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Research Article

Exploring the feasibility of streamlining ethics processes in India: a qualitative study

Stephanie P Jones[1*] Ranjit J Injety[2] Rachel Georgiou[1] Jeyaraj D Pandian[2] PN Sylaja[3] MV Padma[4] Maree L Hackett[1,5] Catherine E Lightbody[1] Caroline L Watkins[1] and on behalf of the NIHR Global Health Research Group on IMPROVIng Stroke CarE in India (IMPROVISE) Collaboration

[1]School of Nursing and Midwifery, University of Central Lancashire, Preston, UK
[2]Department of Neurology, Christian Medical College and Hospital, Ludhiana, India
[3]Department of Neurology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, India
[4]Department of Neurology, All India Institute of Medical Sciences, New Delhi, India
[5]The George Institute for Global Health, Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia

[*]**Corresponding author** Sjones10@uclan.ac.uk

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Abstract

Background: The IMPROVIing StrokE care in India programme aimed to investigate the feasibility of introducing three packages of care (swallowing and hydration, early neurological deterioration, and patient and unpaid caregiver education post stroke) in three major stroke centres in India, all of which had extensive research experience and were members of the INDian STRoke Clinical Trial Network. The INDian STRoke Clinical Trial is a strategic initiative, which is overseen by the Indian Council of Medical Research and funded by the Government of India to enable the development of stroke research capability and engagement in India. Within IMPROVIing StrokE care in India, multiple applications for ethical review were made across multiple organisations. This complex process inspired us to map current ethical review processes, identify challenges, enablers and explore the feasibility of establishing a streamlined multicentre ethics approval process for stroke research within the INDian STRoke Clinical Trial Network.

Methods: Semistructured interviews and focus groups were conducted using purposive sampling of IMPROVIing StrokE care in India principal investigators, hospital Ethics Committees' chairs and secretaries from within the INDian STRoke Clinical Trial Network. Focus groups also involved members representing the Indian Council of Medical Research, Forum for Ethics Review Committees in India and principal investigators from the India and the UK. All interviews were digitally recorded, transcribed verbatim and verified by the interviewers prior to thematic analysis using an inductive approach. Six interviews took place with Ethics Committee representatives (four member secretaries, one chair and one Ethics Committee convenor). A further six interviews were conducted with principal investigators (consultant neurologists), representing the six IMPROVIing StrokE care in India sites. A focus group took place with six principal investigators and a second with 11 participants (2 existing principal investigator participants and in addition 3 principal investigators involved in research in India but based in the UK, 3 members representing Indian Council of Medical Research and Forum for Ethics Review Committees in India, 3 members of the project team and a facilitator).

Results: Analysis of the interviews and focus group data resulted in five main themes (Indian Council of Medical Research regulations, Ethics Committee processes, Ethics Committee member roles and workload, suggested solutions and the impact of the COVID pandemic).

Conclusion: At the time of the study, multiple changes to Ethics Committee processes were already underway and further changes took place due to the COVID-19 pandemic. Suggestions for further improvements include expedited

review for observational studies; greater collaboration between Ethics Committees so that questions, clarifications and amendments needed send to researchers are consistent; and use of existing research Ethics Committee infrastructure. Any recent or future changes could be evaluated, and lessons can be learned and examples of good practice can be shared between both high-income and low- and middle-income country organisations.

Limitations: Firstly, the study focused on including participants from research active organisations, primarily from within the INDian STRoke Clinical Trial Network and therefore the findings may not be generalisable to other organisations. The principal investigators were all experienced and more likely to be familiar with the ethics approval processes and procedures for a range of study types. The study took place during the COVID-19 pandemic when major changes within organisations were taking place.

Future work: Future work will explore sharing examples of good practice being between high-income and low- and middle-income country organisations.

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Background

Stroke is a significant global health challenge and is associated with high levels of morbidity and premature mortality. The burden of stroke is rapidly increasingly in low- and middle-income countries (LMICs),[1] where 70% of strokes occur.[2] Life expectancy in India has recently increased to over 60 years of age,[3,4] leading to an increase in age-related, non-communicable diseases, including stroke.[5,6] In India, the incidence of stroke ranges between 105 and 152/100,000 people per year.[7] The rising incidence of stroke is associated with a greater socioeconomic burden as stroke occurs at a younger age in LMICs.

To address the rising burden of stroke in India, reliable data on stroke incidence, prevalence, treatment and outcome are needed to inform healthcare policies and the organisation of stroke services and to track the impact of any changes in care.[8] Research studies in stroke care are needed to provide evidence to underpin practice change and improvements relevant to the population of India, which can be implemented across the Indian healthcare system to improve patient outcomes and reduce the burden of stroke. Health research studies in India require ethical review and approval from a recognised research Ethics Committee (EC) that follows national guidance and regulations.[9]

Ethical approvals often begin with the study protocol and associated documentation being reviewed by a scientific review committee. Scientific review committees assess the rationale for the conduct of the study and the underpinning methodologies. Following the evaluation and approval by the scientific committee, the study is then subjected to a review by an EC that evaluates the study protocol and ensures that the study aligns to the ethical principles outlined in the World Medical Association Declaration of Helsinki for medical research involving human subjects, and in India specifically, the ethical standards set out in the Indian Council of Medical Research (ICMR) guidelines.

