

Ethics Monitor

Key advantages for each role

"The time saving alone is phenomenal."

Pro Vice Chancellor for Research, UK University

Researcher

Researchers benefit from using straightforward, easy-to-use forms which only show relevant questions.

Forms are routed to the correct approver automatically and the researcher is kept informed of the progress of the application via automatic email updates throughout the approval process.

The approval process is faster, avoiding delays in enabling the researcher to start their research.

If additional information is required, it's easy for the researcher to make changes and resubmit their form, and easy to read reviewer comments against each question in their application.

Following approval researchers are automatically prompted for project updates, and it is straightforward to submit requests for approval of significant amendments, and reports of adverse events.

Committee member

Committee members and reviewers across the institution benefit from receiving automatic prompts and reminders whenever they are required to take action. Application forms and attachments are presented clearly to review online. Comments can be left inline against individual questions on the application form.

It is straightforward to return applications to applicants for more information and to see the current and previous versions upon resubmission. Changes made by the applicant are highlighted saving the reviewer time in identifying what has changed.

Committee review and discussions can happen asynchronously fitting in around the reviewers schedule.

Committee secretary

Applications are easily scheduled for committee meetings or sent to individual reviewers for comment. Requests for additional information and resubmissions are straightforward, with previous versions of submissions automatically saved and changes to applications highlighted.

Correspondence is streamlined with automatic alerts, template text for all outcome notifications, and automatic notifications to supervisors and co-investigators.

Reports are automatically produced and available to all authorised users online. The streamlined process results in faster approvals with key service indicators met and often exceeded.

Ethics Monitor

Key advantages for each stage

Ethics Monitor provides significant advantages over current practices throughout the entire ethics review process.

DESIGNING AND COMPLETING ETHICS APPROVAL FORMS

Previous practice	Ethics Monitor key advantage
Designed as a Word document to be submitted by email.	Online forms provide far greater flexibility and are submitted and routed to the correct approver automatically.
Restricted in how tailored the form can be for different groups of applicant. Having multiple template forms for different categories of applicant and different subjects can be confusing for users and reviewers to know which form to use. Maintaining multiple forms requires additional administrative effort to update all forms and loses a standard approach across the institution.	Online forms can be tailored to individual users from different disciplines, different categories, dealing with different risk levels and in response to questions answered during the form. Using an online form, applicants will always use the most up to date version.
A form which is too simple to draw out the detail required, results in more back and forth as reviewers ask for additional information from applicants.	A highly tailored online form with mandatory questions and embedded guidance notes, enables the right information to be gathered from the applicant upon first submission, reducing the number of times it needs to be returned for further information. Forms use a variety of question formats to elicit the most appropriate response - drop down options, check boxes, text fields, file uploads.
Either all questions have to be completed on a form or complex rules provided for applicants on which questions to answer depending on the answers to previous questions.	Using an online form, only questions relevant for the applicant are displayed. Questions or entire sections which are not applicable and do not need to be answered are hidden to avoid cluttering the form. Certain questions can be mandatory for certain categories of applicant.
Restricted by how much guidance can be provided within or alongside the form without the form and guidance becoming unwieldy.	Guidance notes are displayed alongside specific questions and revealed or hidden as required by the user, enabling additional information to be provided when it is needed but not cluttering up the form.
Cumbersome to copy, edit and resubmit an application for similar research to a previously submitted application.	Applications can easily be copied, edited and submitted for approval where research is similar to a previous project.

DESIGNING AND COMPLETING ETHICS APPROVAL FORMS

Previous practice	Ethics Monitor key advantage
Handling requests involving external bodies requires convoluted guidance for researchers and more variations to the standard application form.	Every variation of application is supported including variations for whether approval is required for an external body or whether the institution needs to be notified of approval by an external body. The researcher is presented with the required questions automatically with no need to read and understand complicated guidance on how to submit different types of application.

