Agenda item:	11
Attachment:	A

HRA Board meeting

17 May 2023

Title of paper:	Approvals Service Improvement Approach and Plans 2023
Submitted by:	Jonathan Fennelly-Barnwell, Deputy Director, Approvals and Nicola Burgess, Improvement and Liaison Manager
Summary of paper:	This paper provides an overview of the Approvals Service's approach to continuous improvement in the context of wider HRA developments in this area. It also highlights some noteworthy improvement activities, including plans on recommendations from Think Ethics, and where recommendations remain on the pipeline for future consideration.
Reason for submission:	For information
Further information:	N/A
Budget / cost implication:	N/A
Dissemination:	With Board papers
Time required:	10 minutes

Approvals Service Approach and Plans 2023

Contents

Background

The formation of the Approvals Service followed the functioning of HRA Approval –the largest change in service provision and structure since HRA was established. HRA Approval had been implemented from 2015 through iteration and learning. In parallel with the HRA Implementation Programme, where formal process and business change was overseen, the RES/Assessment Group oversaw and agreed the detailed continuous improvements required to ensure HRA Approval was established sustainably, learning for user feedback and staff experience as we iterated changes to our service. The Approvals Service was formed in 2018 through a managed organisational change, effectively merging the Research Ethics Service in England and the Directorate of Research Systems and Standards.

Since the closure of the RES/Assessment Group, on the creation of the new directorate structure, Approvals Operations have maintained a register of planned improvements based on staff ideas, user feedback reports, and other UK-wide factors.

This register formed the basis of the decision to establish the Think Ethics programme, and a number of planned activities were subsumed into the programme to add visibility and programme management. COVID-19 also played a part as the virtual meetings we had been exploring became a necessary way of working.

Context and Approach

While Think Ethics has developed some of the improvement activities and idea from that register over the last three years, other improvement work in the HRA and in the UK-wide regulatory framework has continued with the Divisions of the Approvals Service – Operations, Support and Improvement, and, with a special focus on UK Approval, the Coordination and Standardisation.

To respond to the need to oversee and coordinate improvement activities, to ensure efficiency and alignment, in 2021 the Approvals Service re-established the post of Improvement and Liaison Manager, updating it for the unified Approvals Service Directorate. The postholder, Nicola Burgess, has created a proportionate system for us tracking improvement work within the directorate, and crucially, in ensuring alignment with other HRA teams' own work.

The management team responsible for service delivery, support and improvement have discussed and agreed principles to underpin the way we work which then ensures that Continuous Improvement is a conscious aim and ethos within the teams. Adapted from ISO 9001[1] these interconnected principles set out the way we aim to work more broadly:

- Alignment with HRA Strategic Aims
- Accordance with the Care Act (2014)
- Customer Focus.

[1] ISO is the International Organization for Standardization. ISO 9001 is its standard which sets out the criteria for a Quality Management System, based on a number of quality management principles.

- Leadership.
- Involvement of People.
- Process Approach.
- Continuous Improvement.
- System Approach to Management.
- Factual Approach to Decision-Making.
- Relationship Management

Pro tem, we adopted the following definition of Continuous Improvement:

> *"A company culture that encourages all employees to look for ways to enhance the business's operations. This includes suggesting ideas to improve efficiencies, evaluating current processes, and finding opportunities to cut unproductive work."*

The definition used will adapt to align with the outputs of the improvement definitions project once they have exec support and sign off. This will include breaking down the continuous improvements to be clear when they are breakthrough improvements and when they are incremental. We recognise the value in Continuous Improvement undertaken at team level following established principles and ways of working, distinct from, but complementary to the formal management of projects and programmes to Government Functional Standards. Moreover, some improvement activities are handled formally or informally as projects, adapting functional standards and using CPO expertise and managed as part of the portfolio overseen by Portfolio Delivery Group on behalf of the Executive Committee. However, we nonetheless see the need to track and coordinate improvements, to ensure best use of resources (noting that teams' Continuous Improvement work does not attract additional resource) and to ensure alignment with our strategic aims to include, accelerate and improve. So, while planned, done and appraised at local level, with team leaders taking ownership and responsibility for inclusion of relevant teams in HRA and outside, the work is overseen by a Quarterly Improvement Group. This group supports the prioritisation of proposed Continuous Improvement activities as well as discuss the detail of interdependencies and the sequencing of Continuous Improvement. This meeting reports to the Approvals Oversight Group (a broad range of team leaders in Approvals, where we discuss the totality of our work, its risk and issues progress and interdependencies) and the Approvals Senior Management Team.