The frequency that the EC convenes varies between various medical institutions and teaching hospitals from a monthly basis to every quarter. In line with ICMR guidelines, across India, both scientific and ECs are merging to form a single committee.

Different types of research studies may also require additional approvals. The Health Ministry's Screening Committee (HMSC) regulates foreign-assisted and/or collaborative biomedical/health research projects, applications for which are required to be submitted by Indian investigators to ICMR. In addition, overall approval and monitoring of drug-related clinical trials are overseen by the Government of India and the Drugs Controller General of India (DCGI). At the time of the study, EC guidelines were set out in the National Ethical Guidelines for Biomedical and Health Research involving human participants.[10]

Although national standards and guidance exists in India, there are differences in how committees operationalise requirements. There are variations in how often committees meet, the documentation required, timescales for review outcomes and response and whether there is a cost for the review. The differences in how committees work is particularly apparent for research studies involving multiple organisations, where different requirements, processes and opinions can result in delays. The complexities of working across research ECs can be seen as a barrier to research, particularly where more than one organisation is involved and the funding is located outside of India.

The ICMR recognises the need to support a robust ethical review process while enabling research studies to take place. They have undertaken work to support more consistent and streamlined ethical review processes to allow research studies to begin in a timely fashion. An expedited approval process was introduced in response to the challenges of COVID pandemic to ensure that COVID research studies could take place.

Between 2017 and 2022, the IMPROVIng Stroke CarE in India (IMPROVISE) programme, led by the National Institute for Health Research Global Health Research Group on IMPROVISE Collaboration, aimed to undertake a series of stroke research studies investigating the feasibility of introducing three packages of care in three major stroke centres in India, all of which had an extensive research profile and were members of the INDian STRoke Clinical Trial (INSTRuCT) Network. Funded by the Government of India through the Department of Health Research, Ministry of Health and Family Welfare, the INSTRuCT Network is a strategic initiative overseen by the ICMR to enable the development of stroke research capability and engagement in India. Within IMPROVISE, applications for ethical review were made across multiple organisations; building on this experience, we aimed to map current ethical review process, identify challenges, enablers and explore the feasibility of establishing a streamlined multicentre ethics approval process for stroke studies within the INSTRuCT Network.

Design

Mixed methods – mapping exercise, semistructured interviews and focus groups.

Setting and subjects

One-to-one interviews were conducted with a purposive sample of principal investigators (PIs), EC chairs and secretaries from hospitals within the INSTRuCT Network. Focus groups discussions were conducted with a purposive sample of PIs (India and UK), members of Forum for Ethics Review Committees in India (FERCI) and individuals representing the ICMR.

Patient and public involvement and engagement

There was no patient and public involvement in the study, as the study focused on and involved PIs with the responsibility for submitting research to ECs or EC chairs and secretaries, members of FERCI and ICMR, who were responsible for regulatory processes and procedures.

Methods

The interview and focus group guides (*Appendix 1*) were informed by published research and were developed collaboratively by the research team. While not formally piloted, the guides were revised following feedback from PIs at the included hospitals. Interviews and focus groups explored participants' views of the ethical approval processes within their own hospitals and at a national level, exploring the challenges and potential solutions. E-mail invitations to take part in the study were sent to 35 EC members from within the INSTRuCT Network and to 10 PIs (7 from Indian and 3 from the UK) involved in the IMPROVISE programme.

The purpose of interviews with PIs was to explore their experiences of applying for ethical approval for research studies, including the things that worked well and the challenges and any suggested changes to current ethical approval processes, particularly for foreign-funded, multicentre or non-randomised trial study designs. Interviews with EC chairs and secretaries focused on their role, the AQ7
structure and requirements of the research EC and about what currently works well and what could be improved. The specific requirements that are needed for different types of AQ8
research projects and any suggested changes to current the ethics approval processed for multisite studies.

Following synthesis of the interview findings, focus groups then took place. Focus groups also involved members representing the ICMR, FERCI and PIs from the UK who were involved in the IMPROVISE programme. The purpose of the focus group discussions was to explore potential solutions to streamlining ethical review processes in India across a range of study designs. All interviews were digitally recorded, transcribed verbatim and verified by the interviewers prior to analysis using an inductive approach.

To support the analysis and further discussion, a supplementary exercise was undertaken to map the ethical processes required for different study types. The findings from the mapping activity enabled cross-validation of the interview and focus group findings (*Appendix 2*).

Data collection

According to participant's preference, interviews and focus groups were conducted in English and took place over digital platforms or telephone between June and September 2021. Interviews were undertaken by two researchers with postgraduate training in qualitative data collection methods [one based in the UK (SPJ) and one based in India (RJI)]. One focus group was facilitated by RJI and SPJ and the second by MLH. No repeat interviews or focus groups took place.

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All interviews and focus groups were digitally audio-recorded, transcribed verbatim and verified by the interviewers prior to analysis. Field notes were taken to support discussion and to add context. To maintain participant's anonymity within the published findings, each interview and focus group was assigned a numerical code, which was used by the research team internally to identify participants.

