EHU ethics, SRECs, HREC applications via Haplo

The process and top tips for a smooth journey

Dr Kate Knighting

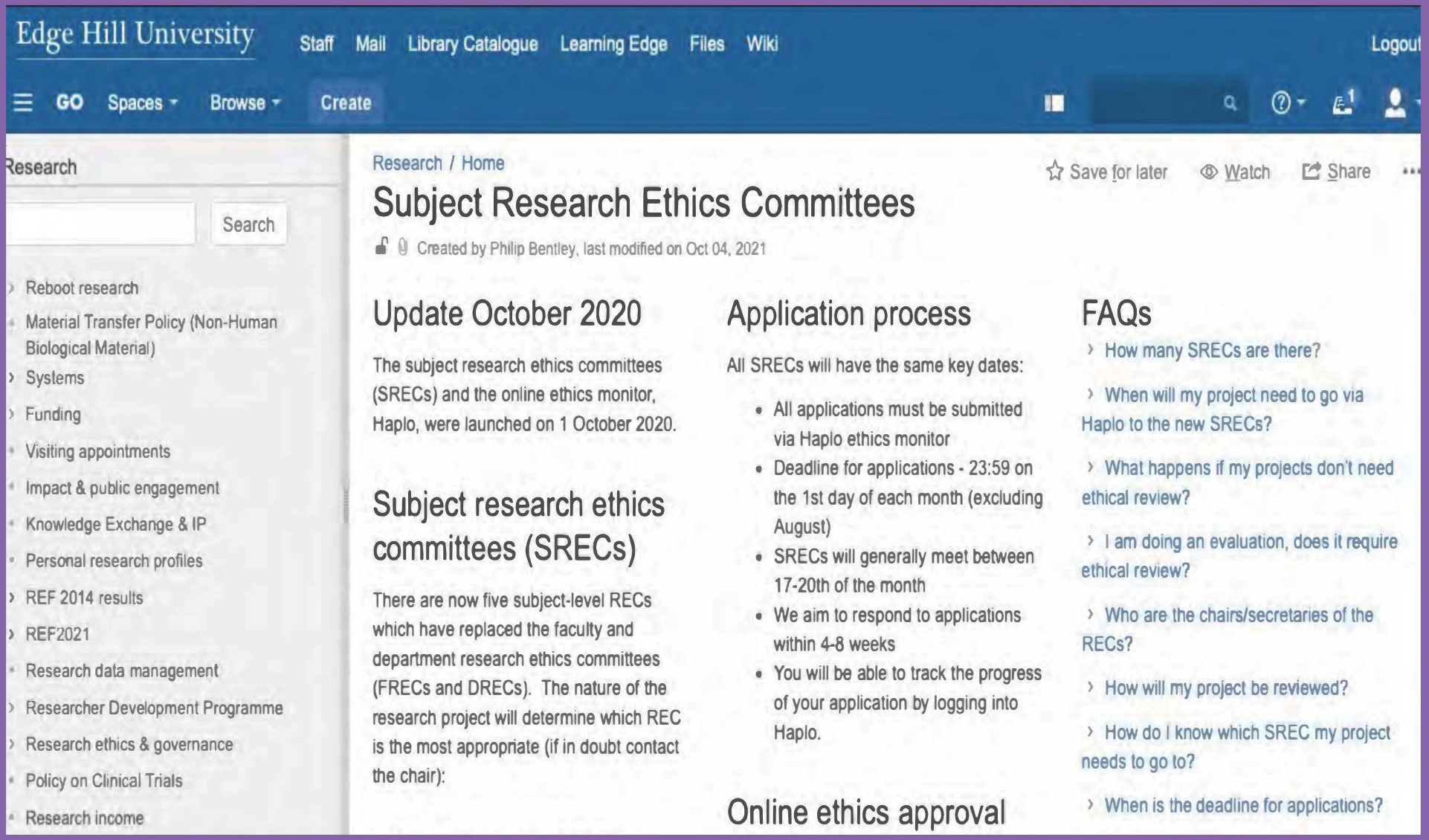
Chair, HREC

Ethics and Governance at EHU

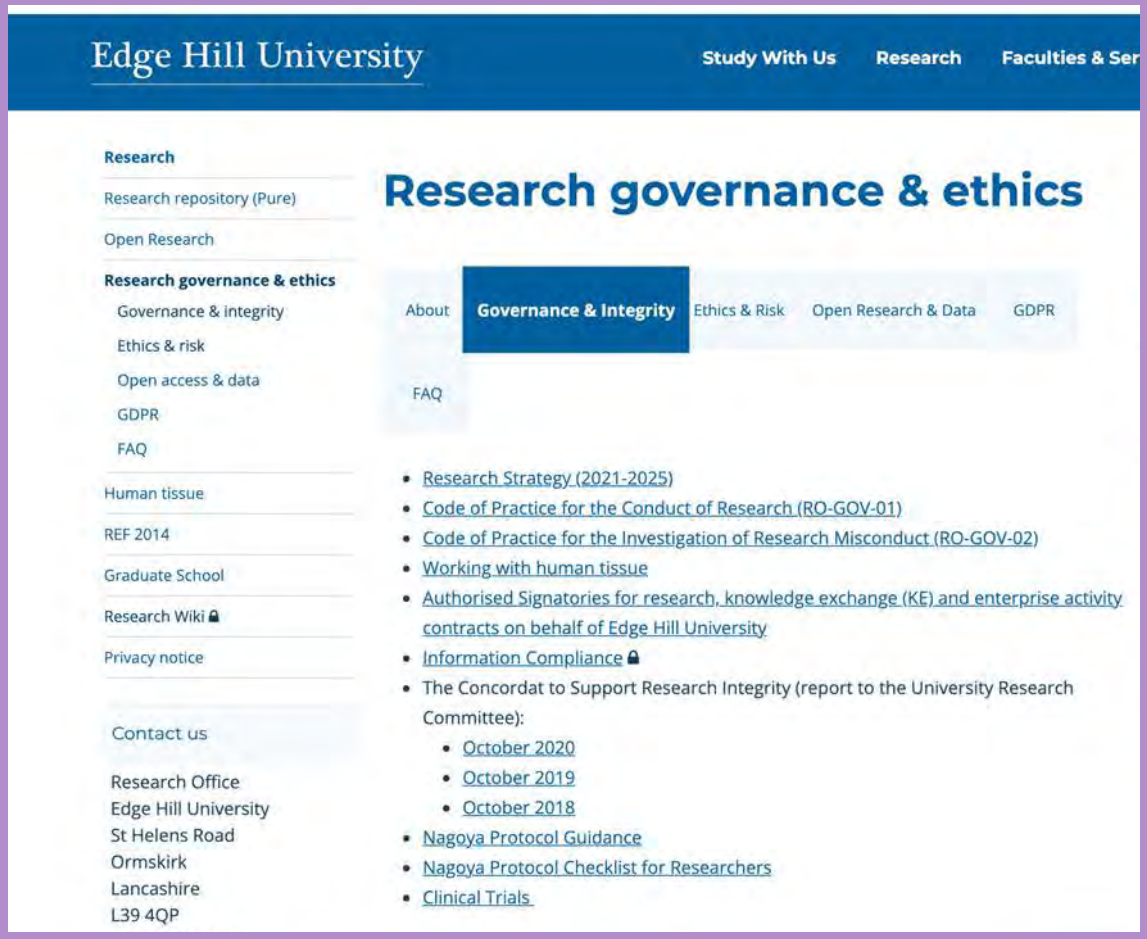
Research Governance & Ethics

- All PGR and staff research projects and evaluations need to be registered
- Each application will undergo ethical review:
  - Standard
  - Expedited (low risk)
  - Enhanced
- Review is undertaken by the relevant subject research ethics committee (SRECs)
  - Art and Humanities (AHREC)
  - Education (EREC)
  - Health-related (HREC)
  - Science (ScREC)
  - Social Science (SSREC)

Click image to open this web page



EHU Research Governance and Integrity



The University has a governance framework within which all members of Edge Hill community must act when engaging in research or knowledge exchange.

The University **Research Ethics Policy** (2020-2023) and the **Code of Practice for the Conduct of Research** are the principal documents for guiding researchers in ethical conduct.

Research Ethics Policy (2020-2023)

- EHU approach to promotion, monitoring and integrity of research
- SOP for RECs (SRECs)
- Applies to **anyone** conducting research **sponsored** by EHU
- **ALL** research must undergo ethical review (Haplo)
- **Key principles:**
  - Legal and professional concerns (Codes of prof conduct)
  - Responsibility and duty of all roles (Breaches and Misconduct)
    It is your responsibility to gain approval and consult where needed)
  - Benefit, integrity and quality – worthwhile, benefits outweigh any risks
  - Sensitivity and duty of care – to all involved, throughout and after the study
  - Independence of the research

Human Tissue Act 2004

Research involving sensitive material (Terrorism, dark web, distressing)