More recently the Resources Directorate have begun to define key terms for the organisation, in work that has CEO as SRO, and to describe a model for continuous improvement. Not only does the Approvals Service work align with this, but we hope it also makes a positive contribution to the development of our organisation wide approach to continuous improvement.

The Approvals Service Improvement Activity log can be used by the organisation to take assurance of what improvement activities are undertaken in Approvals –

- why we are doing something, or why we are not;
- who is leading;
- who else is involved;
- what the benefits are, who are the beneficiaries and how will we know
- what are the related commitments
- how the activity contributes to the strategy and business plan commitments
- progress

The log can be sorted and interrogated in different ways depending on what is being asked. We do not report the whole log routinely – this is not its aim, nor the request of Executive Committee in the emerging framework for continuous improvement. There will however be a mechanism for identifying and feeding up the small, stepwise improvements where their sum-total have been particularly impactful or something the organisation may wish to publicise.

Think Ethics

In line with the reset of the Think Ethics programme in Q2 2022/23, at programme closure the Programme Board supported recommendations from its constituent projects, with a view to implementation by HRA and Devolved Administrations. These recommendations were adopted onto the Approvals Improvement Activity log, and are from the Think Ethics projects:

i. Quality Standard for Participant Information, and Design and Review Principles

ii. Methods of Review - institutional review of studies within a programme; staff review; an online Think Ethics tool

iii. Ethics in focus – activities which make REC reviews more focussed on ethics issues and more consistently approached across REC, and also making REC more transparent and accessible to public observers

As set out in the principal improvement activities, highlighted in yellow, depending on the project and the programme's recommendations, these are in implementation planning and UK-wide negotiation; development and testing; or on the pipeline pending capacity and other triggers.

Principle Improvement Activities 2023/24

The Improvement Activity Log currently captures around 130 activities undertaken within Approvals, overseen by the Improvement and Liaison Manager. It is the nature of continuous improvement that many will improve our service in line with the principles set out on page 3, while sometimes not visible to users who nonetheless benefit. Benefits are typically measured in KPIs reported to Executive. Where recommendations and ideas are progressed without clear benefits realisation plan, separate more focussed assessment of

trial periods will be done, such as monitoring of trends in volume and nature of REC conditions. We have set out below some of the more significant improvement activities contributing to delivery of the strategy and business plan, detailing the origin of the work. There are other key improvement on the portfolio e.g. preparing for regulatory change as opposed to service improvements regardless of regulatory change, these have not been included.

Accelerate

Activity description: To move the Quality Standards for Participant Information and Design Principles from development to implementation
Origin: Think Ethics
Purpose: The quality standards for participant information and design principles were created to set the standard for applicants developing their information and consent materials and provide principles for both their design and review. The purpose of the next step, taking place at the moment, is to raise the awareness of the standards and principles with RECs at the regional REC development days. **Benefits:** • Improvement of the quality of participant information submitted for ethical review, measured by impact on REC conditions or findings associated with Participant Information. • A consistent approach for RECs to use to support their review, measured by comparison across REC in application of Review Principles and REC outcomes. **Intended Impact:** Increased participant focus in the development of participant information, in design and usefulness to aide consent considerations.
Related Strategic Priority/Focus: Encourage researchers to do a better job of putting people first. Talk in a way that everyone can understand. **Related Business Plan Commitment:** Being clear what good looks like and setting the standard.
Timelines: **Q1 Apr-June-** UK agreement in parallel with testing with RECs **Q2 Jul-Sep-** Engagement and comms **Q3 Oct-Dec-** Implementation

Activity description:

Ethical approval for sub-studies within a programme of research.

Origin: Think Ethics

Purpose:
After initial testing with stakeholders in Think Ethics of a loose idea for institutions to be able to review the Ethics of studies within a programme of research, that has been reviewed by HRA (and/or possibly Das) , the programme recommended further exploration and testing applied to actual applications to inform further progress.

This work explores the feasibility of offering a service to review and approve applications for programmes of research, where the scope of the programme of research can be described in a master protocol. Two live applications are in preparation for submission, with involvement of HRA senior development staff. They ill be tracked through the review process as part of the exploration, which will then isolate any residual ethics issues which might require institutional review, to inform engagement with the institutions on how these would be handled and the organisational tolerances, or where subsequently submitted sub-studies require confirm of being within scope of the programme review. Both are submitting master protocols for approval, with the details of the individual studies within the protocol to be detailed as they are identified and ready. The work will provide initial evidence on the limitations for organisations' involvement in this kind of review.