IMPLEMENTING ROUTING RULES

Previous practice	Ethics Monitor key advantage
Rules on who to submit the form to are necessarily kept simple to avoid presenting convoluted instructions to the applicant.	Sophisticated routing rules sends the application to the most appropriate reviewer automatically.
Forms can easily be sent to the wrong person for review with no visibility of where the form has been sent. For instance, taught students may send the form to the wrong supervisor.	The possibility of misdirected applications has been eliminated, and there is visibility of who is reviewing the application at any time.
Convoluted rules for researchers to follow on how to submit non-standard applications such as those involving external bodies.	Applications involving approval by external bodies are routed automatically to the most appropriate reviewer.

REVIEWING AND APPROVING APPLICATIONS

Previous practice	Ethics Monitor key advantage
Forms and multiple attachments are either submitted by email through which it is cumbersome for reviewers to read multiple attachments, or on paper which causes delays in reviewers receiving the application.	Online forms containing multiple attachments are submitted online. Reviewers are instantly alerted and can comfortably read the form and accompanying material online.
Manual checking of forms to ascertain whether they are correctly completed and all mandatory questions answered is time consuming for reviewers and applicants, and subject to human error.	Automatic checking of completion of questions improves the quality of applications submitted.
Difficulty enforcing mandatory questions and file uploads, so forms have to be returned to applicants for resubmission if incomplete, resulting in time wasted for reviewers and delays in approving applications.	Application cannot be submitted unless all mandatory fields are completed and all required files uploaded, improving the quality of submissions and ensuring all required information is ready for the reviewer.
Feedback is provided in a separate document having to manually note which question the feedback refers to.	Feedback is entered against each line of the online application making it easier for applicants to understand what changes are being requested. Changes to the application are clearly marked upon resubmission, making it easier for reviewers to see what has changed.

REVIEWING AND APPROVING APPLICATIONS

Previous practice	Ethics Monitor key advantage
Feedback and correspondence about an application is spread across multiple emails and documents.	All correspondence about an application from multiple reviewers and committees is kept in one place, making it easier for applicants and reviewers to read, and providing a reliable audit trail for the institution of decisions made and advice provided.
No automatic reminders to busy reviewers where they have not responded to applications.	Reviewers are automatically reminded of outstanding applications awaiting their attention.
Cumbersome to track versions of applications going back and forth and their responses.	All versions of the application are saved alongside the most current version. Changes and comments can be clearly tracked.
No automatic notification to the applicant when applications progress through each review stage.	Applicants are automatically notified as applications progress through each review stage and have visibility of the current status online at any time.
No visibility of the status and progress of all applications.	Research Governance Officers and Committee Secretaries can easily monitor the progress of all applications across the institution via one single system and identify where an application has been delayed by a reviewer.

NOTIFYING APPLICANTS OF OUTCOMES

Previous practice	Ethics Monitor key advantage
Applicants have to wait to receive approval with no communication on the progress of applications. Approvals can typically take many weeks to process during which time the researcher is not permitted to start their research.	Up to date information on status of application available to applicants and supervisors at all times. Faster decision times and faster notifications once a decision has been made.
Time consuming to manually produce letters for each outcome. With potential delays due to administrator availability.	Outcome notifications are automatically produced using templates with standard text for every outcome. Automatic generation of notification letter using university letterhead created as PDF instantly upon confirmation of approval of application. No reliance on an Administrator to produce the letters.
Time consuming to lookup and copy in supervisors and co-investigators into outcome notifications.	Supervisors and co-investigators are automatically copied into all key correspondence.
Time consuming to manually input key details from the application into the final outcome notification.	Key information about the application is automatically added to the notification.
No transparent, searchable or central place for storing all formal outcome notifications.	A central online archive of all formal outcome notifications sent provides the university with a reliable record of approved research.

NOTIFYING APPLICANTS OF OUTCOMES

Previous practice	Ethics Monitor key advantage
Responsibility of researcher to keep a copy of the final outcome. If they lose it and need it later, it is more time consuming for an administrator to re-produce.	All supporting documentation and notifications are stored in the system and clearly linked to the application record, visible to the researcher at any time.
Unclear how to appeal the decision to not approve and difficult for committees to handle appeals and changes of outcome decision.	Where permitted, it is straightforward for applicants to submit an appeal against a decision. Committees can review the appeal online. The applicant is notified automatically of the progress and outcome of the appeal. Changes to the outcome decision are automatically updated with a full audit trail provided of all decisions made in relation to the application.

