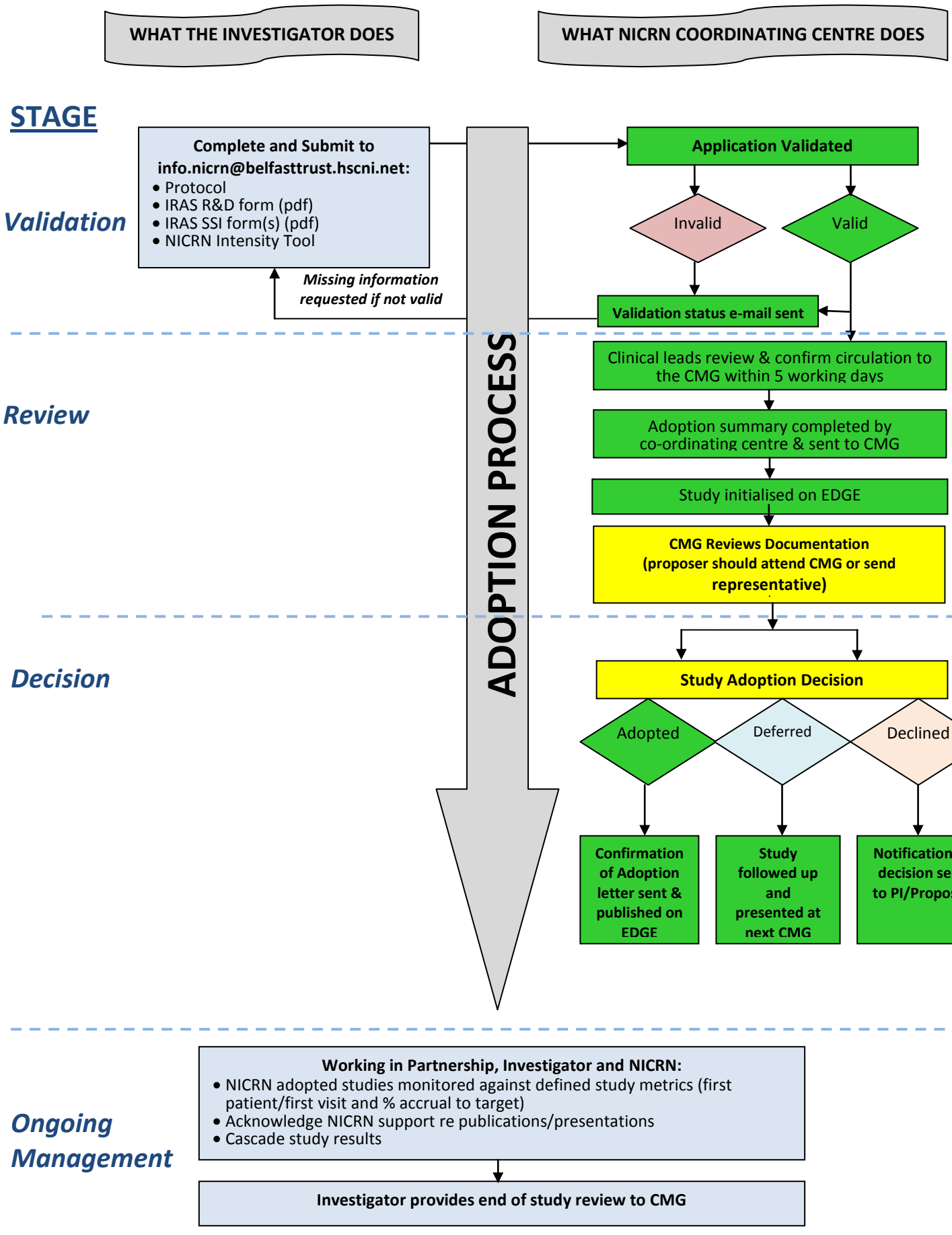
NICRN Adoption Process



NICRN Adoption Process Guidance

This guidance is to provide direction on the NICRN adoption process to all Proposers.

Please note that ALL proposals should be sent to NICRN CC via e-mail info.nicrn@belfasttrust.hscni.net

Expression of Interest

If a Proposer is interested in firstly receiving an expression of interest (EoI) from potential NICRN Interest Groups, to inform national bids for example, then the process will be to submit this request to the INFO.NICRN@belfasttrust.hscni.net address. This is then cascaded by NICRN Coordinating centre adoptions staff to the relevant groups clinical lead(s) who will either decide to cascade to known Northern Ireland PI's. To ensure an accurate assessment of whether proposed study is deliverable locally we will need to receive a protocol synopsis or other briefing document describing the proposed research for review.