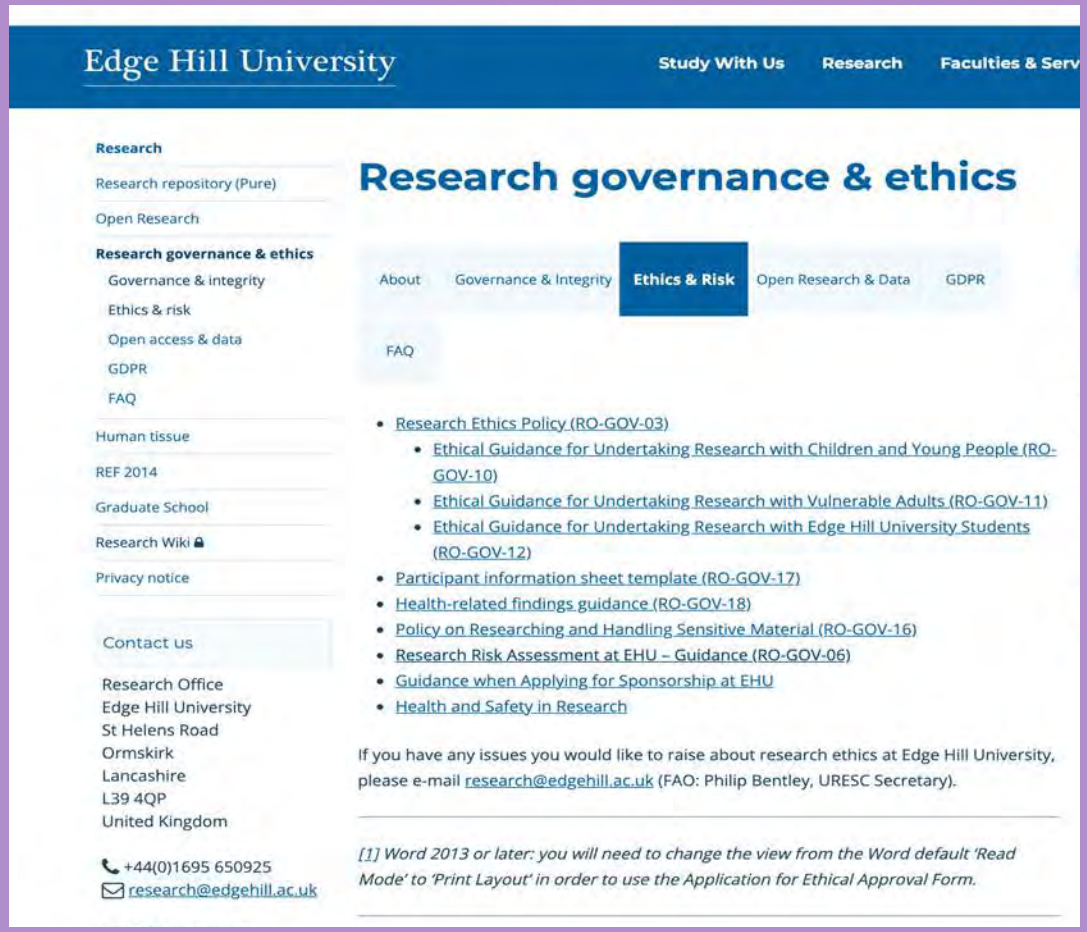
Genetic resources

Conduct of Research (2019)

- Framework - Guiding principles and standards of good practice
- **ALL** who conduct, supervise or support research
- **Key principles:**
  - Excellence
  - Honesty
  - Integrity
  - Co-operation
  - Accountability
  - Building capacity
  - Safety

Information on all stages of the research journey and different roles

EHU Specific Policies for Groups



Some groups require consideration of legal frameworks and additional ethical issues e.g. children, vulnerable adults, Edge Hill students.

Health-related findings decisions and process

ALL studies typically require a risk assessment (H&S) and sponsorship

To summarise.....

- Ethical considerations should be at the heart of every research study.
- All proposals should addresses ethical issues and shows consideration of any approvals needed. Proposals should **not** be full registration viva documents and/or reports.
- Ethical review and research governance processes are rigorous both internally at EHU and externally.
- If in doubt about what permissions are needed for the study in your proposal assignment please talk to your supervisor or SREC Chair

How it actually works in practice…….

1. Determine what approvals are needed for your study
    - *EHU only*
    - *EHU and external organisation e.g. Health Research Authority (HRA)/ NHS REC*

2. EHU approval for research – Subject-specific Research Ethics Committee (SREC)

3. NHS studies – who is involved?
    - NHS staff – HRA approval, no NHS REC approval required
    - Patients/carers – HRA and NHS REC

- If EHU acts as the sponsor, SREC approval is mandatory before NHS application
- If your study involves clinical tests or potential for risk to patients/staff, speak to the Research Office to confirm EHU insurance/indemnity will cover it **before** applying to SREC
- Is it research? (HRA decision tool)

HREC – Is it right for your study?

All studies seeking NHS/HRA approval

All studies involving the Human Tissue Act (ScREC or HREC)

Health-related findings

Health or social care related

Committee members: medical school, psychology, perioperative studies, biology, sport and exercise science, nurse education, applied health and social care, paramedic and pre-hospital care

Reps from other SREC, PGR rep.

Special advisors

What is the role of HREC?

Research Governance & Ethics

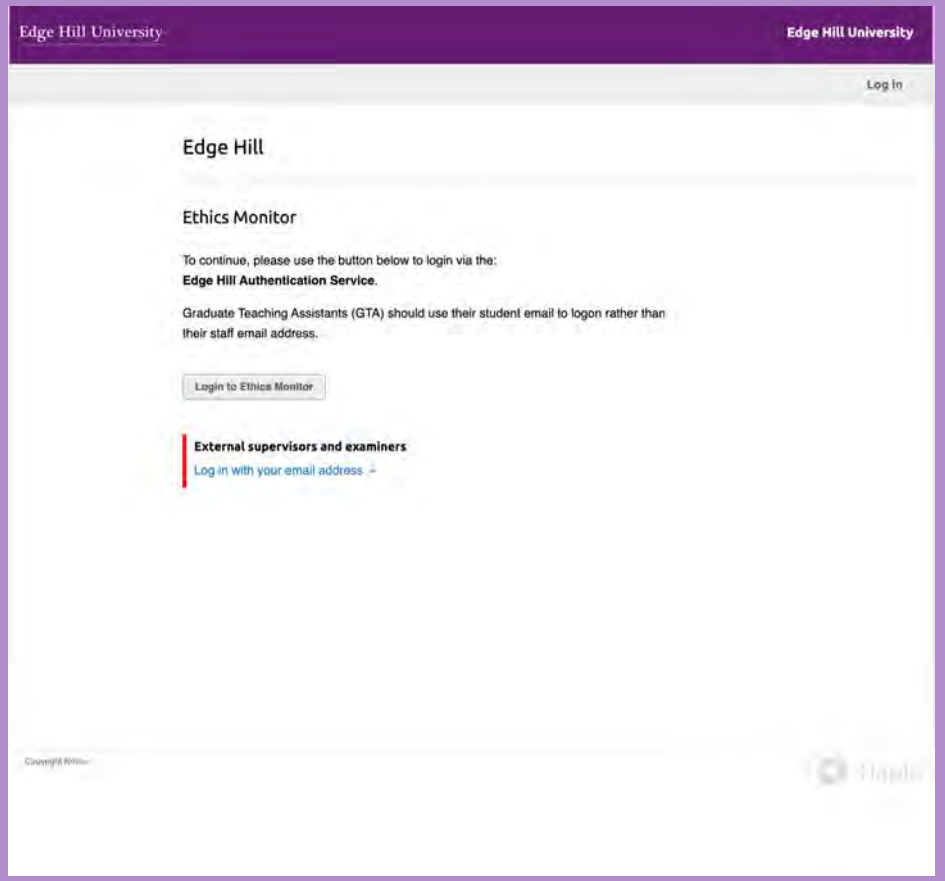
- **Terms of Reference** – remit, membership, process, principles
- **Ethical scrutiny** – autonomy, beneficence, non-maleficence, informed consent, veracity (trust), confidentiality/ anonymity, justice (equity)
- *Governance checks* – Appropriate risk assessment and HoD support (Compliance with regulations/ policies/ standards, risk assessment, reputation, professional registration).
- *Sponsorship* – organisation with responsibility for study conduct and reporting, insurance/ indemnity

Haplo Ethics Monitor

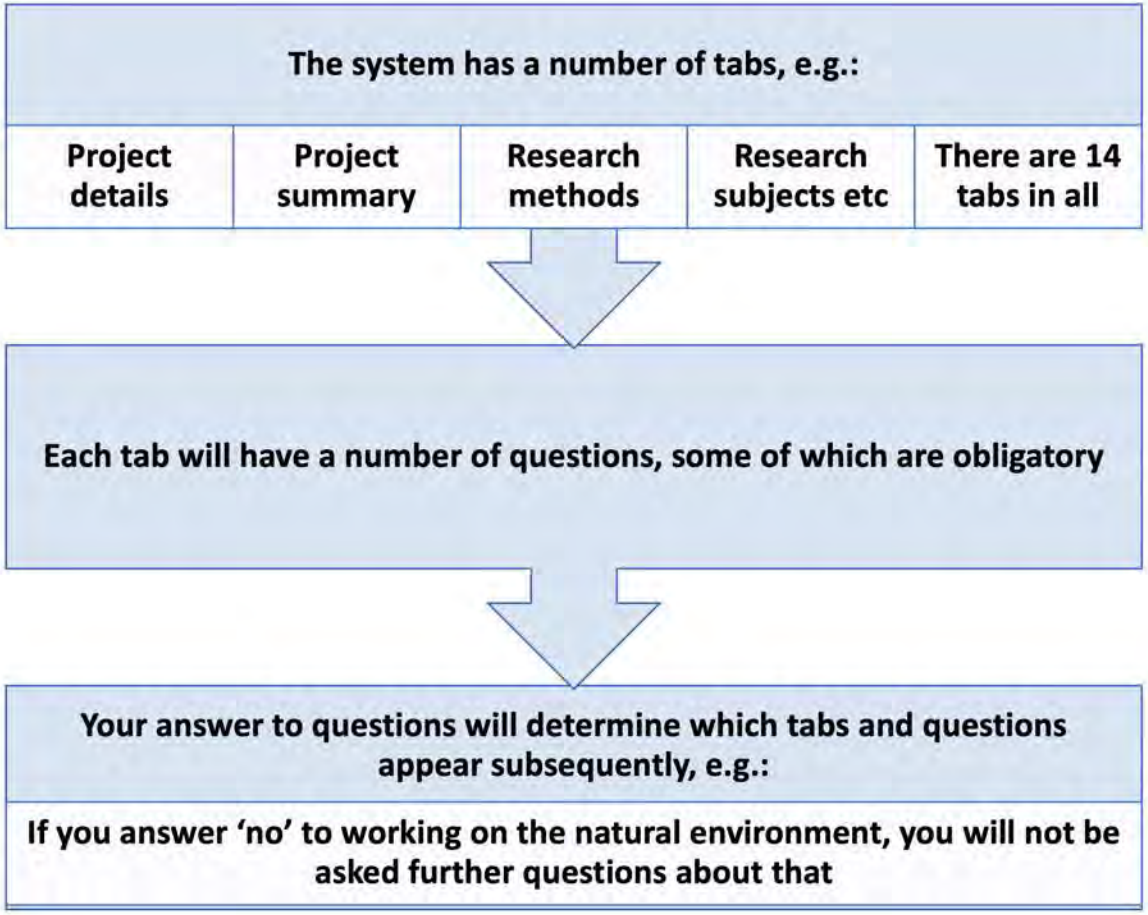
Taken from the Greek word ‘haplóos’ meaning ‘***simple***’ or ‘***single***’.

Logging in

- Haplo is accessed via your EHU username and password
- You can login wherever you see the Haplo icon (on the ethics wiki pages and the research governance webpages)
- You can access Haplo remotely as you can Pure and other University software systems



Navigating the system



Navigation cont.