Analysis

Interviews and focus groups took between 34 hours and 1 hour and 36 minutes. Each transcript was read in full, and data were explored using open coding and were thematically analysed using an inductive approach.[11] All interview and focus group transcripts were coded by all members of the project team (RJI, SPJ and RG) and confirmative/contradictory results were discussed with the wider project team for consensus. Data were analysed thematically using NVivo software (version 1.5.2.) (QSR International, Warrington, UK). This manuscript was prepared in accordance with the Consolidated Criteria for Reporting Qualitative Research guidelines.[12]

Reflexivity

The project team had expertise in stroke research (RJI, SPJ, RG and MLH). All interviews were undertaken by RJI, a male research project manager (BDS, MPH), and SPJ, a female associate professor (PhD, MA, BA), and one focus group facilitated by MLH, a female professor (PhD, MA, BA), who were unknown to participants and who were conducting the interviews for the purposes of the wider IMPROVISE study. RJI, SPJ, RG and MLH were involved in the data analysis. RJI is of Indian origin and SPJ, RG and MLH are non-Indian researchers with epidemiology backgrounds who conduct research in India and have applied to UK and Indian ECs. RJI, SPJ and RG are based in the UK and MLH is based in Australia. All interviews were held during COVID-19; dependability of the data may vary based on changes to ethics processes that took place in India during or following the research. Interviews and focus groups were undertaken with participants from 10 hospitals across geographically diverse areas; therefore, the findings may be transferable to other similar hospital settings in India. Data were collected until no new themes emerged. The main themes were shared with participants to ensure that they were an accurate reflection of the discussions that took place.

Results

AQ9 Six interviews took place with the EC representatives (four member secretaries, one chair and one EC convenor); three (50%) were female, representing four government teaching hospitals and two private teaching hospitals based in Northwest India (n = 2) and one of each from Northeast India, West and East India. Six interviews took place with PIs; one (17%) was female, representing four AQ10 public teaching hospitals, one private teaching hospital and one charitable hospital.

Participants in the first focus group were all experienced PIs (ranging from 2 to 22 years and a total of 76 years' experience); two (33%) participants were female. Participants were representing four government teaching hospitals and two private teaching hospitals from AQ11 across India.

Following the interviews and the first focus group, there was a second focus group with 11 participants which included: 2 existing PIs, representing one government and one private teaching hospital in India (North n = 1, Northwest n = 3, Northeast n = 2, South n = 2, West n = 2, East n = 1); and in addition, 3 PIs involved in research in India but based in the UK (representing 2 UK Universities); 3 members representing FERCI and ICMR; 3 members of the project team and a facilitator (MLH); 8 (72%) of the participants were female.

The results of the interviews and focus groups resulted in five main themes: ICMR regulations, EC processes, EC member roles and workload, suggested solutions and the impact of COVID.

The Indian Council of Medical Research regulations

A study says that 'ICMR is the apex body in India, responsible for the formulation, coordination and promotion of biomedical research'.[13] It is a requirement that all recognised ECs in India register with the ICMR. All registered ECs are required to follow the guidance set out in the National Ethical Guidelines for Biomedical and Health Research. EC members outlined the ICMR regulations that determine the way in which their committees operated, including their adopted processes, membership and training. All participants agreed that systems and processes that governed and underpinned ECs were as a result of National Ethical Guidelines for Biomedical and Health Research.[13]

> *We follow the ICMR guidelines, so we have a lay person, a pharmacologist, a medical scientist, a basic scientist, a lawyer, and we have a legal person also.*
>
> *EM6*

Our (Ethics Committee) Chairperson has been serving for the last 7–8 years. Every three years we reconstitute committees.

EM2

They (Ethics Committee members) receive training. For example, whenever the Ethics Committee is reconstituted, some new members are added and GCP [good clinical practice] training session is conducted.

EM1

Ethics Committee processes

Participants were positive about current ethical review processes. All were familiar with the ethical review regulations and processes within their individual organisations, including the required documentation, external approvals, timelines and processes. EC members and chairs largely agreed that individual organisational EC processes worked well, including research committees or committees specifically for student research projects, for example:

We have two stages of Ethics Committee approval. First, we have a Technical Advisory Committee which looks at the scientific aspects of this study and once that is clear, then it goes to the Ethics Committee.

FG1

The study has to go through the Research Committee and then the Ethics Committee.

FG2

Subtheme: frequency of meetings

However, there was a variability in how the committees operated in the different organisations. Having reliable access to ECs was a concern for some PIs, particularly in relation to the timings of committee meetings and the potential impact that this may have for any external approvals and potential delays to study set-up.

If there are two or more revisions, they usually take it to the next main meeting, that will be four months later on.

PI1

Our normal frequency of meetings is once in six weeks. But during the COVID period that schedule was disrupted, we have been meeting less frequently … The approval process may be longer because if there are clarifications, major clarifications that we are seeking, so that information we send to the PI, the PI goes back to sponsors and then they get a clarification. So, it may take longer than six weeks.

EM2

In some circumstances, the dates for meetings were unknown as the committee would met only if there were sufficient applications to review and/or were dependant on the availability of members, and this was more frequent over holiday periods. One hospital did not have its own EC and applications were submitted elsewhere.

We come under the [Ethics Committee name] and the [Hospital Association name] and all our projects go there … So, since it is quite far and only quarterly meetings happen, there are problems.

