PI if NU led

Head of Institute:

- Approve application in NUP
- Approve electronic application if required

Pro Vice Chancellor:

- Approve application in NUP if required

NHS Finance:

- Check application and NHS costings and consider VAT and excess treatment costs
- Approve application
- Sign paper version of application if NHS led
- Submit electronic application along with PI if NHS led

7. Outcome from Funder

Potential Award:

- *Clinical Fellowship* – Funder invites Applicant for interview - contact CAO immediately to arrange a mock interview

Awarded WITH Amendments:

- Amendments requested by Funder – PI engages with Relevant Teams for further support - Mailto: tnu-tr.NJRO-Awards@nhs.net

Awarded NO Amendments:

- Notify Institute/RO/NJRO – Mailto: tnu-tr.NJRO-Awards@nhs.net

Unsuccessful:

- Notify Institute/RO/NJRO – further Research Idea Generated and process starts again - Mailto: tnu-tr.NJRO-Awards@nhs.net

7. Successful NO Amendments:

Mailto: tnu-tr.NJRO-Awards@nhs.net

NJRO will coordinate acceptance and negotiate with the Funder on behalf of NU and NHS also initiate an Award Meetings with the PI and Relevant Teams as required.

8. Acceptance of Award on behalf of NHS and NU:

NJRO:

- Negotiate/agrees contract with Funder
- Accepts award on behalf of PI and NU and NHS
- Arranges an Award Setup meeting with relevant support teams for clinical, collaborative, complex projects - issues to discuss (using template agenda):
 - HRA/Ethics/Sponsorship
 - Pharmacy
 - CTU involvement

- Financial implications - reprofiling
- Contracting issues – collaborative vs site, and any others agreements required
- IP and commercialisation
- Biobanking
- PCPI
- Human Resources

AoB

PI discusses various issues with Institute:

Health & Safety, Insurance, Procurement, Equipment, Human Resources etc

9. Confirmation of NHS & NU Sponsorship:

PI & Support Teams:

- Initiate ethical and sponsorship documents

Faculty:

- Provides ethical and sponsorship approval

NJRO:

- Confirms Sponsorship - provides advice for IRAS submission and any applicable authorisations ie HRA, MHRA etc

10. Collaboration, Site, Vendor, Delegation agreements etc initiated:

NJRO:

- Initiate Collaboration Agreements using CBB for finances
- Initiate Site Agreements – linking with NHS Finance
- Initiate RES account setup with Contract Financial Management (CFM) & NHS Finance
- Informs Management Accounts of fEC awards

CFM:

- Generate RES account in SAP

NHS Finance:

- Provide per patient budget for site agreements
- Generates research account in NHS

11. Project Commences:

PI:

- Undertakes Research Project

Faculty:

- Provides Training and Development for PI

NJRO:

- Processes any amendments from Funder/Collaborator including duration/funding/transfers/additional parties/termination/non recruitment etc etc

Institute/PI:

- Monitors spend on Project
- Monitors PI training and development needs

CFM:

- Monitors spend on Project
- Processes amendments

NHS Finance:

- Monitors spend on Project
- Processes amendments

12. Amendments:

Return to Relevant Teams to discuss implications.

13. Project Ends:

PI/Institute:

- HR implications/contracts
- Publications – within 12 months update relevant databases with trial results eg EudraCT
- Innovation & Exploitation, Impact
- PI returns to Research Idea Generated



Business Development & Enterprise:

- Innovation & Exploitation

NJRO:

- Impact, Biobanking, Public Engagement

CFM:

- RES account reconciled & closed

NHS Finance:

- Account reconciled & closed

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