Benefits:

- Facilitate quicker set-up of individual research projects by removing a requirement for each individual project to be submitted for ethical review.
- The service could benefit the research ethics service by reducing the volume of applications which are submitted for review.

Intended Impact:
To be determined following the exploration

Related Strategic Priority/Focus:

Support new ways to do research.
Work with research teams to explore new ways to do research and make them happen.

Related Business Plan Commitment:

Working in partnership with the research community.

Timelines:

Q1 Apr-June- Test applications submitted
Q2 Jul-Sep- Analysis
Q3 Oct-Dec- Further proposal/decision

Activity description:

Standardising use of the Ethics Review framework.

Origin: Think Ethics

Purpose:
To make it easier to follow the agreed framework, and to make review more transparent.
Embedding it in a user-centred way into the research systems
At a later stage, to test early briefing of applicants and key information from first reviewer ahead of REC meeting.

Benefits:

- Improved consistency of approach REC review, measured by trends in opinions.
- Increased transparency to applicants and observers about what RECs consider in ethical review.

Intended Impact:
Adding clarity to the role of the lead and second reviewer
Increased awareness of the ethical considerations made by RECs.

Related Strategic Priority/Focus:

Connect the steps that are part of doing research and make them easy to follow.
Make transparency the norm.

Related Business Plan Commitment:

Being clear what good looks like and setting the standard

Timelines:

Q1 Apr-June- Staff/member training
Q2 Jul-Sep- Wider user and monitoring of ERF
Q3 Oct-Dec- Review point and discuss pre-meeting info to applicants

Activity description:

Piloting the parallel submissions of the CAG and REC applications for research which uses Confidential Patient Information (CPI) without consent and therefore require both REC and CAG approval

Origin: Process Review/ Feedback/SDDR

Purpose:
The majority of applicants undertake the entire REC review process before applying to CAG, resulting in a long overall timeline to gain HRA and HCRW approval. CAG and REC review, though both managed by the HRA have historically been managed as separate processes with minimal interaction between staff and committees undertaking the review. The pilot aims to co-ordinate the REC and CAG submissions using the revised CAG application form, co-ordinated REC and CAG processes, combined communications, CAG and REC meetings scheduled within a week of each other and applicant attending the CAG meeting.

Benefits:

- Reduction in the average co-ordinated research approval timelines by 25%.
- Increasing user satisfaction

Intended Impact:
Improved user experience and slicker process for research using confidential patient information.

Related Strategic Priority:

Support new ways to do research.

Related Business Plan Commitment:

Joining up and connecting across the system

Timelines:

Q1 Apr-Jun and Q2 Jul-Sep- pilot
Q3 Oct-Dec and Q4 Jan-Mar- review, decision, implementation

Activity description:

Exploring alternative pathways for senior staff studies.

Origin: Process Review/Feedback

Purpose:
To explore different pathways for senior staff studies which are a. taking place in the NHS and b. have minimal impact on it. This includes testing a reduced IRAS question set and encouraging a more proportionate approach from R and D departments undertaking C & C checks.

Benefits:
- A proportionate, risk- based approach to senior staff studies taking place in the NHS.
- A faster application completion and review process

Intended Impact:
A reduction in the time taken from idea to set-up

Related Strategic Priority/Focus:
Support new ways to so research
Work with research teams to explore new ways to do research and make it happen

Related Business Plan Commitment:
Always look for ways to do things better

Timelines:

Q1 Apr-Jun- planning
Q2 Jul-Sep- pilot
Q3 Oct-Dec- decision

Include

Activity description: Publication of the newly created people centred hallmarks and related guidance
Origin: Research Resilience and Growth (RRG)
Purpose: To increase the researcher, sponsor, REC and others' awareness of the importance of people-centredness **Benefits:** • Significant HRA contribution to RRG • Researchers guided and enabled to conduct clinical research in people centred ways **Intended Impact:** • Better quality research with people at its heart • Creation of opportunities for more people to take part in clinical research, making it better for people who take part, ensuring better health and care decisions and reducing waste.
Related Strategic Priority: Include everyone in research Supporting new ways to do research **Related Business Plan Commitment:** Working in partnership with communities and people with lived experience
Timelines: **Q1 Apr-Jun-** Consultation **Q2 Jul-Sep-** Steering Group decision **Q3 and Q4 Oct-Mar-** Development of recommendations for researchers

Activity description: Managed system of supported observer ships at REC meetings, for members of the public, researchers, staff, Board
Origin: Think Ethics
Purpose: Following the pilot with a dementia charity, and feedback from current arrangements for observers, this work intends to: • make it easier to observer a REC meetings in a way that is meaningful to the individual for their interests and purposes. • standardise how we debrief observers and use feedback to inform HRA work **Benefits:** • Service improvements informed by wider range of feedback and insights • Greater understanding of how RECs works in our staff, Board and stakeholders • Increased transparency to applicants and observers about what the RECs consider as part of the ethical review.