FG1

Subtheme: review timescales

The length of time the review would take and the uncertainty of meeting dates were accepted but were recognised as a potential cause of delay to the start of a study.

Once the project starts, the next step is the funding and the approvals, and they take quite a long time in our setting. The gestation period for a project is two years. To set timelines in research, that is very difficult as of now, we do not know where and when we will be able to start it exactly.

PI2

If you want to start any clinical trial, whether it's from overseas or funded within the country, you need to really give one year period before all the centres start recruiting patients.

FG2

Subtheme: study types

It was also identified that the ethical approval processes for observational studies were straightforward in comparison to multicentre and genetics studies, where processes were more complex.

For a single centre observational study or some case control study or a population-based study it [the ethics approval process] is very straightforward.

FG2

With regards to observational studies, single centre studies, there are no issues at all. The major issues are mostly with the clinical trials and multicentre [studies]. Now, the main process problem which we are facing

is multicentre studies. They want the clearance and everything of all the standards to be given to the Ethics Committee before they are going to give the final clearance, especially if you are the national PI or the main PI, then it will be very important that you get all the Ethics Committee approvals of all the centres. Also, a MOU, I'm asking for an MOU with each of these [hospital sites] and as it is very variable depending upon the studies. So in that aspect, there is no uniformity.

FG1

I had one genetics study, it took almost one year for it to get cleared.

PI5

The sequence of EC approvals at a national level was sometimes unclear to the PIs, particularly the approval required from HMSC. This was described as a 'chicken and egg' situation between the HMSC and hospital ECs; in some instances, HMSC and hospital ECs were providing provisional approvals that were dependent on the approval from the other committee. This created a circular dependency that was difficult to resolve. In addition, requirements were often applied differently across organisations.

They submit for HMSC clearance, we say approved in principle, subject to submission of HMSC clearance detail or the CTRI registration or whatever.

EM6

Currently there is this problem of the Ethics Committee, they will tell us, get the HMSC approval and then they will approve it. So then there is a problem, which already [name of focus group participant] has put forward. I'm not sure, whether that's correct or not, but that is the way it is but what's happening is the HMSC clearance is required for the local Ethics Committee to approve it. So then there is the issue, I think, that also needs to be taken care of.

FG2

Ethics Committee member roles and workload

Ethics Committees, as mandated by the ICMR's National Ethical Guidelines for Biomedical and Health Research, have between 7 and 15 members who are trained in human research protection and conversant with ethical guidelines and generally serve a term of 2–3 years working within ECs' standard operating procedures (SOPs). Members include the EC chair and secretary, medical or non-medical scientist(s), clinician(s), legal expert(s), social scientist/philosopher/ethicist/theologian and lay person(s). As roles and SOPs were predetermined, there were sometimes difficulties in addressing operational challenges, such as difficulty recruiting to some member roles, and the workload of the EC members.

Each Ethics Committee has a chairperson, secretary and we have 15 members, so the majority of the members, 8 members are from outside the institute and 7 are from [Institution name] … So we follow the ICMR guidelines, so we have 1 lay person, 1 pharmacologist, a medical scientist, a basic scientist, a lawyer, we have a legal person also.

EM6

Normally as per our SOP, members have a term of 3 years and inducted for a tenure of 3 years, and after that we give them an option that they like to continue … Training, which is mandatory, is that all members serving on Ethics Committees, CDSCO [Central Drugs Standard Control Organisation] registered, they need to be trained in the principles of GCP, good clinical practice. In India, we have this GCP guidelines, which are now incorporated in something called the New Drugs and Clinical trial act, which came out in March 2019, replacing our earlier schedule. So that's very basic training that is required, GCP training and training in new drugs and clinical trials. Apart from this training ICMR guidelines and the allied guidelines, guidelines, WHO guidelines, for instance, so these are the kinds of training we expect all our members to have. We have to submit the certificates to CDSCO.

EM2

We have to go through the Good Clinical Practice (GCP) Certification. All the topics related to the research about the effects, about all whatever's wrong, SAE's (Serious Adverse Events] and the roles and responsibility of each member. So that training is a must for each and every member. Without this they are not included also for the investigator, the GCP is a must before submitting the projects to the EC (Ethics Committee).

EM4

Individual EC members viewed their role as one of facilitating research, but undertaking their role alongside other responsibilities was sometimes difficult due to workload pressures. The roles and responsibilities of members did not only cover the ethical considerations for studies but also included a role in monitoring and overseeing studies following approval, progress reports, study monitoring and closure. There were examples when the workload of EC was at capacity and there were waiting

lists, resulting in delays for PIs. This was often a particular challenge when hospitals did not have their own EC.

> *Ethics Committees' actual activity or job does not end with the approval process. Yes, the Ethics Committees are meant to monitor that things are going as planned, like the safety and well-being of patients are being adequately protected … If there are serious adverse events being reported, then there are very well-defined timelines within which the Ethics Committees have to give their opinion to the government of India's Central Drug Control regarding the serious adverse events and the causality*
>
> *EM2*

> *We [the Ethics Committee] are approached by some of the independent hospitals which does not have an EC.*
>
> *EM4*

> *We have a data safety and monitoring committee that goes and does on site monitoring of trials and also acts as a DSMC [Drug Safety Monitoring Committee] safety committee as well. For both serious adverse events monitoring and on-site monitoring we have a separate committee.*
>
> *EM1*

Suggested solutions to ethical approval process delays and complexities

Ethics Committee members were keen to facilitate approval where possible between meetings, where research studies needed to start urgently. Members were positive towards expedited approvals and for changes to streamline processes. PIs also spoke positively about expedited processes.

