

# Research governance

Ethics Monitor is an online easy-to-use solution for streamlining the review of applications for ethical approval. With comprehensive reporting, transparency and time-savings at every stage, Ethics Monitor assures good research governance across an institution.

Ethics Monitor is configured to display your institution’s forms, workflow, terminology and processes. The Ethics Monitor team works closely with institutions throughout the configuration process to ensure a successful implementation.

*“Ethics Monitor has been a resounding success for us - reducing decision times, introducing transparency to all stakeholders, and providing an online virtual replacement for scheduled committee meetings.”*

Dr Laura Boubert, University of Westminster

## Online forms

Customisable forms	<p>Forms can be customised to reflect the needs of different disciplines and categories of user. The forms reflect the terminology, committee names, and methodology of an institution.</p> <p>The forms are clearly laid out guiding the user through the application process. Users only see questions that are relevant to their category or discipline, or the answers provided to previous questions.</p>
Embedded guidance notes	<p>Guidance notes provide additional information about each question in the ethics application form. They can incorporate links to further information, such as relevant parts of the institution’s ethics code.</p>
File uploads	<p>Files can be uploaded as part of the ethics application form, and Ethics Monitor supports all file formats. If supporting documents are required, the applicant will be unable to submit an application until the required documentation is provided.</p> <p>Once submitted, reviewers can view uploaded files as part of the online application. Reviewers can download a PDF of the completed application form including all supporting documents.</p>
Saving drafts	<p>Applicants can save drafts and return to edit them later, enabling them to gather supporting documentation, complete necessary training or gather further information required to complete the form. Reviewers can see draft applications. Forms cannot be submitted until they are fully completed.</p>
Revising and resubmitting applications	<p>Applications that have been returned to the applicant for changes can be revised and resubmitted. Copies of all previously submitted versions are stored.</p> <p>Ethics Monitor clearly tracks all amendments, revisions and comments from reviewers.</p> <p>The 'Show changes' feature clearly marks both old and new versions of changed answers, viewed on their own or as part of the full application.</p>
Copy applications	<p>Applicants can copy previously submitted applications, edit and resubmit where they are undertaking similar research.</p>

## External ethical approval

Registering applications that require external approval

Applications requiring approval by external organisations (e.g. NHS) can be supported in line with the institution's processes.

Draft applications can be reviewed within Ethics Monitor, enabling the institution to provide internal feedback before final submission to the external body.

Formal acknowledgement of external approval

When the applicant confirms external approval has been granted, the application can be forwarded within Ethics Monitor to the relevant university committee.

## Streamlined approvals

Automatic routing

Applications are routed to the most appropriate reviewer and committee, based on the category of applicant, discipline, and class of application.

Delegating tasks

If a reviewer (either at supervisor or committee level) is unavailable or unable to complete an assigned task, they can delegate it to another reviewer. If a reviewer sees that a task has stalled with an unavailable assignee, they can reassign the task to themselves.

Signing off low risk applications

Low risk applications can be signed off at an early stage in the review process, removing the need for unnecessary review at higher levels, if allowed by the institution's policy.

Assigning reviewers

Applications can be assigned to individual members of an ethics committee for review, or to other users within the institution who've been selected for their expertise.

Reviewing submissions from taught students and postgraduate researchers

Prior to submission, applications from postgraduate researchers and taught students can automatically be routed to the applicant's supervisor for review.

Automatic prompts and reminders

Each user automatically receives an email and task notification when they're required to complete an action within Ethics Monitor, with a direct link to the record requiring action.

Reviewers, ethics committee secretaries, members and applicants receive an email with a direct link to the page requiring their attention.

All users receive a weekly reminder that clearly lists outstanding tasks, helping them to manage their workload more efficiently.

Commenting on specific answers

Reviewers can comment on answers to specific questions within an application.

Returning applications for changes

Applications can be returned to the applicant to revise and resubmit.

Visibility of applications at every stage

Both the applicant and assigned reviewers can track the progress of an application at every stage.

Reviewers and committee members can see comments from other reviewers and monitor the progress of an application once they have completed their task.

Applicants can track their application as it moves through the review process.

### Streamlined approvals

Editable notification templates	<p>Applicants and their supervisors are notified of an application's outcome through template notifications. Administrators can edit notifications, adding any information that applicants might need.</p> <p>Template emails for every possible outcome can be generated and stored within the application record.</p>
Automatic routing of high risk applications	<p>Applications ranked as high risk can be routed directly to committee level, where they can be reviewed or redirected as appropriate.</p>
Flagging and re-routing conflicts of interest	<p>Any conflict of interest between an applicant and prospective reviewer can be flagged and the application forwarded to alternative reviewers.</p>

### Supporting committees

Committee review	<p>Committees can view outstanding applications, set up meetings, enter comments, and communicate easily with their members. Applications can be approved, rejected, returned to the candidate with requests for amendments, or forwarded to another committee or reviewer for further advice.</p>
Committee meetings	<p>Committee meetings can be organised and conducted through Ethics Monitor. Committee secretaries can schedule applications for discussion at an upcoming meeting, and discussions between committee members can be held online.</p>
Automatic agendas	<p>Once a meeting has been scheduled, an agenda featuring all necessary information is automatically generated and sent to all attendees a week before the meeting.</p>
Automatic minutes	<p>Once a meeting has concluded, minutes detailing the actions taken are created automatically.</p>