The questions you are asked reflect the old Word form that researchers were required to complete previously

Alongside questions related directly to ethics, there are also questions concerning risk: e.g. are you working with human tissue; are your participants vulnerable adults

Answers to these questions will help the SREC chair to determine which sort of review is required: expedited, standard or enhanced

While you will have a default SREC based on your department affiliation, it is the project that determines the appropriate SREC

Key considerations

- It is important that you answer fully all questions to allow the reviewers to make an informed decision
- There are information buttons to advise you about appropriate responses
- You must have all your documentation ready to attach (e.g. PIS) – you will not be able to submit your application if the documentation not attached

Deadlines

- All SRECs will have the same application deadline: 23:59 on the first of each month
- Your HOD must have endorsed it by this date: please ensure that you submit in good time so this does not delay the submission
- We aim to review the application within 4-8 weeks – that depends on the availability of the reviewers
- You will always be able to see where your application is in the review process by logging in

Haplo launch October 2020

Finessing/tweaks have been ongoing

Feedback from applicants and committees has improved it

Keep sharing your feedback to improve the system

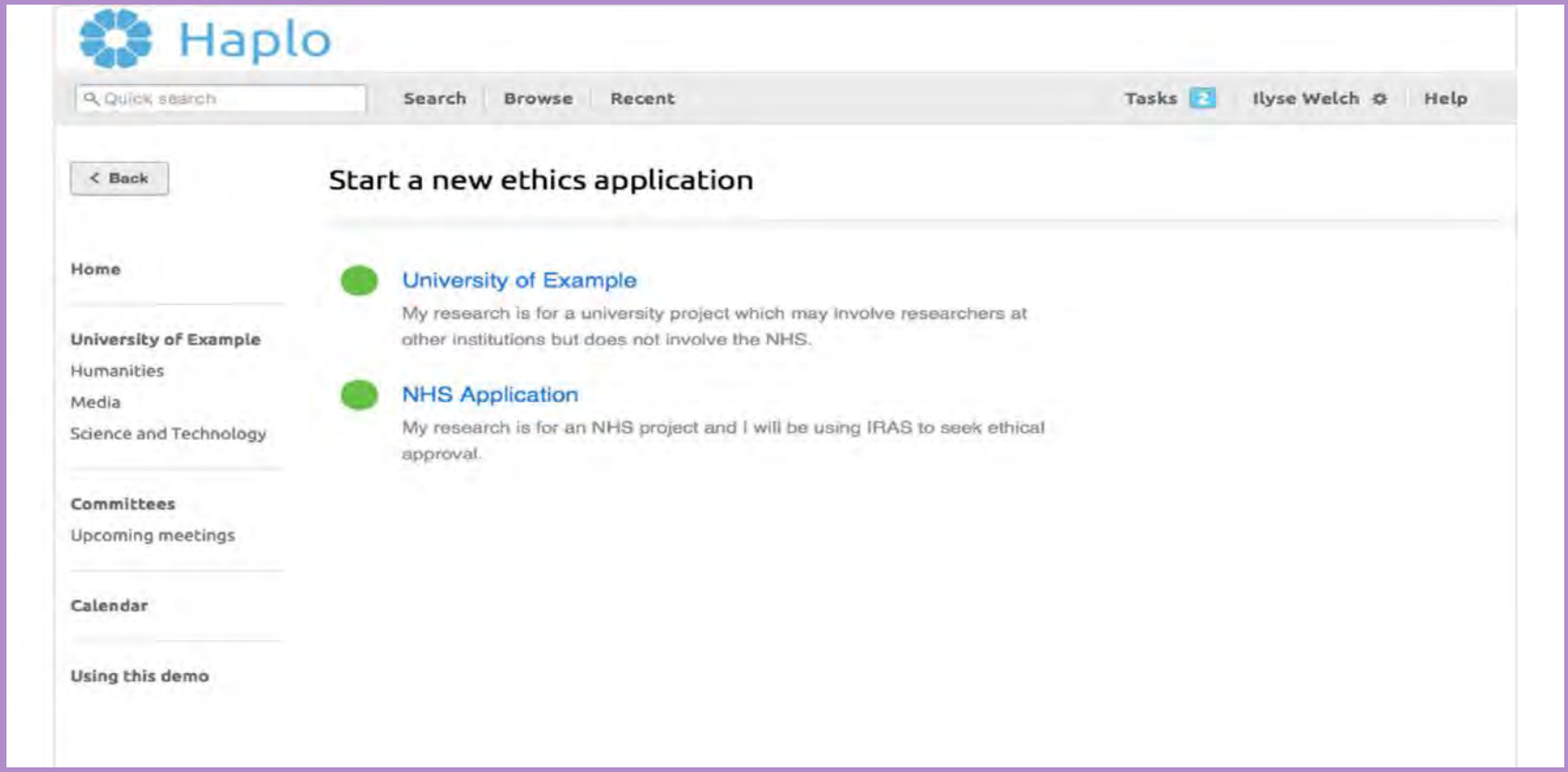
For further information

- FAQs are available on the wiki
- The chairs and the secretaries can offer advice about submitting an application and broader questions about ethics
- The Research Office can also provide advice about the system and risk assessments
- The University research governance webpages have the relevant policies and guidance documents including the Research Ethics Policy and its Standard Operating Procedures (SOPs)

