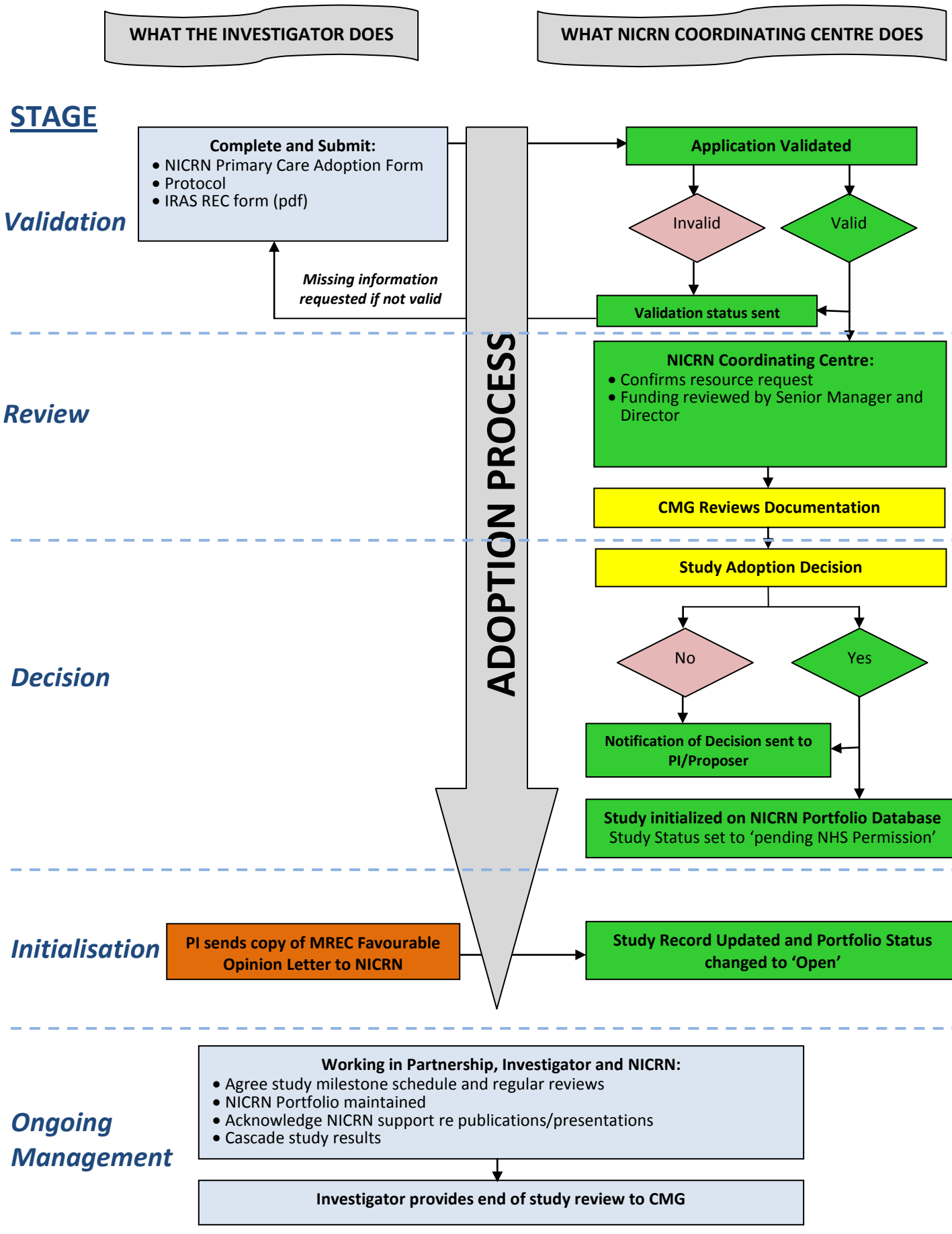
Adoption Process



Adoption Process Guidance – Primary Care

This guidance is to provide direction on the NICRN adoption process to all Proposers for Primary Care studies.

Expression of Interest

If a Proposer is interested in firstly receiving an expression of interest from the Primary Care interest group before proceeding with the formal adoption of their study, NICRN is willing to give a basic review and opinion of the proposed study. NICRN will need to receive a study proposal, protocol synopsis or other brief document describing the proposed research for review. They would also need to be provided an estimate of possible support requests.

The documentation will be forwarded to the members of the Primary Care 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

NICRN will return comments and initial recommendations to the proposer within two weeks of receipt of the initial request.

Adoption

The NICRN study adoption process is designed to work in *parallel* with the study Ethics applications so as not to increase approval timelines.

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

- NICRN Primary Care Adoption Form
- Protocol
- IRAS REC form (pdf)

The NICRN 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.

Once an application is valid, the NICRN Coordinating Centre team will confirm the resource request. The funding of the study will be reviewed by the NICRN Senior Manager and Director.

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?
- Is the study suitably funded?
- 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 decision. If adoption is agreed, the status of the study remains 'pending NHS permission' until the Proposer/PI sends a copy of the NHS REC Favourable Opinion letter to NICRN. The study will then be added to the NICRN Portfolio database and the status changed to 'Open'.

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

- Agree study milestone schedule and have regular reviews
- Keep the NICRN Portfolio up to date with screening and recruitment numbers
- Acknowledge NICRN support
- Inform NICRN about study results.

What NICRN expect in return

Regular review of study milestone schedule

After adoption, NICRN agree a study milestone schedule with the PI to help us plan NICRN resources that we have agreed to commit. Researchers need to make time to talk to our Coordinators every few months to ensure the milestone schedule is kept up to date to enable us to deliver the support you need.

Keeping the NICRN Portfolio up to date

Research teams we support must provide and update information about their studies for the NICRN Portfolio Database. This includes a summary of your project, information about the study design, the organisation that is funding the research and contact details. Our Coordinators can help you input the necessary information about your study onto the Portfolio Database.

You must also supply information about the numbers of people recruited, usually once a month.

Acknowledging NICRN support

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

We encourage research teams to use plain English in all material they produce to make sure it is accessible to as many people as possible.

Tell us about your results

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.