> *If this study needs to be expedited, then the PI needs to inform us that we require an expedited approval. Depending upon the nature of the project, and if we are convinced that, yes, it does require an expedited approval, we have a mechanism where we can go in for the expedited review even without full committee meeting. So, we do that on an expedited review basis. For instance, in this lockdown period, we have been hearing some projects related to COVID diagnosis … So available members sit, or we can even discuss through e-mails and webinar and we issue approval. But that approval is often provisional. So investigators can start preparatory work and start the preliminary work, but that the provisional approval needs to be ratified by the full [Ethics) Committee at its next meeting.*
>
> *EM2*

> *In exempt cases some expeditors will request from the investigators that the particular trial has this requirement and consideration can be given and any emergency condition with the decision of Chairman and all. Then we can give that trial approval, in two weeks it can be considered. After meeting within 4–5 working days we communicate to the investigators regarding any documents which can be considered, local requirements of the documents may differ. We will give a conditional approval and once that documents submitted and approved, we will finalise it.*
>
> *EM4*

Participants were positive when asked about any potential moves towards a more centralised review for some types of research (observational, non-drug/device clinical trials), but the consensus was that applications would still need to be approved by their individual institutions or approval provided by a government regulated body.

> *Now, if we had a centralised Ethics Committee which can approve large clinical trials or multicentre studies, then it'll be easier for the local Ethics Committee to just to screen.*
>
> *FG2*

> *That would we great if the central approval is there and you can inform the institute that the ICMR has given the approval and there is no need to get separate Ethics Committee approval from the centre … It has to be given from a government institution, not from any other.*
>
> *EM7*

> *There is a provision where there should be a MOU [Memorandum of Understanding] between the committees. The other committees of the institutions accept the approval which have given by our EC [Ethics Committee] we should accept the trials which have been approved by the other committees. So the mutual understanding has to be there for carrying out multi-centric study approved by one EC [Ethics Committee] to be accepted by all Ethics Committees.*
>
> *EM4*

> *All the pharma funded drug trials. They go through the DCGI [Drug Controller General of India] for approval … They also can look into it then, even the pharma funded trials would be expedited and other studies - observational, multicentre, clinical trials funded by ICMR. any other government funding agencies could come through ICMR as central. So, this is one of the models I have been thinking of to streamline the ethical process in this country*
>
> *FG1*

Participants described the requirements for developing different processes for different types of studies based on potential complexity and risks, for example, drug trials versus observational studies and different funding sources. Focus group participants agreed that ICMR could potentially give a generalised approval which would then make it easier for organisations to give permission.

> *All the overseas funded observation studies or clinical trials, probably, you know, if we have a centralised Ethics Committee with HMSC, we can review that, then you can make it faster. Second is all the pharma funded drug trials. They go through the DCGI, drug controller of India for approval.*
>
> *FG2*

> *But now what they have started doing is they give a provisional kind of an approval, and in that statement, they mention that we are clearing this, we are giving you an Ethics Committee approval pending your HMSC approval. So that is there recently. Previously, they used to ask us to resubmit the HMSC but that has changed now.*
>
> *FG1*

> *Centralised approval – I think the best way to do a centralised kind of rule would be under the umbrella of ICMR to have a separate committee, which can specifically look into it and give a central approval, which will be very helpful … Otherwise, for all these studies, depending upon the type of study and centre they can be delayed depending upon the Ethics Committee. So, this is just helping. It is not completely that we should take the centralised approval as the law. If that approval is there, that will make the things faster for the local Ethics Committee, institutional Ethics Committee to get it done fast.*
>
> *FG2*

Impact of COVID

The impact of COVID changed how EC worked, in terms of the methods and frequency in conducting the EC meetings and approval processes of studies.

> *Usually, it would be once in a month or once in the two months depending upon the study protocol. Usually it happens in once in a month but because of COVID, it was delayed. I mean that particular COVID period we had only one Ethics Committee otherwise usually it would be once in a month or once in two months.*
>
> *EM7*

> *After the COVID second wave we have lots of projects which we have twice also in a month, but the minimum requirement is once in two months.*
>
> *EM4*

> *If really there is something which is having some great emergency or unmet need and the risk aspect of the study is not much we can definitely expedite those things. I don't remember such a thing has ever happened. Although in COVID times we did expediate a lot of reviews.*
>
> *EM1*

> *The pandemic has put us on a new learning path. The challenge that we had to review proposals even without a single face-to-face meeting because of the very nature of the project. The timelines are very strict, one or two sponsored projects, unless the project could have been initiated within, say, two weeks or three weeks, we could have become irrelevant. So we have been discussing such projects through e-mails and webinars, but the general feeling among the committee members that it can be an alternative was not a very satisfactory alternative to having a face-to-face discussion with the investigator present to clarify points on a face-to-face basis.*
>
> *EM2*

> *During the COVID time we had (expedited reviews) because there was a need to have the proposals reviewed for people to look over the COVID related studies. At that time, it was an expedited review just by sending the members of the Ethics Committee were sending it to TAC [Thesis Advisory Committee] members and their ethics clearance and the committee.*
>
> *PI5*

> *Sometimes I've had to do emergency meetings for expedited reviews, for COVID related projects. So then again, I've had to make a couple of times. We've had some urgent discussions to do, so last minute request to please come online for meetings.*
>
> *EM5*

Examples of studies that had found ways to make the process simpler across sites were given, including one where an EC had been appointed as the lead committee.