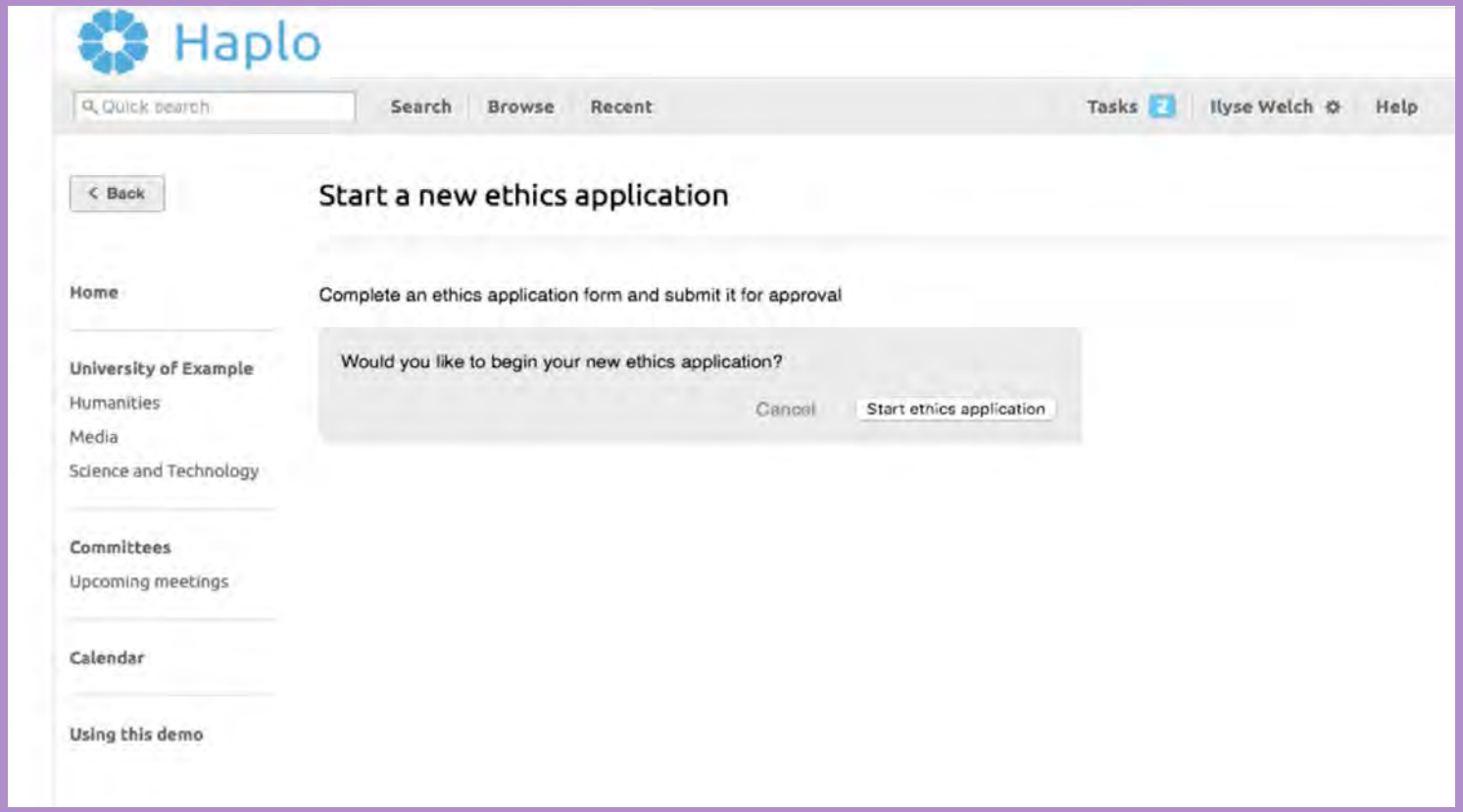
Applications

Ethics Monitor

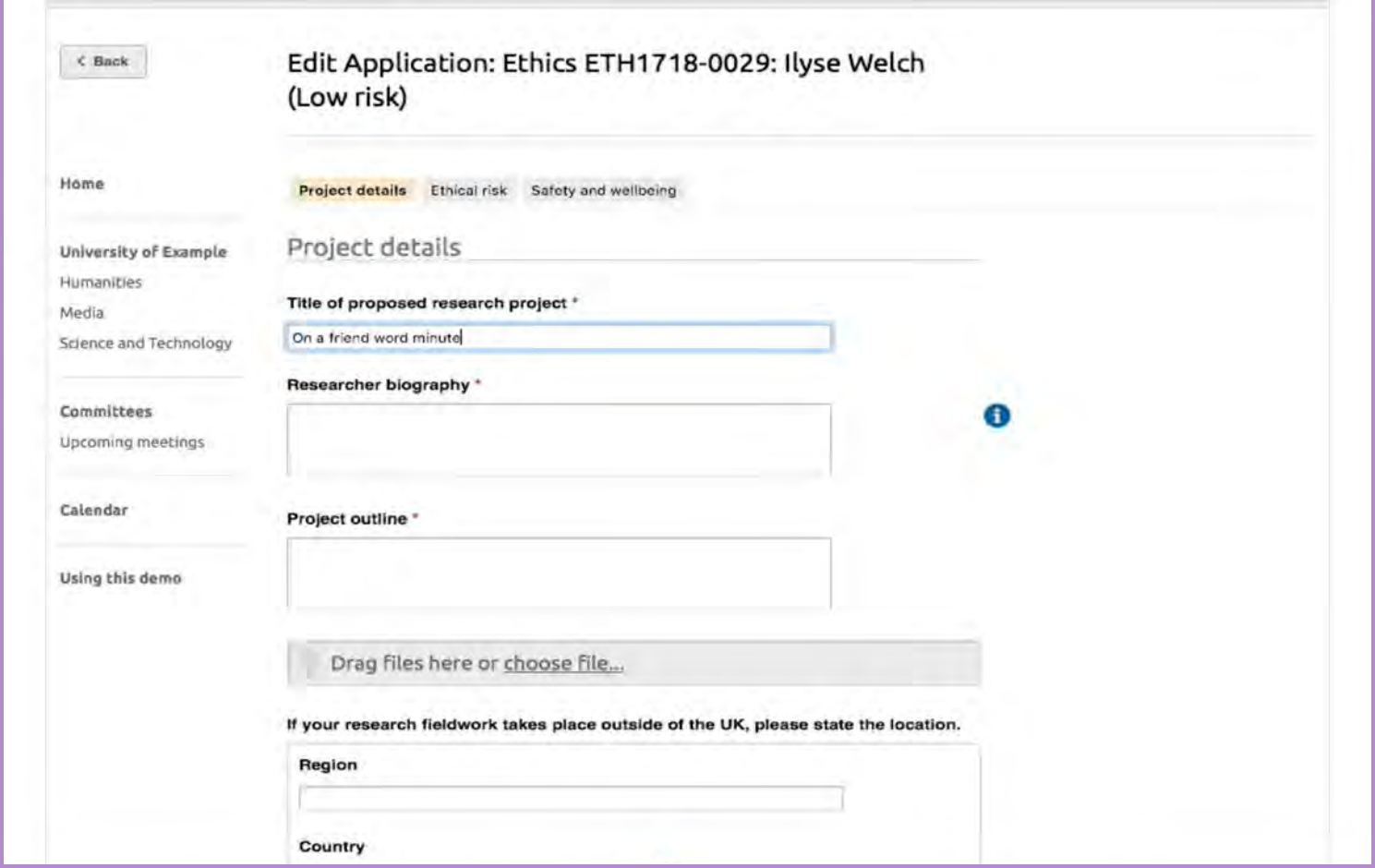
Submit your application for approval via Haplo



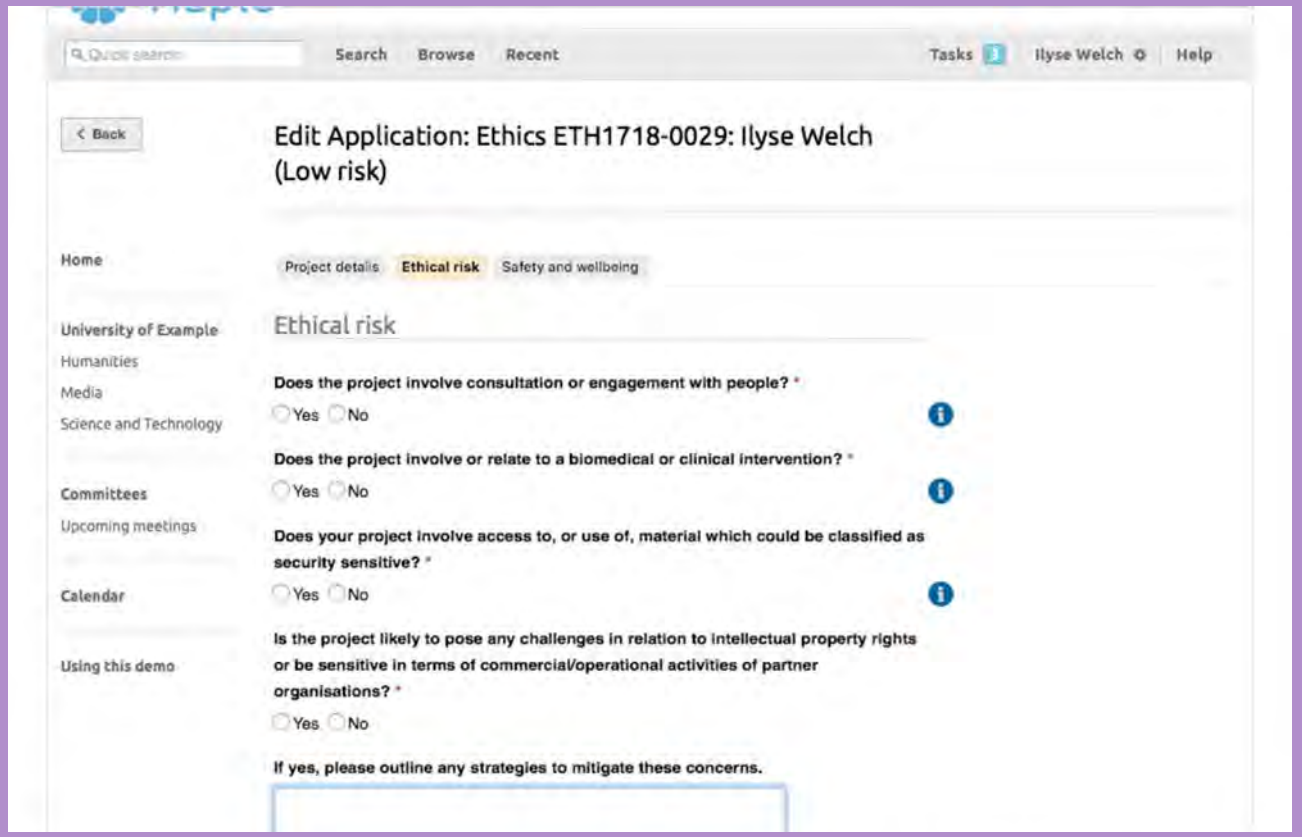
Guidance notes from the university and a blank form can be reviewed before beginning an application