- Possible aid to REC member recruitment and diversity

Intended Impact:

Greater awareness of HRA and transparency of REC business

Related Strategic Priority/Focus:

Make transparency the norm.

Timelines:

Q1 Apr-Jun- Stakeholder engagement
Q2 Jul- Sep- Development of process and tools with selected observers
Q3 Oct-Dec-BAU

Improve

Activity description:

Creation of seasonal RECs using the existing membership pool

Origin: Process Review/Feedback

Purpose:
To increase the REC review capacity in August and December, due to the high levels of bookings and demand for REC slots before applicants break for the holiday period.

Benefits:

- Increasing review capacity when its required
- Decreasing the wait time for applicants submitting applications at busy times

Intended Impact:

- Improved service and review time for applicants conducting research in the UK, increasing its attractiveness.

Related Business Plan Commitment:

Always looking for ways to do things better
Working in partnership with the research community

Timelines:

Q1 Apr-June- Implemented
Q2 Jul-Sep- Monitoring
Q3 Oct-Dec- BAU

Activity description:

Exploring the streamlining of the proportionate review (PR) process with a view to removing the subjective elements of the staff screening.

Origin: Process Review/Feedback

Purpose:
To consider the screening process staff undertake before sending applications to PR RECs with a view to removing the subjective elements within the staff screening, reducing the applications promoted to Full REC review.

Benefits:

- To reduce the number of applications promoted from PR to Full REC review by staff
- To increase the number of applications receiving a proportionate review, decreasing their review timelines.
- To reduce staff time reviewing applications for screening purposes.

Intended Impact:
Improved applicant satisfaction, proportionality and speed of review.

Related Business Plan Commitment:

Always look for ways to do things better

Timelines:

Q1 Apr-June- Pilot
Q2 Jul-Sep- Implementation decision

Activity description:

Creation of a Phase I knowledge exchange between Phase I REC chairs and CROs

Origin: Feedback

Purpose:
To promote awareness and understanding between phase I CROs and phase I RECs

Benefits:

- Increased REC awareness of Phase I research e.g. methodological changes and mechanics of running it in the UK from a CRO perspective
- Improved CRO awareness of the ethical considerations for Phase I research and how they can be factored into initial applications to the REC

Intended Impact:

- Increased attractiveness of the UK as a place to conduct phase I research

Related Business Plan Commitment:

Working in partnership with the research community.

Being clear what good looks like and setting the standard **Related Strategic Priority:** Embed a learning culture where learning opportunities are meaningful and help us deliver our mission.
Timelines: **Q1 Apr-Jun-** First group meeting **Q2 Jul- Sep- Q3 Oct-Dec** Development of remit, materials and review

Explored and Not Currently Being Taken Forward

In agreeing Approvals Service Improvement activities, some activities are considered which, while not without merit, may not clearly enough align with HRA strategic aims and are deprioritised accordingly with regard to available focus and resource. Some activities may accord with our strategic intention though the ratio of benefit to resource, even when taking account of combinations of improvement activities. means that we put them on a pipeline for regular review of level of priority and available capacity. Similarly, some proposals are dependent on other activities completing, so will also be added to the pipeline. And almost inevitably, the usefulness of some activities diminishes when the context changes. These discontinued activities as well as pipeline activities are recorded and reviewed. Current pipeline proposals include:

Activity description: Staff Review of applications
Origin: Think Ethics
Summary of work, purpose and benefits: The work was to explore staff reviewing applications some application types which currently receive a REC review with a view to applying a more proportionate approach for low-risk studies. Views were sought as part of the public consultation and discovery work undertaken to establish appetite and feasibility.
Description of why not taken forward: Staff review scored the lowest in the decision-making framework which considered stakeholder responses, service benefits, REC cist, feasibility and business change. Key reasons included: • Cost of moving volunteer functions to staff and additional capacity that would be required to undertake the function at a staff level. • The feasibility of determining which application types would be appropriate and consistently low-risk to be routinely directed to staff review. • Infeasibility across the UK-wide service with current staff structures **Pipeline-** Yes **Triggers for review** • Following the implementation of the quality standard and principles (to see how staff can play a role in measuring against the standard)