> *During COVID times, the ICMR completely took over some of the major discussions that were going on in the country. For example, there was a trial and the ICMR gave the central approval, and it was given to the state governments. And every state had one nodal*

> *centre and they coordinated the study, and it was a centralised approval. And it was so easy for them to get the trial approved. And all the Ethics Committee and ICMR had at least an advisory that there are separate guidelines, approval of research during COVID times. So that really helped everyone, all the committees to process the approvals very quickly. And so, it is possible in a situation like COVID, ICMR was able to come up with a centralised approval and which all the other participating centres in the trial they adapted. And it was set throughout the country to another, I would say, the fastest trial that was conducted in our country, entirely designed by Indian researchers, funded by ICMR. It was a neutral trial, but it was expedited.*
>
> *FG1*

Discussion

To our knowledge, this is the first study in India that has mapped current ethical review processes and identified the challenges, enablers and feasibility of establishing a streamlined multicentre ethics approval process for stroke studies within the INSTRuCT Network.

This study identified a number of strengths, including streamlining of the current two-stage scientific and ethical review processes into a single EC review process, and recent requirements for all recognised ECs to be registered and accredited with the ICMR Department of Health Research and operating according to ICMR regulations, including constitution, tenure and training requirements (e.g. good clinical practice). However, it is recognised that the study has a number of limitations. Firstly, the study focused on including participants from research active organisations, primarily from within the INSTRuCT Network, and therefore the findings may not be generalisable to organisations outside of the INSTRuCT Network. The PIs involved in the study were all experienced and are more likely to be familiar with ethics approval processes and procedures for a range of study types. The study took place during the COVID pandemic when major changes within organisations were taking place.

Participants represented a broad range of organisations (ICMR, FERCI, public teaching hospitals, private teaching hospital and a charitable hospital and UK Universities). Providing participants with a choice of interview method (telephonic or online platforms) enabled adherence to COVID protocols and supported the inclusion of participants under COVID restrictions at the point of interview.

In recognition of the potential benefits of international collaborative research, many funding streams actively promote and/or require co-operative efforts.[14] This trend is particularly evident in health research, where collaborations are viewed as essential for addressing global health disparities and to build research capacity in LMICs.[15] However, our study has identified challenges, particularly for PIs in terms of obtaining ethical approvals, often due to variability in how often the committees met (different organisations met between monthly to quarterly) and the complexity of processes, including different approvals needed for internationally funded (multicentre trials in particular), which could lead to delays in research study set-up of up to 2 years.

While different types of research studies in India require additional approvals (e.g. HMSC regulates research projects involving foreign assistance and the DCGI is responsible for the overall approval and monitoring of drug-related clinical trials), there was a general consensus that the approval process could be expedited and/or streamlined, depending on study type and funding sources using a range of approaches, including expedited review for observational studies, collaboration between ECs to ensure that consensus could be reached regarding questions, clarifications and amendments needed, and the utilisation of existing research EC infrastructure, for example within the INSTRuCT Network. However, these processes would require SOPs formulated by a centralised body, for example ICMR or DCGI, where applicable. During the study, ICMR was in the process of piloting a streamlined approvals process; further details about the pilot were unavailable at the time of writing, but further information will be available from ICMR in due course.

Ethics approval for collaborative research studies should include ethical approval from both high-income countries (HICs) and LMIC institutions whenever possible,[16] but challenges can arise from changes being requested to key study documentation following approval by one country or organisation, resulting in amendments to the original documentation and the subsequent requirements to submit minor/major amendments, often leading to further delays. The recent change to the combining of scientific and ECs in India may help to alleviate some of these issues, but further lessons must be learned from recent international, multicentre studies and examples of good practice shared between both HIC and LMIC organisations.

While the COVID pandemic resulted in many challenges, it has also highlighted the possibilities of expediting ethical approval for multicentre studies; and, there are

now processes in place and precedent for streamlining processes for multicentre research studies within India.[17] As a result of COVID, there had also been a number of changes to EC procedures, such as online meetings, allowing greater flexibility for meetings and ensuring committees to have quorate, electronic systems for the submission of ethics applications, and virtual committee meetings. However, there was mixed feedback from EC members with some preferring to meet face to face rather than virtually, while others felt that it was easier to clarify questions remotely with PIs rather than waiting for set meeting dates. Despite the differences in opinion, there are many changes that occurred as a result of the COVID pandemic, which are likely to be sustained and may reduce the workload and facilitate timelier streamlined ethical approval processes.