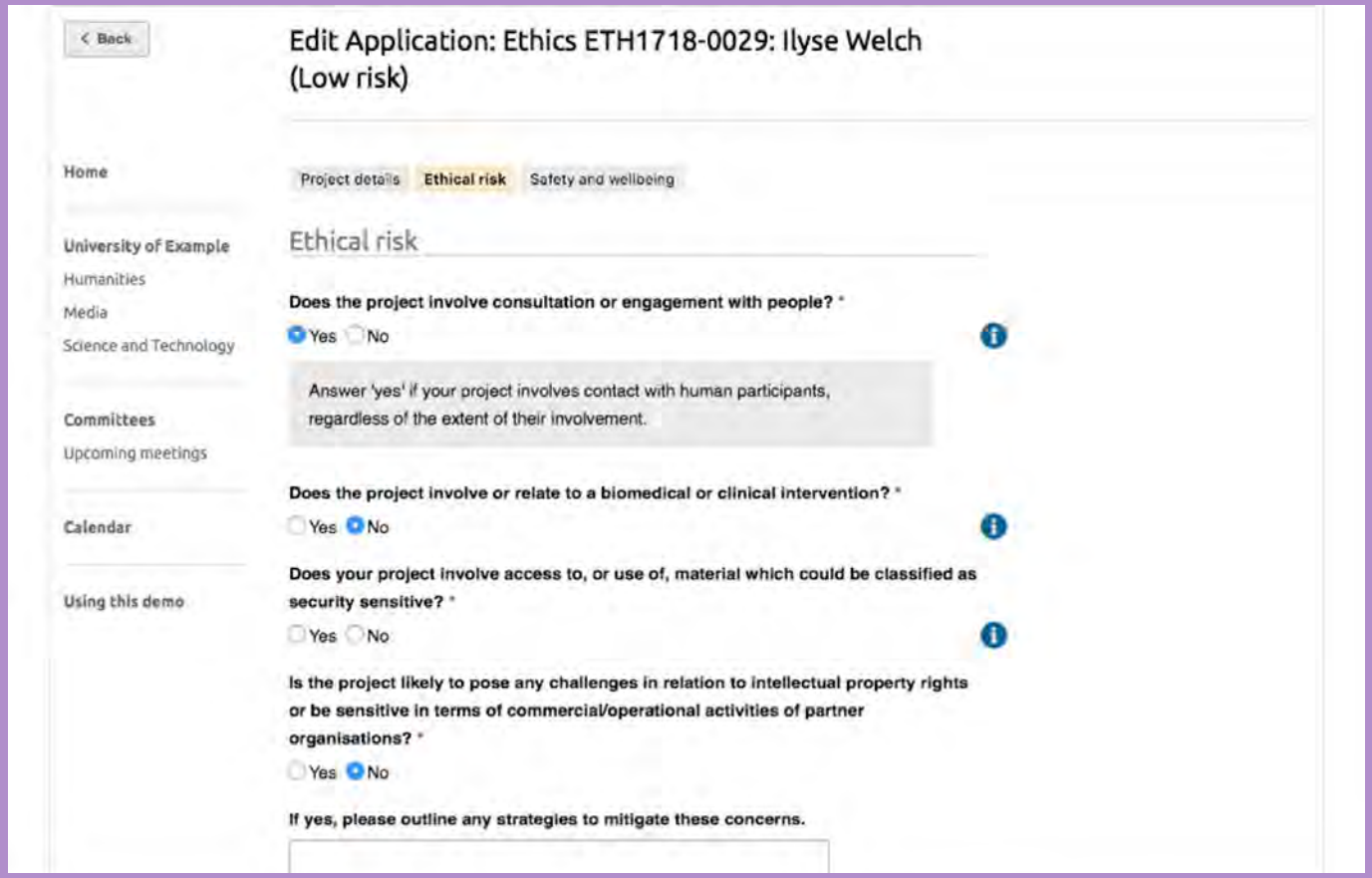
Complete the project details tab



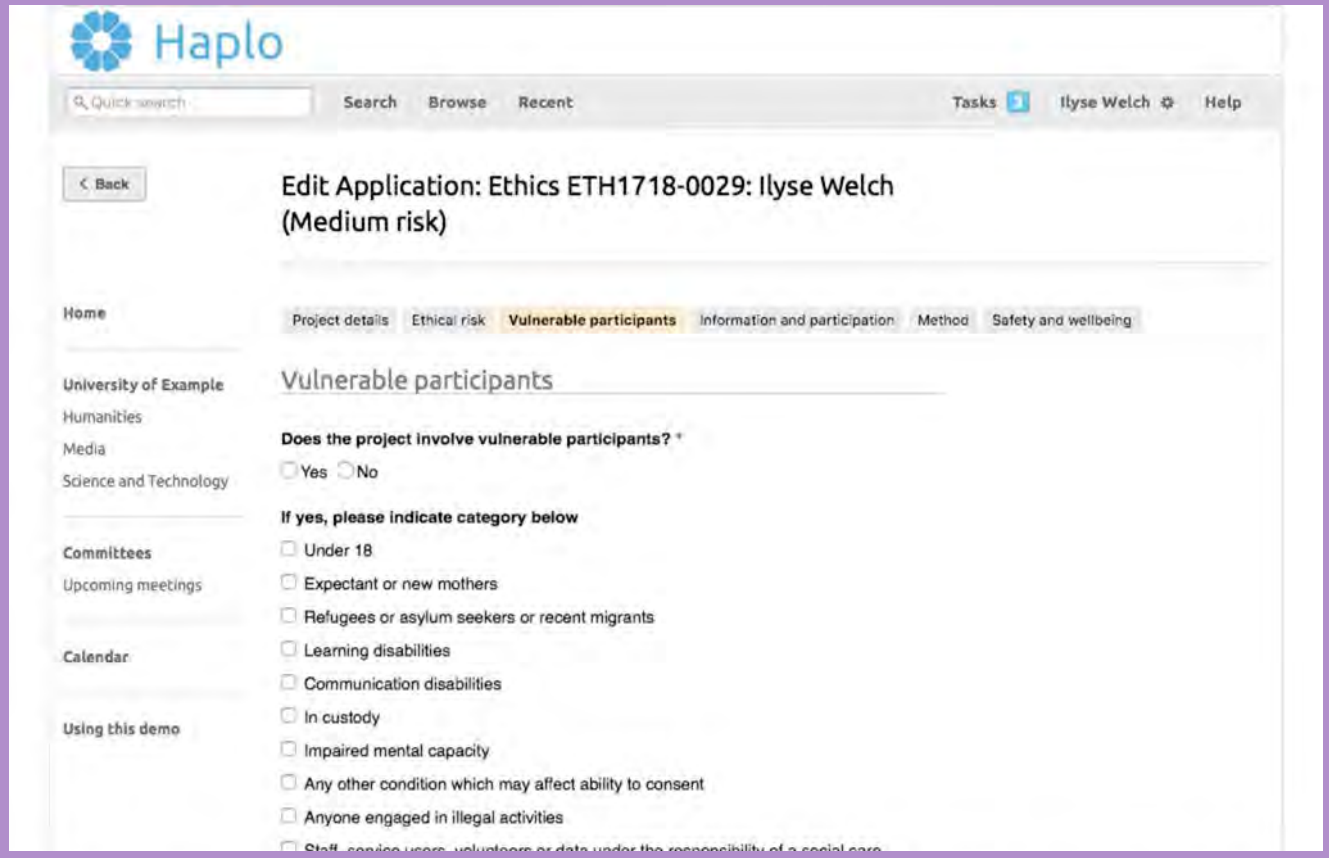
Filter questions are answered to determine risk and sections to be completed



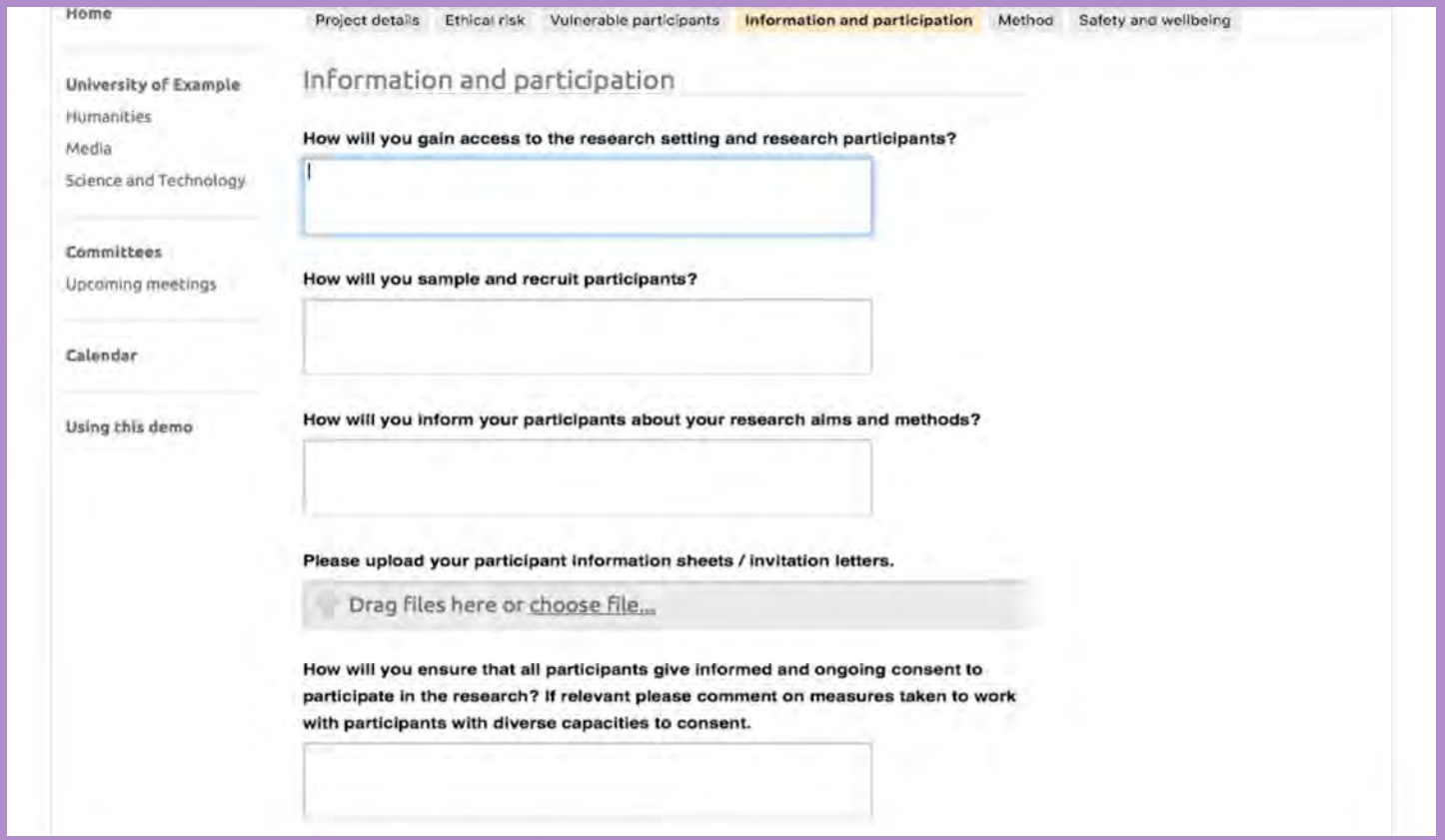
You can view guidance notes for questions



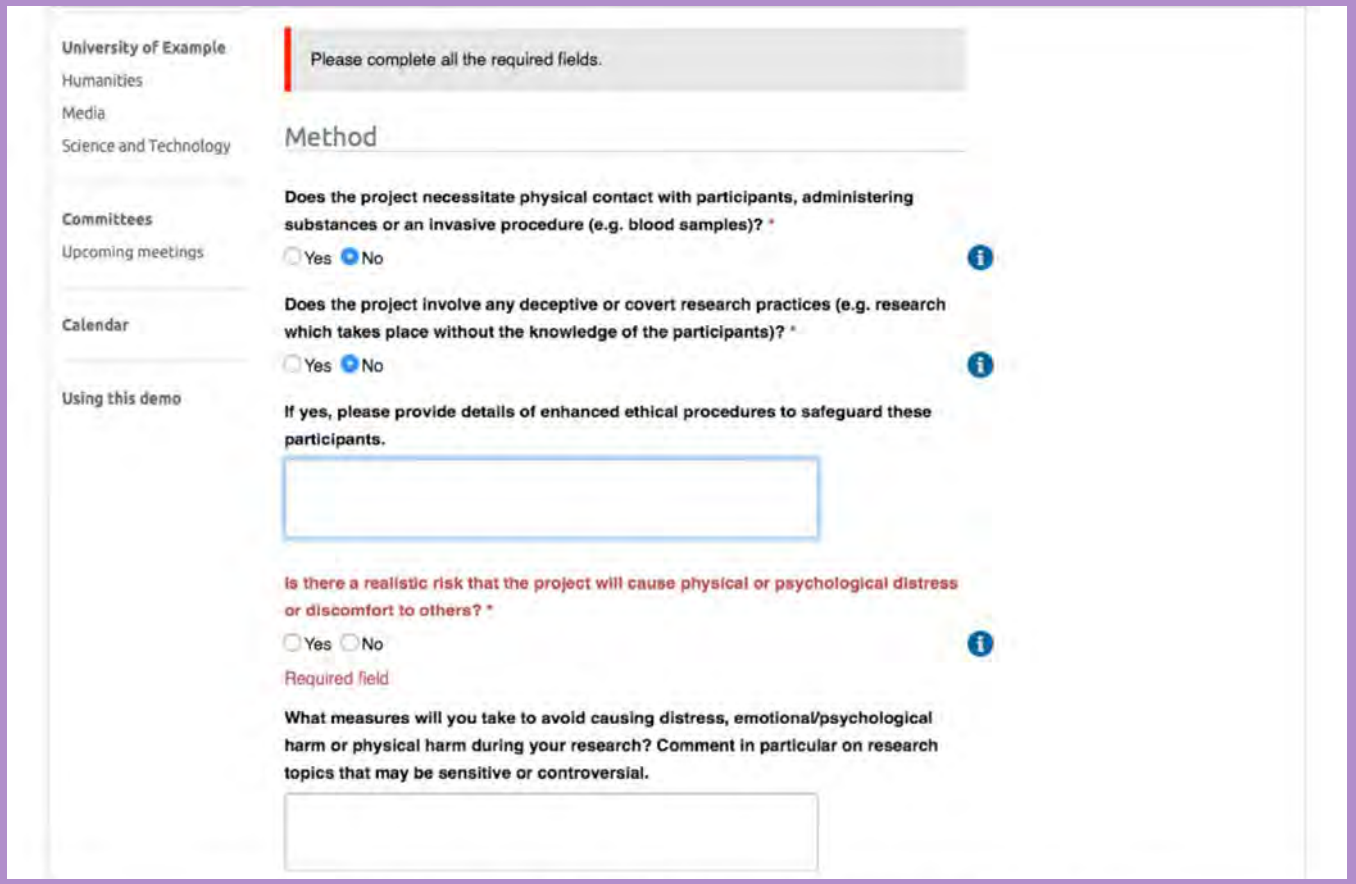
Based on answers new tabs may appear and the risk level can change