MANAGING COMMITTEES

Previous practice	Ethics Monitor key advantage
Committee review subject to availability of committee members to attend. Committee meetings frequently rescheduled due to staff availability, creating delays to decisions.	Using the online decision function, committee discussion can take place online asynchronously and in response to application submissions.
Committees implement restrictive rules as to how far in advance applications can be sent to be scheduled for discussion at the next meeting due to the time required to circulate applications to committee members.	No frustrating delay for researchers who have 'missed the deadline' waiting for the next committee meeting for a decision. Circulation of applications to committee is streamlined enabling applications to be submitted at any time and speeding up time to review.
Committee documents saved on a shared drive. Applications circulated as unwieldy email attachments or printed, both being time consuming for an administrator to prepare.	Central single online committee document repository available to all committee members Committee members are automatically alerted to documentation they should read prior to meetings.
Time consuming and error prone to manually produce agendas and minutes.	Meetings easily scheduled, agendas automatically compiled and reminders automatically sent.
Tracking progress of applications is done by a spreadsheet, prone to human error and delays in being updated.	Progress of each application is automatically tracked and available to view by all stakeholders.
Unfeasible to track expiry of ethical approval.	Prior to expiry of ethical approval, researchers are automatically prompted to submit a request to extend ethical application or update the committee that the research has been completed.

MONITORING LOCAL COMMITTEES

Previous practice	Ethics Monitor key advantage
Difficult to efficiently support review of applications by subject-experienced staff in local committees whilst maintaining overview across the institution for quality and assurance.	Local committees benefit from online tools to operate efficiently, whilst the institution benefits from visibility of all decisions made in local committees. Committee representative can assign appropriately experienced staff to review applications whilst easily maintaining overview of the process
Difficult to ensure key service indicators such as days to decision are being met by all committees. Annual reporting by committees happens too late to improve poor performance during a year.	Institution has visibility of the progress of applications across all committees in real-time, and real-time dashboards of key service indicators across all committees. Committee members and reviewers are notified as deadlines approach to improve turnaround time.

IDENTIFYING HIGH RISK RESEARCH

Previous practice	Ethics Monitor key advantage
Requiring researchers to self-identify their research as high risk is error prone.	Risk is assigned by the responses to a range of questions, rather than selected by the applicant helping to avoid inaccurate classification
High risk applications are not visible to the institution.	High risk applications are clearly marked and made visibility to the institution via special routing rules, email alerts and real-time dashboards.
Lack of transparent audit trail of all discussions and decisions related to a high-risk application.	Online submission system automatically records every decision relating to a high risk application, including which committee reviewed and approved the application. All documentation is stored together with a full audit trail of who took what action and when in a central, secure system.

MONITORING RESEARCH POST ETHICAL APPROVAL

Previous practice	Ethics Monitor key advantage
Difficult to implement and monitor status updates on the research project required from researchers post-approval.	Researchers can be automatically notified to submit an update. Updates can easily be added to the existing application. Dashboards show where updates have not been submitted on time.

MONITORING RESEARCH POST ETHICAL APPROVAL

Previous practice	Ethics Monitor key advantage
Difficult to administer suspension/cancellation of approval.	Ethical approval can easily be suspended in order to allow the committee to review a change in circumstance and determine if approval should be cancelled.
Cumbersome for researchers to notify adverse effects.	Researchers are easily able to report adverse events linked to the original application. Real-time dashboards show number of adverse effects reported.

MANAGING REQUESTS TO APPROVE AMENDMENTS TO RESEARCH

Previous practice	Ethics Monitor key advantage
Requests for approval of amendments are not easily linked to the original application, sometimes requiring the applicant to find and resubmit details of the original application and approval alongside a request for approval of amendments.	Amendments are easily linked to the original application.
Records of original approvals would not normally show that a subsequent amendment had been requested.	Using an online system, the original application automatically displays links to any subsequent amendment applications.
How to submit a request to approve amendments, or even knowing there is a requirement to do this, is often non-obvious for researchers.	The option to submit an application for an amendment is clearly displayed on all approved applications. The form is automatically routed to the most approver reviewer or committee. This can follow the same route or a different route to the original application.