Equity, diversity and inclusion

Streamlining ethical review processes will develop the capability to support future research, providing further evidence to inform stroke practice. The study participants were recruited from a range of organisations regardless of the institution type (government, charitable and private) or individual characteristics (gender, ethnicity and ability). Interviews and focus groups were conducted in a manner, whereby participants felt that they could contribute and participate in a way which ensured that they were valued and respected. We have reported the views and experiences of both male and female participants from across India.

Conclusions

Overall, PIs and EC members were positive about current ethical review processes, but there remained some challenges for organisations where ECs met less frequently and for internationally funded, multicentre trials, requiring multiple approvals. At the time of the study, multiple changes to EC processes were already underway and further changes took place due to the COVID pandemic. Further improvements could include expedited review for observational studies, collaboration between ECs to ensure that consensus could be reached regarding questions, clarifications and amendments needed, SOPs developed and the utilisation of existing research EC infrastructure, for example within the AQ13 INSTRuCT Network. Any recent or future changes could be evaluated, and lessons can be learned and examples of good practice can be shared between both HIC and LMIC organisations.

Policy and practice recommendations

- Existing EC expertise and infrastructure within the INSTRuCT Network to be utilised to maximise the timely review of research ethics applications.
- SOPs to be developed to support expedited reviews.
- Future changes to the ethics review processes and procedures to be evaluated and findings to be shared. AQ14

Additional information

CRediT contribution statement

Stephanie P Jones (https://orcid.org/0000-0001-9149-8606): Formal analysis (lead), Project administration (lead), Validation (lead), Visualisation (equal), Writing – original draft (lead), Writing – reviewing and editing (lead).

Ranjit J Injety (https://orcid.org/0000-0003-1403-8336): Formal analysis (equal), Project administration (lead), Validation (lead), Visualisation (equal), Writing – original draft (lead), Writing – reviewing and editing (lead).

Rachel Georgiou (https://orcid.org/0000-0002-0920-0602): Conceptualisation (equal), Funding acquisition (equal), Methodology (equal), Supervision (equal), Writing – reviewing and editing (equal).

Jeyaraj D Pandian (https://orcid.org/0000-0003-0028-1968): Conceptualisation (equal), Funding acquisition (equal), Methodology (equal), Writing – reviewing and editing (equal).

PN Sylaja (https://orcid.org/0000-0003-4896-8275): Conceptualisation (equal), Data curation (equal), Funding acquisition (equal), Methodology (equal), Writing – reviewing and editing (equal).

MV Padma (https://orcid.org/0000-0001-7615-9411): Conceptualisation (equal), Funding acquisition (equal), Methodology (equal), Writing – reviewing and editing (equal).

Maree L Hackett (https://orcid.org/0000-0003-1211-9087): Conceptualisation (equal), Funding acquisition (equal), Methodology (equal), Supervision (equal), Writing – reviewing and editing (equal).

Catherine E Lightbody (https://orcid.org/0000-0001-5016-3471): Conceptualisation (equal), Data curation (lead), Funding acquisition (equal), Methodology (equal), Project administration (equal), Supervision (equal), Writing – reviewing and editing (equal).

Caroline L Watkins (https://orcid.org/0000-0002-9403-3772): Conceptualisation (lead), Funding acquisition (lead), Methodology (lead), Supervision (lead), Writing – reviewing and editing (equal).

ODA statement

At the time of the study, our primary beneficiaries of the research were defined as LMIC countries according to the DAC list. We worked with colleagues within India who were key contributors and leaders in the field of stroke and who held strategic positions in guiding policies within health care and research. We were mindful that the work that we were undertaking needed to guide practice. We developed interventions that will enable the maximum amount of benefit to the most amount of people. We also selected interventions that were appropriate for a low-resource environment. This is in keeping with the principles of ODA.

Data-sharing statement

This study did not generate any new data as it used existing sources and all data are contained within the manuscript. Any queries should be addressed to the corresponding author.

Ethics statement

Ethical approval for the study was granted by the Science, Technology, Engineering and Medicine Ethics Committee at the University of Central Lancashire (STEM 826). In addition, permission to undertake the study was granted by the Government of India Health Ministry Screening Committee (HMSC), the Indian Council for Medical Research (ICMR) and the Research and Development departments at each hospital site (Indo-Foreign/Neuro/Online/1/2018-NCD-1). Written/fingerprint, verbal/witnessed informed consents were obtained from all participants.

Information governance statement

The University of Central Lancashire is committed to handling all personal information in line with the UK Data Protection Act (2018) and the General Data Protection Regulation (EU GDPR) 2016/679. Under the Data Protection legislation, the University of Central Lancashire is the Data Controller, and you can find out more about how we handle personal data, including how to exercise your individual rights and the contact details for our Data Protection Officer here: www.uclan.ac.uk/legal/data-protection.

Disclosure of interests

Full disclosure of interests: Completed ICMJE forms for all authors, including all related interests, are available in the toolkit on the NIHR Journals Library report publication page at https://doi.org/10.3310/GJCW0423

Primary conflicts of interest: Maree L Hackett reports grants from the National Health and Medical Research Council of Australia outside the submitted work. Caroline L Watkins was associated with the HTA Commissioning committee, 2011–5. Caroline L Watkins was an independent Data Monitoring and Ethics Committee (DMEC) member, MAPS2 (APS-2 trial Metoclopramide for Avoiding Pneumonia after Stroke 2) 2021–5, and was an independent DMEC member, HomeHealth trial 2020–5.