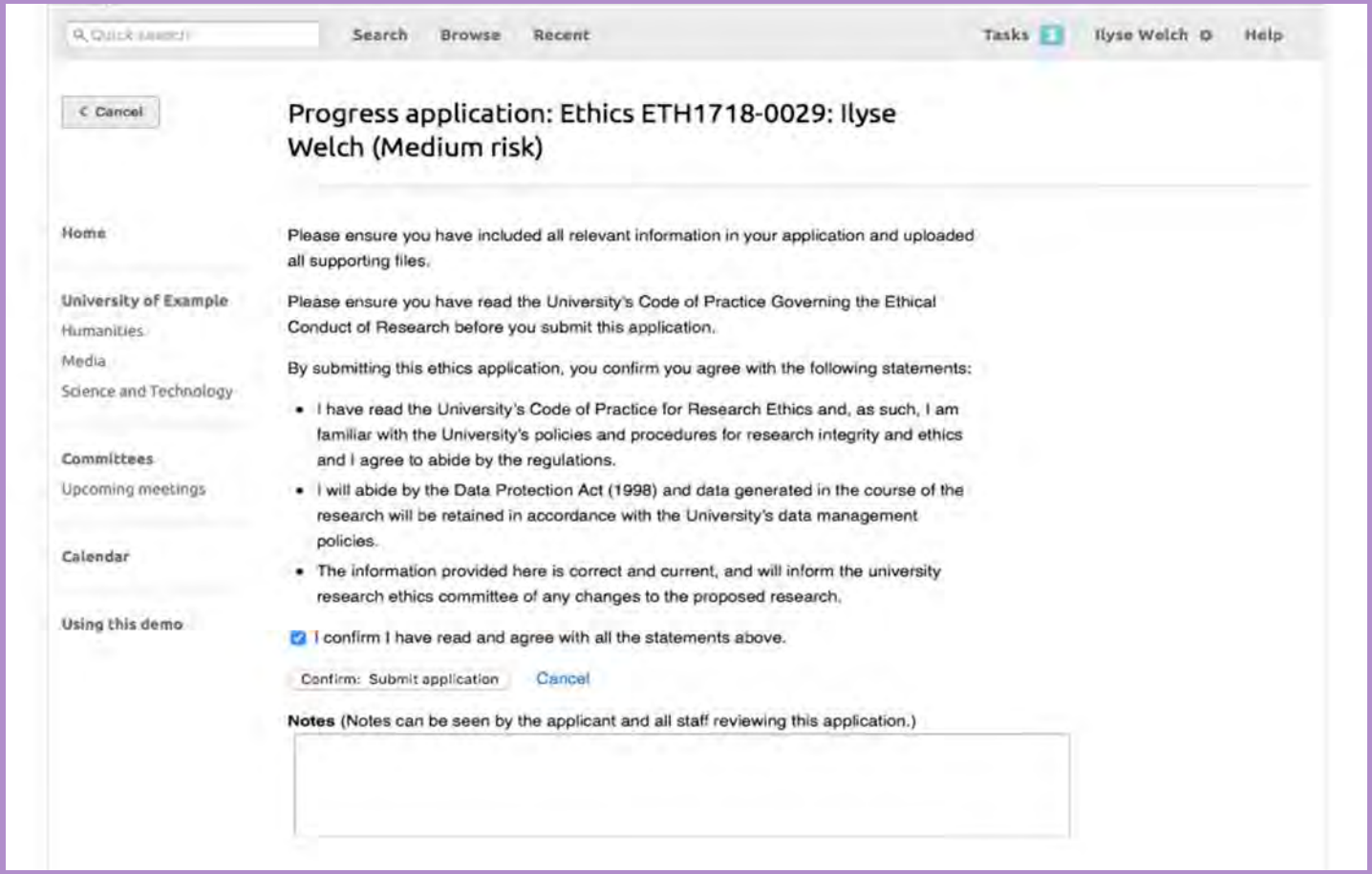
Supporting documentation is uploaded at the end e.g. proposal, PIS, consent forms (*Refer to HREC examples)*