### Significant amendments

Approving significant amendments	<p>Where a research project changes sufficiently to require additional ethical approval, an application for approval of significant amendments can be submitted through Ethics Monitor.</p>
Reviewing significant amendments	<p>Applications for approval of significant amendments are submitted to the appropriate reviewers and committees, in accordance with the institution's processes.</p> <p>Once submitted, Ethics Monitor notifies reviewers or committees that they have a new task with a direct link to the application to review.</p>

## Adverse events

Reporting adverse events	If an adverse event occurs following ethical approval, the researcher can submit details within Ethics Monitor linked to the original application.
Adverse event notifications	Once an Adverse Event form is submitted, email notifications are sent to all users involved in reviewing and approving the original application, and to any other roles that need to be notified according to the institution's processes.

## Appeals

Appeals	Where permitted by the institution, applicants can submit an appeal against a decision to not approve. The appeal is forwarded to the appropriate approver or committee. The applicant is notified if the original decision is upheld or overturned with reasons for the decision. A full audit trail of the appeal and appeal outcome is recorded.
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## Cancellation

Cancellation	<p>Authorised users can cancel ethics approval in the rare cases where the research or circumstances around the research have changed so substantially as to warrant cancellation.</p> <p>Approvals are suspended whilst under review and either cancelled or reinstated depending on the outcome, with a full audit trail of all decisions made.</p>
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## Reporting

Automatic ID	Ethics Monitor automatically assigns a unique, sequential ID to all applications.
Real-time user engagement dashboards	<p>A variety of dashboards provide visibility of ethical approval processes, producing reports on both current and historical applications.</p> <p>Standard reports include: the status of all current applications, the outcome of all completed applications, number of applications per risk category and category of applicant, number of applications by risk category and faculty, days to decision, status and outcome of any appeals, number of applications reviewed per reviewer each year showing fastest and slowest response times.</p>
Highlighting high-risk applications	<p>Ethics Monitor classifies applications according to risk levels. These are determined by the answers provided in the application form.</p> <p>High-risk applications are highlighted on dashboards for easier monitoring.</p>
Filtering and exporting results	Ethics Monitor can filter reports according to a variety of criteria, i.e. risk level, submission date, status, faculty, department or name. Results can then be exported to Excel.
Easier auditing	Dashboards enable users to track the entire approval process and ensure that best practice is being observed at all levels. If there are concerns about a specific application this can be fully audited showing all reviewers' comments and decisions.
Delegation and oversight	Ethics Monitor provides central oversight of approval processes delegated to subject-specific committees.



# Ethics Monitor

## University of Westminster Case Study

The need for ethical approval of the research undertaken within academic institutions is an integral part of the research process and important to an institution for compliance, duty of care, and risk management.

One of the challenges of research ethics is the scale of work involved for committee members – who are mostly faculty members – and the difficulty of tracking applications and decisions. Both are required to support the process and ensure that all applications are treated fairly.

The time involved in performing this work is often underestimated by universities – the variety and complexity of decisions requires extensive discussion and negotiation.

Even more challenging are the logistical issues of organising committee meetings, which are traditionally held face-to-face and require quorate attendance.

The University of Westminster introduced Ethics Monitor in 2014 to facilitate the management of Research Ethics committees, to help track the progress of applications and to allow discussions to occur and be managed virtually.

### **The challenge**

Ethics committees were being stretched by a time-consuming email and paper-based approval process - these were unreliable and far from transparent, leading to long review and approval lead times.

Scheduling face-to-face committee meetings during busy times was also extremely difficult, leading to further delays in decision making.

The university needed a robust, comprehensive platform to boost efficiency, increase transparency and streamline the process from submission through to final approval.

### **The solution**

After introducing Ethics Monitor, the university reported the system had been “a resounding success” and that it had succeeded in “reducing decision times, introducing transparency to all stakeholders, and providing an online virtual replacement for scheduled committee meetings”.

### **Increased time-efficiency**

The intuitive online forms and user-friendly workflows in Ethics Monitor have saved committees significant time, with time-to-approval for a sample of taught student applications “halved, from 15 days to 7 days”.

Rather than being limited to discussing applications when sufficient numbers of committee members were physically present, committee members can now discuss applications and make properly considered decisions whenever, and wherever they happen to be.

### **Greater transparency**

The ability to hold virtual discussions and committee meetings through Ethics Monitor has facilitated quicker, more constructive decision-making and greater transparency. The ease of communication through the platform has also engineered a more collaborative approach to improving ethical practices and understanding.

**A simplified process**

Ethics Monitor's automatic notifications and ability to display the status of applications in real time has made the University of Westminster's ethical review process quicker and more streamlined for all involved.

**Easier auditing and review**

Application records include full history of all actions, decisions, notifications, and all versions of forms and files, making it easier to audit decisions made and review the quality of decision making.

By freeing up more time, Ethics Monitor has changed and broadened the role of committees, enabling them to regularly evaluate core ethical concepts and check these are reflected in departmental procedures and documentation, and ensuring that applications are treated fairly.

*Full report*

An integrated psychology virtual research ethics committee - Boubert, L. and Taylor, D.A.

Published in the Proceedings of EDULEARN16 Conference, 2016.

<https://www.ethics-monitor.co.uk/#case-study>