The authors declare that there are no further conflicts of interest.

Department of Health and Social Care disclaimer

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About this article

The contractual start date for this research was in August 2017. This article began editorial review in December 2023 and was accepted for publication in May 2025. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The Global Health Research editors and publisher have tried to ensure the accuracy of the authors' article and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this article.

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List of abbreviations

DCGI	Drugs Controller General of India
EC	Ethics Committee
FERCI	Forum for Ethics Review Committees in India
HIC	high-income country
HMSC	Health Ministry's Screening Committee
ICMR	Indian Council of Medical Research
IMPROVISE	IMPROVIng Stroke CarE in India
INSTRUCT NETWORK	INDian STRoke Clinical Trial Network
LMIC	low- and middle-income country
MOU	memorandum of understanding
PI	principal investigator
SOP	standard operating procedure

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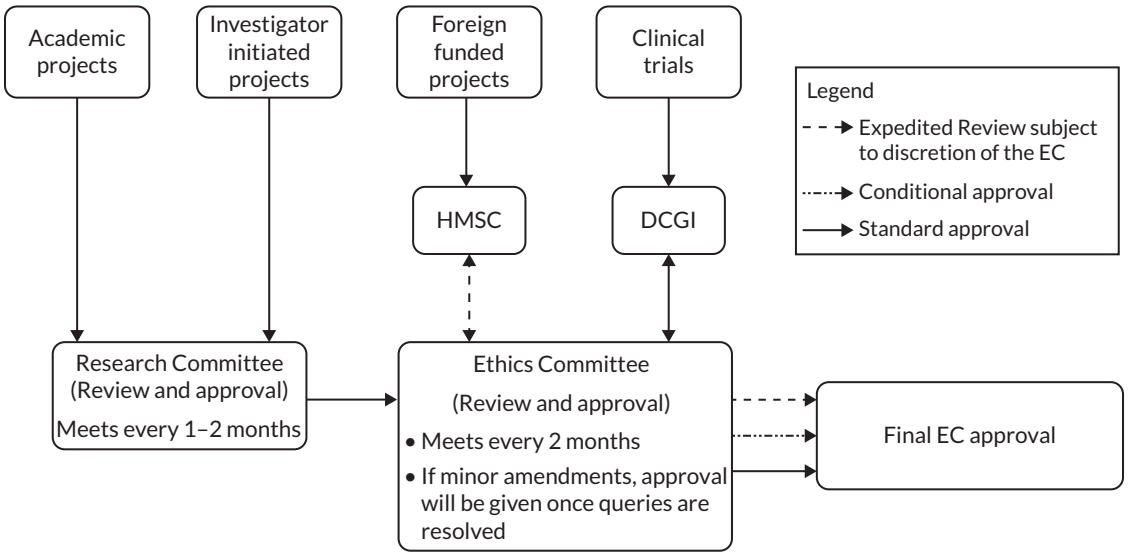
Appendix 1
Interview guide principal investigators

1. Please can you tell me about your professional background?
2. Can you tell me about your experience of applying for ethical approval for research? What, when and where?
3. Can you tell me about your most recent experience of apply for research EC approval?
4. How did you find the process?
5. What did you find the easiest/best about the application process?
6. What was the most difficult/the worse thing about the application process?
7. What do you think worked well about the way the committee operated?
8. What do you think could work better about the way the committee operated?
9. From your experience, what advice would you give to a colleague thinking about applying for research EC approval?
10. Would you change what you did if you were applying for research EC approval again?
11. Has going through the research EC approval process influenced your thoughts on being involved in research studies in the future?
12. Do you think that any changes are needed to current the ethics approval processed for multisite studies?
13. If you have more than one suggested area for change, which would be your priority and why? What would be the benefits of this? What would be the challenges of this? What might prevent changes from happening?
14. Is there anything else you would like to add?

Interview guide Ethics Committee's chairs/ secretaries

1. Please can you tell me about your professional background?
2. Why did you decide to become involved in research ethics?
3. Can you tell me about your role in the research EC? What does that role involve? Have you had any training for your role?
4. How long have you been on the EC? Is there a minimum/maximum time that people are committee members for? How long do people tend to be on an ethics panel?
5. What do you think works well about the way the committee currently operates?
6. Is there anything that you feel could work better about the way in which the committee currently operates?
7. Are there specific requirements that are needed for different types of research projects? For example, foreign-funded or nationally, locally funded research?
8. Given your experience with multisite international studies, what advice would you give to anyone submitting an ethics application?
9. In relation to international studies, what are the most common amendments suggested by the EC?
10. Do you have any experience of reviewing ethics applications for multicentre studies? Can you tell me about your experience in relation to this?
11. Do you think that any changes are needed to current the ethics approval processed for multisite studies? If yes, what changes would you suggest. If no, what works well?

Appendix 2


Academic projects
Investigator initiated projects
Foreign funded projects
Clinical trials
HMSC
DCGI
Legend
Expedited Review subject to discretion of the EC
Conditional approval
Standard approval
Research Committee (Review and approval)
Meets every 1–2 months
Ethics Committee
(Review and approval)
• Meets every 2 months
• If minor amendments, approval will be given once queries are resolved
Final EC approval