The documentation will be forwarded to the members of the relevant Interest Group for review and comment. Their comments will take into account:

- Is study compatible with UK/NI practice
- Potential future benefits for NHS patients
- The availability and anticipated interest of collaborating NI-based investigators
- The prevalence of the target patient population
- Does NICRN have capacity to provide requested staff resources to deliver the trial data reliably and on time

To ensure a timely return of EoI it is the interested PI's responsibility to return completed EoI to requesting party and to cc NICRN coordinating centre via Info.nicrn address. It must be noted that at this point an EoI does not mean the study is or will be adopted and supported by the network. This only occurs following formal submission and approval by clinical management groups as defined below.

Adoption

The NICRN study adoption process is designed to work in *parallel* with the study R&D and regulatory applications so as not to increase approval timelines.

If a proposer wishes to apply to NICRN to have their study supported and added to the Portfolio, the following documents ***must be completed and submitted***:

- Protocol
- IRAS R&D form (pdf) (the final version, not draft)
- IRSA SSI form for each site requesting support (pdf) (the final version, not draft)
- Completed NICRN intensity tool

The NICRN Adoption Coordinator reviews submission and validates application. The application will be considered valid if **all** requested documents have been completed in full and submitted. If it is invalid, the Proposer will be notified and the relevant information will be requested. The proposal date is the date the NICRN cc received all valid documents.

The study documents will be sent to the clinical leads for review against local group strategy, objectives and top level feasibility ie is study design deliverable within local organisational structure. This will occur within 5 working days of the recognised proposal date.

Once an application is valid, the NICRN Coordinator populates NICRN Adoption Summary form with relevant details from submitted forms.

The study is initialised on the EDGE database.

The documentation is submitted to the CMG for review. The decision to adopt a study will be based on consideration of the following:

- Is there a genuine and testable hypothesis or valid research question with a possible future benefit for patients as its objective?
- Is there a statistically valid trial design which is reasonable for the stated main objective and main hypothesis of the trial?
- Have the trial and its design been subject to an adequate protocol review process?
- Is the study compatible with current UK/NI practice?
- What is the level of prioritisation based on NICRN criteria?
- Are the NICRN support costs covered by funding?
- What are potential future benefits for NHS patients?
- Is there sufficient investigator interest?
- Are there sufficient patient numbers?
- Does the NICRN infrastructure have the current capacity to provide requested staff resources to deliver the trial data reliably and on time?
- Are there conflicting studies within the current Portfolio or higher priority studies pending?

The NICRN Coordinator informs the Proposer of the relevant Clinical Management Groups (CMG) decision. If the study is adopted then the confirmation of adoption letter is sent to the proposer and relevant HSC Research Offices and published on EDGE. If the study is deferred it will be added to the next CMG meeting for further review. If the study is declined the proposer will be informed of the decision.

Once the study is open, the NICRN Coordinating Centre, support staff and Investigator will continue to work in partnership to:

- Agree study milestone(s) and schedule (eg first patient/first visit timelines, monthly accrual targets etc.
- Have regular study specific reviews at CMG and other agreed times (These meetings should not be considered alternatives to standard study update meetings, which NICRN would want to occur "regularly" between PI and support staff to ensure good management of study delivery)
- Keep the NICRN Portfolio up to date with screening and recruitment numbers. (Weekly)
- Undertake a study close out review to define study performance and highlight learning outcomes
- Inform NICRN about study results.
- Cascade study outcomes

What NICRN expect in return

Regular review of study milestone schedule

After adoption, NICRN CC will agree a study milestone schedule with the PI to help us assess study progression and plan for NICRN resources that we have agreed to commit. Researchers need to make time to talk/discuss their study with the NICRN CC staff every few months to ensure the milestone schedule is kept up to date to enable us to deliver the support you need. These discussions will normally be undertaken within the NICRN pre-CMG meetings between coordinating centre staff and leads or between staff manager and staff at regulate am meetings.

Keeping the NICRN Portfolio database (EDGE) up to date

Research teams we support must provide and update information about their studies for the NICRN Portfolio Database (EDGE). This includes a summary of your project, information about the study design, the organisation that is funding the research and most importantly the study accrual contact. The NICRN uses the web based EDGE database system as our Local Portfolio Management System. This requires live data entry at site and so the allocated accrual contact will be responsible for timely data entry ie preferably live or weekly.

Acknowledging NICRN support

We also expect the PI to acknowledge NICRN support on any publicity material you produce about your study, including information for participants, websites and papers published in academic journals.

Tell us about your results

At study close out, the study team collectively with NICRN senior management team will scrutinise the conduct of the study against its defined objectives. This process is to allow the network to more accurately predict future similar study deliverables.

And finally, we want you to tell us about the results of your research at the end of your study. We think it is best practice to notify professionals working in services that have supported your research about your findings. We may also be able to help disseminate your results to a wider audience, and encourage research teams to tell participants about the conclusions of the study, wherever possible.