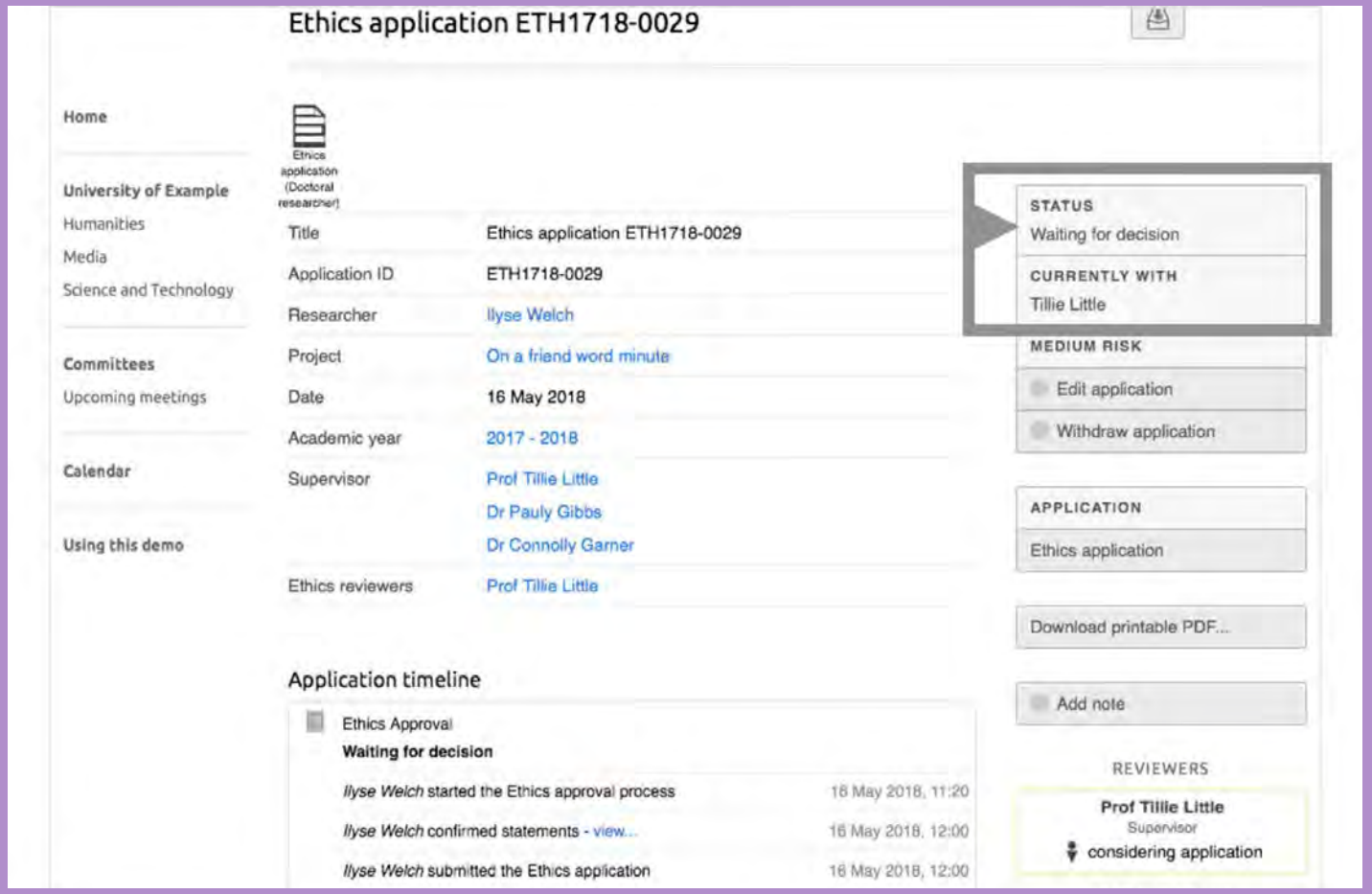
Required fields must be completed



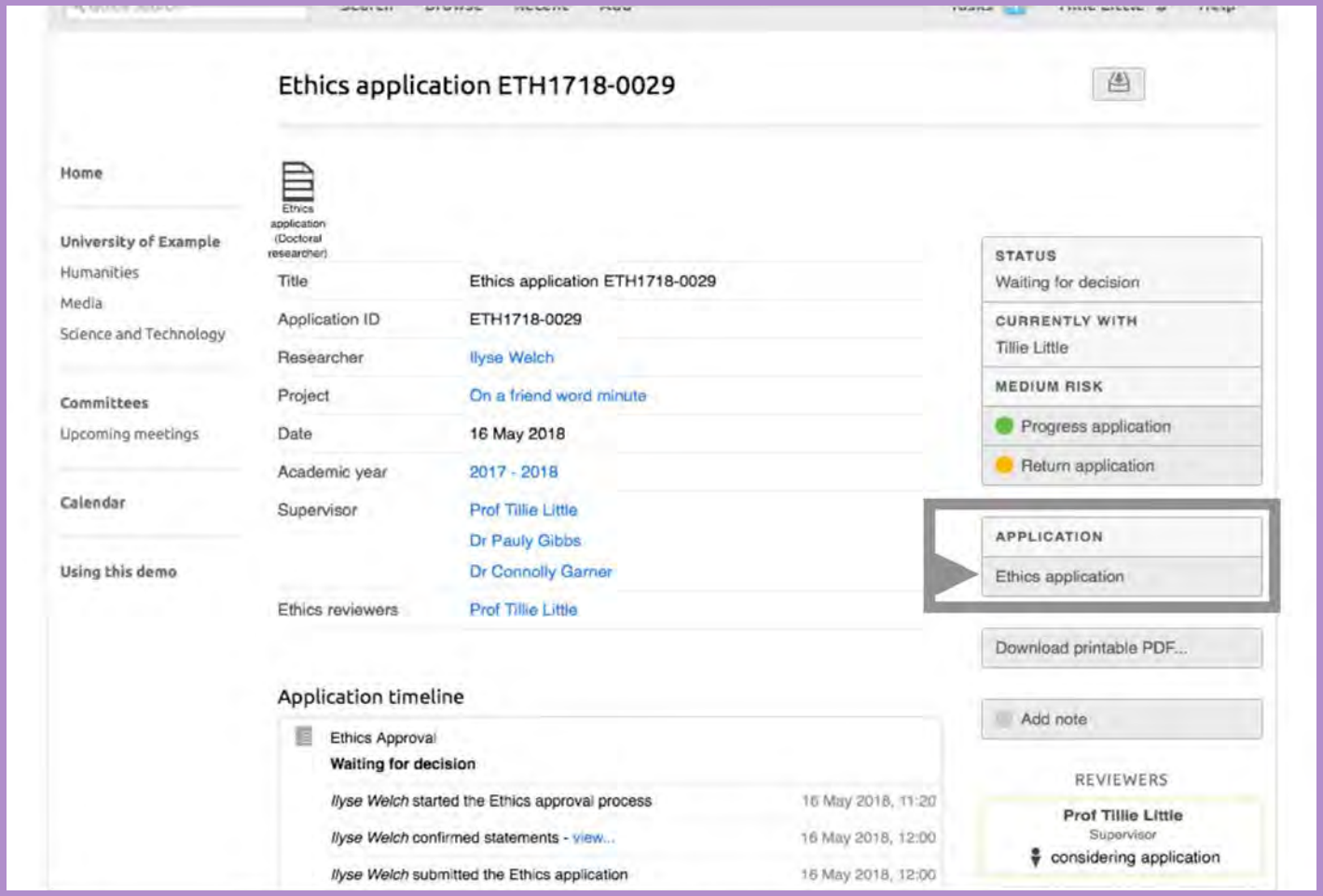
You will be asked to confirm statements



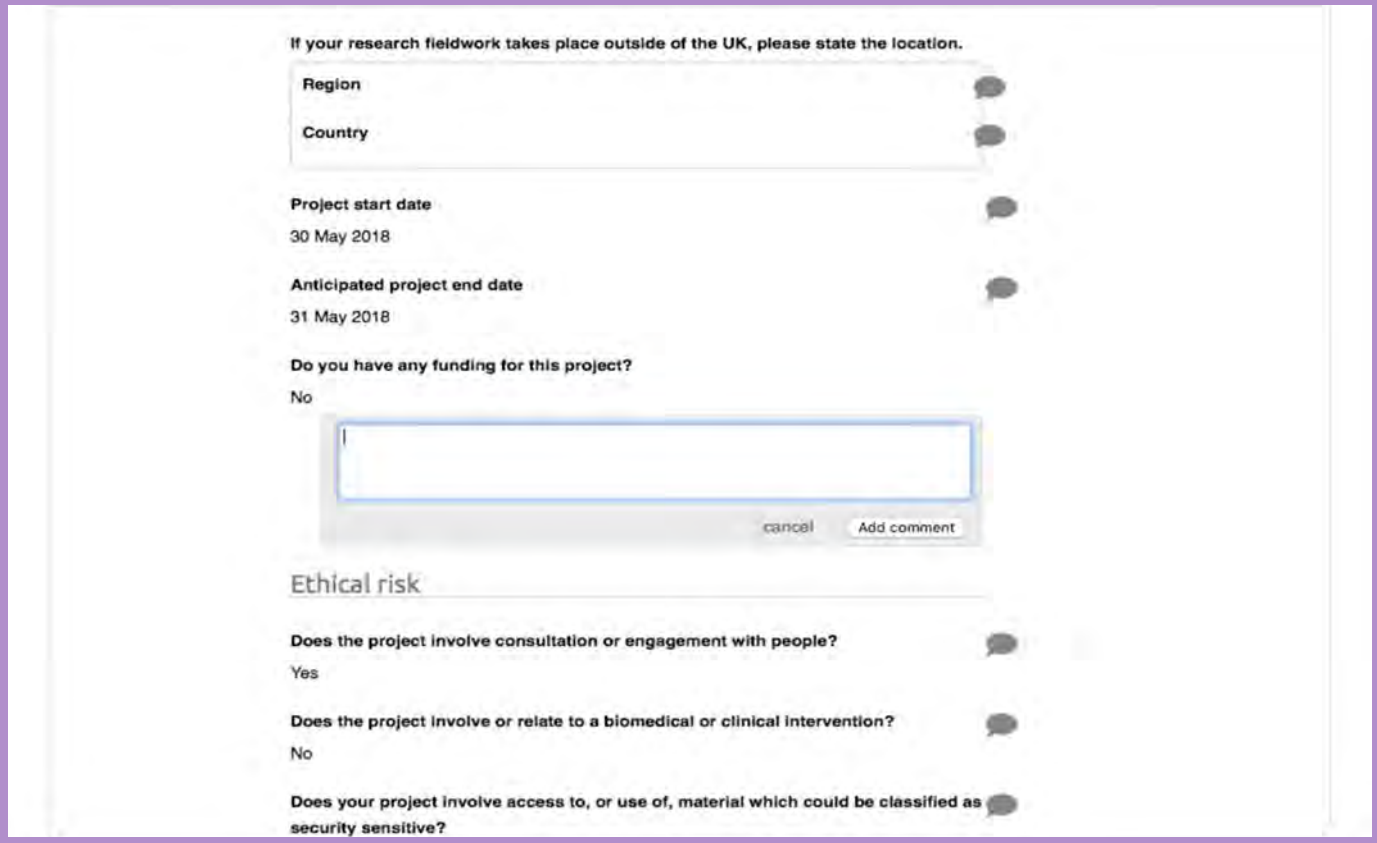
Once submitted for supervisor/ HoD review, you can track the status



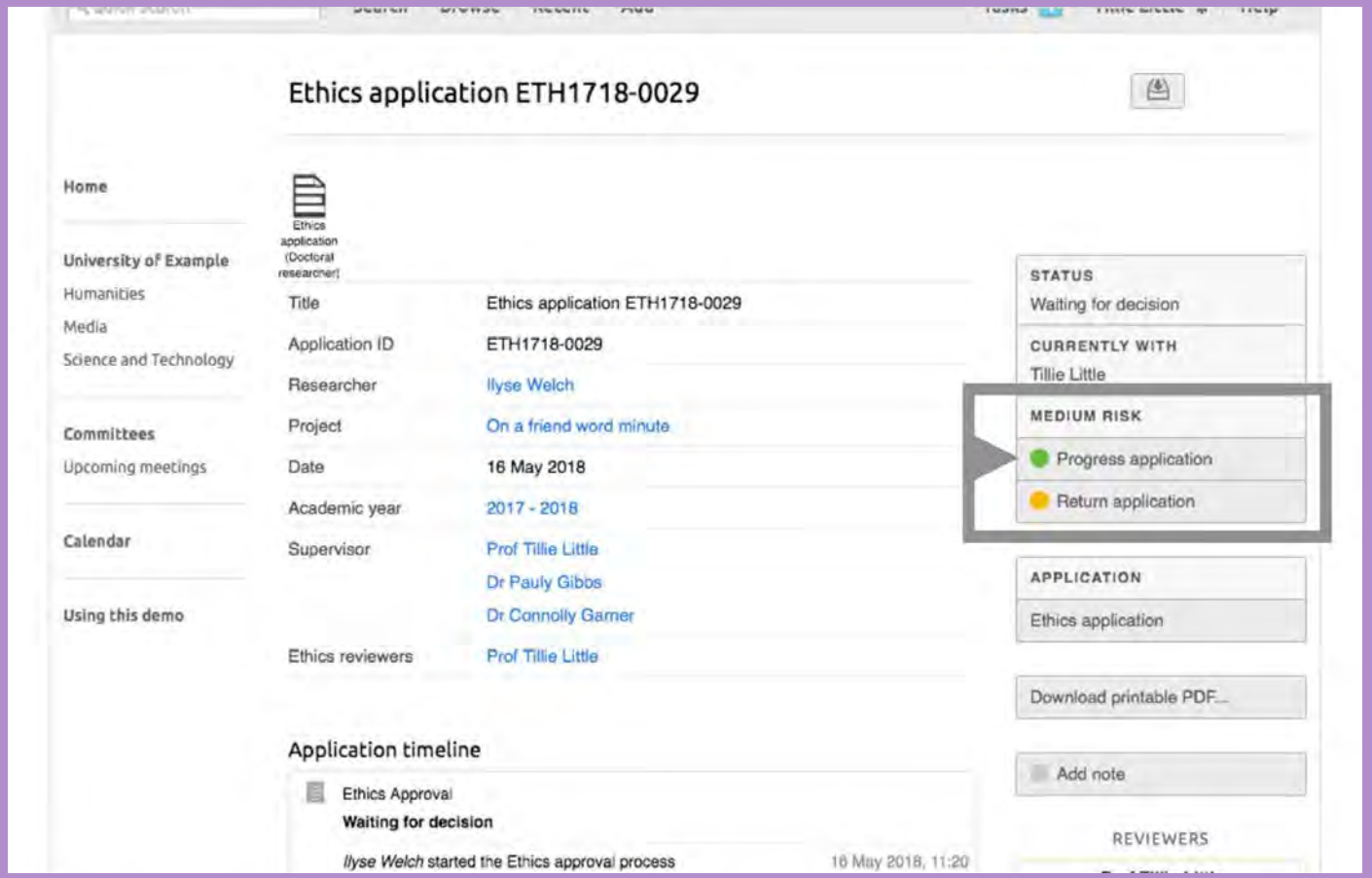
Supervisor/team/HoD can review the application



