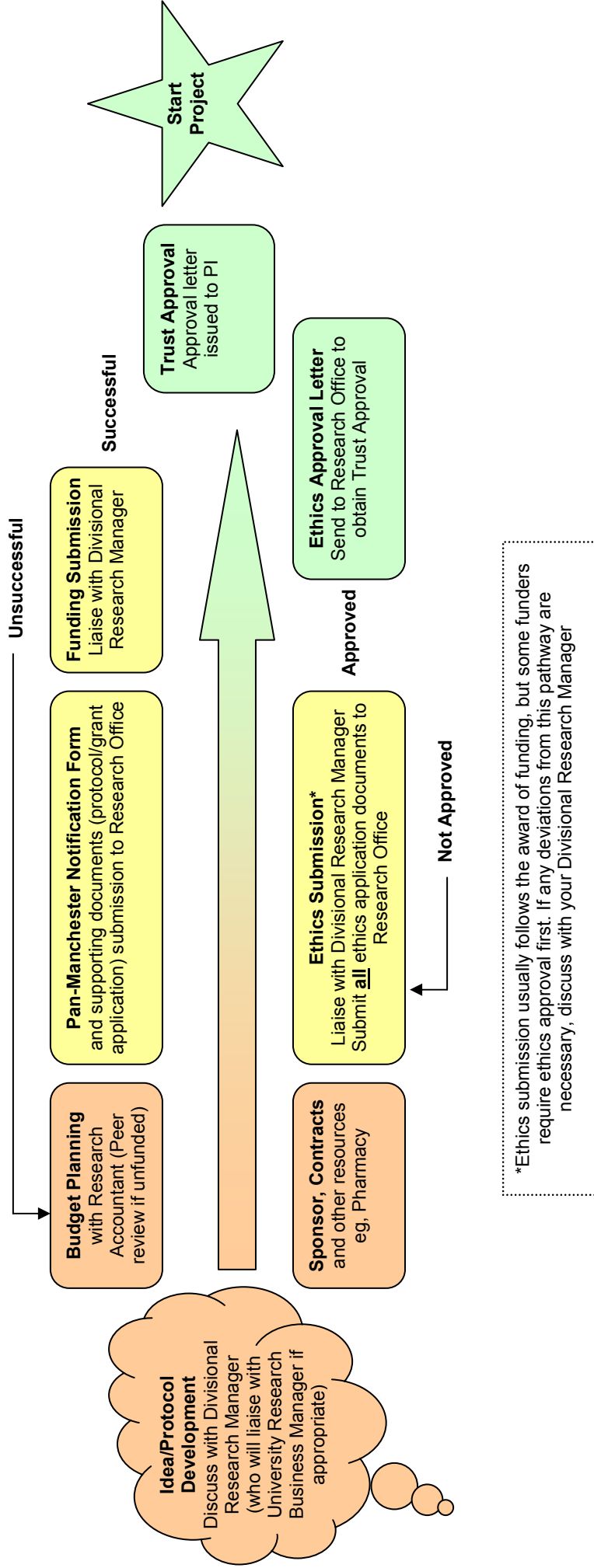


Research Project Approval Pathway - Guide for CMFT Principal Investigators



Research Project Approval Pathway – Detailed Information

Protocol

- Discuss with your Divisional Research Manager (DRM), relevant University of Manchester Research Business Manager (RBM), research & management teams, statistician, other Trust departments to be involved, relevant local/topic Research Networks. Identify appropriate funding opportunities. Involve *TrusTECH* and Industry Liaison Officer if appropriate
- Ensure Good Clinical Practice training of intended research team members is up to date
- Inform your DRM which RBM is involved
- Establish who will be the project's main contact person to liaise with the DRM. Delegate appropriate tasks from this approval pathway to the main contact person
- Devise protocol with version number and date. DRM will arrange risk-assessment.



Sponsor and contracts

Your DRM will help you to:

- Identify which organisation is sponsor (e.g., Trust, University, funder)
- Begin applicable contract and sponsorship negotiations, and Material Transfer Agreement. The Research Office will deal with commercial organisations and lead institutions from multicentre studies for all confidentiality/non-disclosure agreements and contracts.
- Prepare Research Passports for non-CMFT employees
- Discuss details with Pharmacy, and Wellcome Trust Clinical Research Facility if involved. DRM will also advise on attendance at CSS Planning and Resource Group if appropriate



Budget and Peer review

- Cost all aspects of project, discuss with Research Accountant (contact made via DRM who maintains oversight for particular divisional requirements)
- Complete grant application form
- If there is no peer review as part of the funding process then obtain an independent peer review



Pan Manchester Notification Form

- Provide DRM with protocol, grant application/budget and peer review
- The PI/delegated contact person completes the Pan Man form and obtains signatures – your DRM can help with this
- The DRM will register the project on the Trust R&D database, issue you with a project identification number, and submit all documents to the Research Office



Submit funding application

Funding not approved Inform DRM, review and re-apply

Funding approved

- Send award letter to DRM
- Final contract negotiations between Research Office and funder



NHS Ethics (plus tandem MHRA application for clinical trials/new devices – liaise with DRM on this)

- For Multicentre trials led elsewhere, only an SSI needs to be completed. Submit all SSIs to the Research Office.
- Complete application on IRAS (www.myresearchproject.org.uk). Click "Yes" for CSP processing on filter question 5a if eligible for NIHR CRN portfolio adoption – complete portfolio adoption form that this generates. Always include a Site Specific Information (do not need q23 – authorisations if a Pan Man has been completed)
- DO NOT book onto a REC without DRM approval – booking onto a REC will give you a reference code to complete the form. This code lasts ONLY 4 days in which time several signatures need to be obtained. DRM must see and approve application to make arrangements for this
- Email all final versions of ethics application documents to the DRM (e.g., protocol, PIS, consent, questionnaire)
- When application is ready DRM will obtain sponsor signature and application can be submitted

▼ **Ethics not approved** ▲

- Inform DRM, review with DRM and re-apply

▼ **Ethics approved**

- Send approval letter to Research Office



Trust approval given

- Letter of Trust approval issued from Research Office to Principal Investigator. Only when this has been received can the project start
- Inform DRM when first participant is recruited
- Further contact from R&I Division will include Research Governance, such as annual self assessment exercise

Some funders require ethics approval first. If any deviations from the pathway are necessary, discuss with your DRM