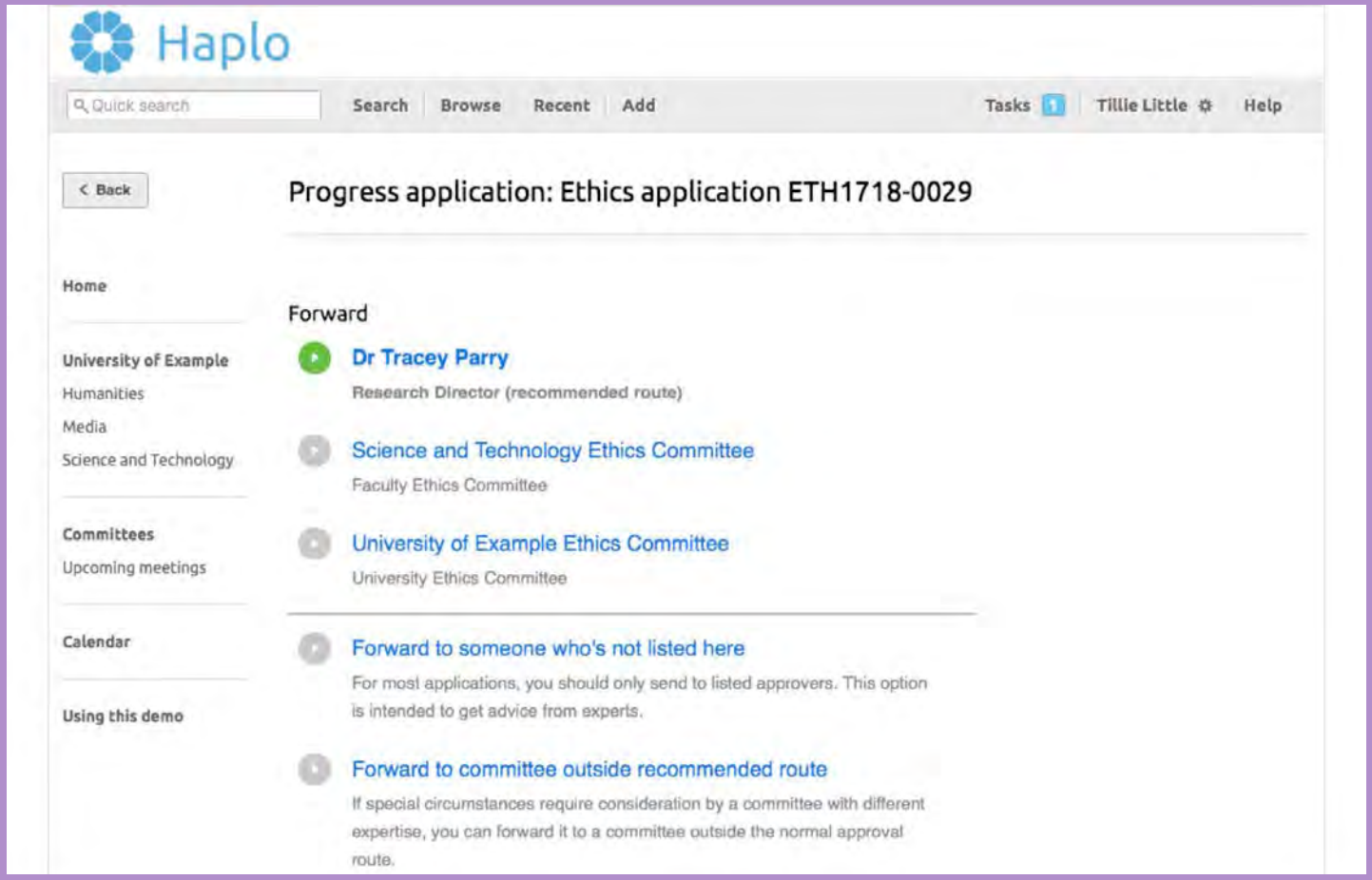
Comments can be made on any line of the application



Once reviewed by supervisor/HoD the application can progress to HREC or be returned



Application can now be progressed to the SREC

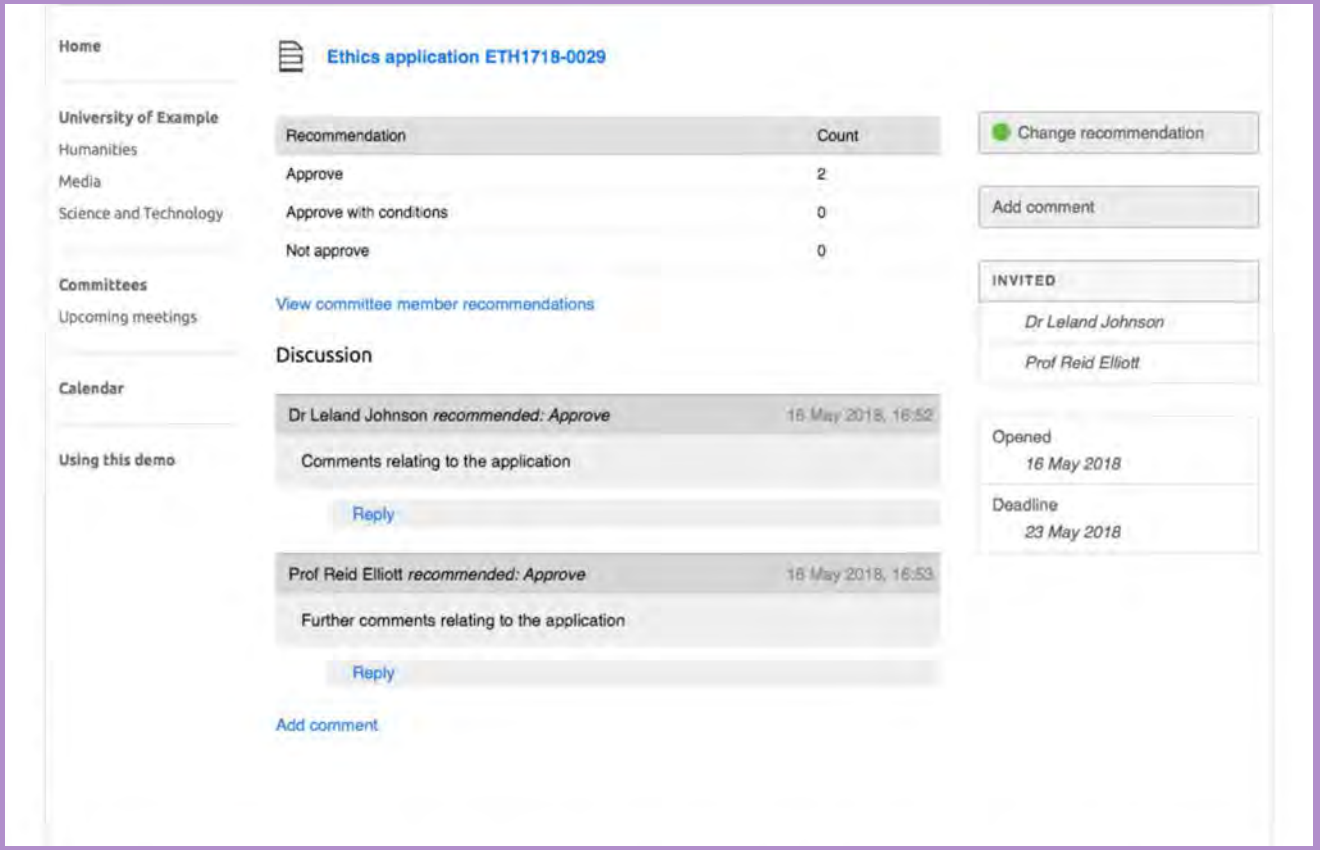


Ensure your HoD knows which committee you want it to go to if it is not HREC as this is likely to be the default

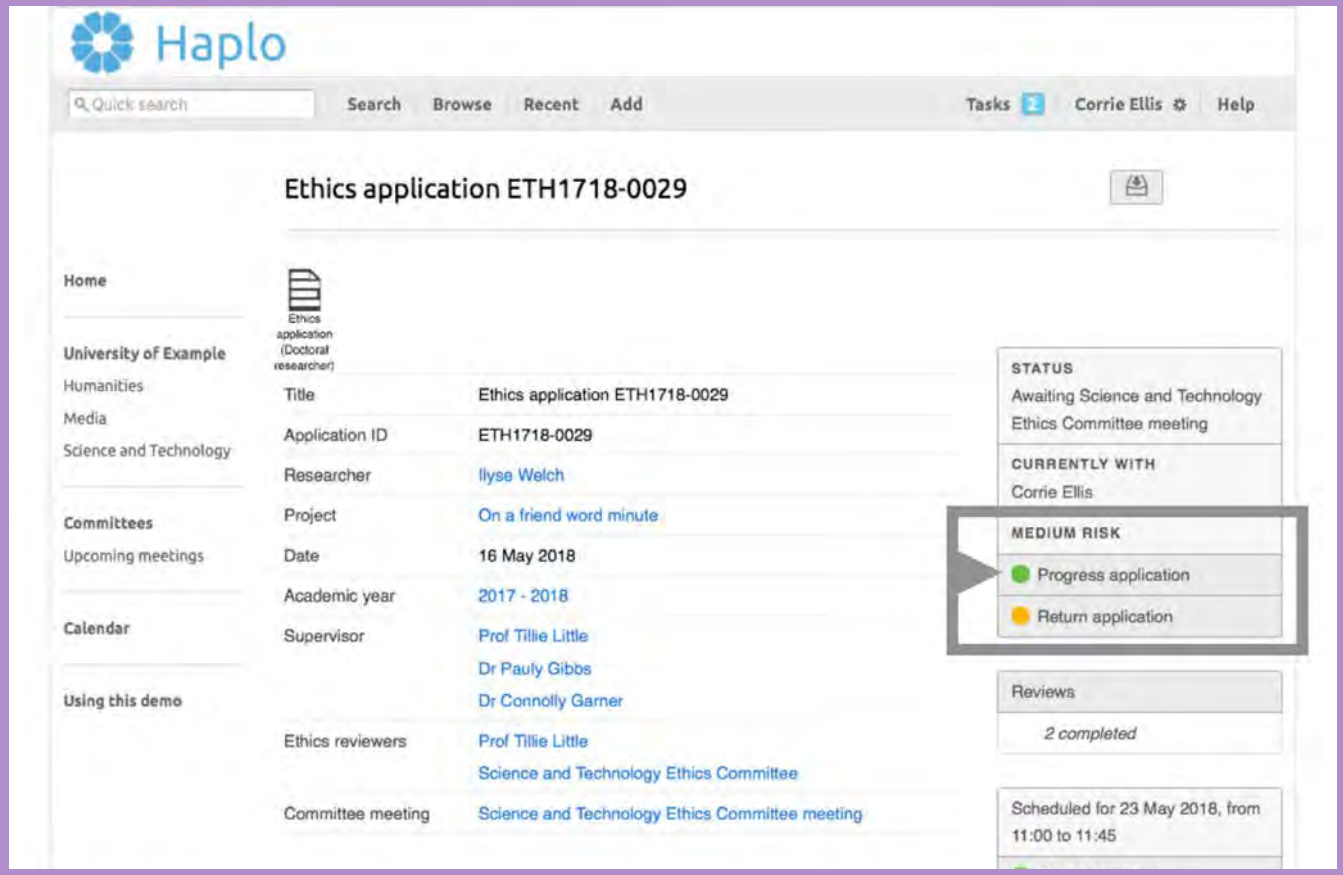
HREC timeline

- 1st-4th All applications received by midnight on 1st month are checked by Chair and Secretary and:
  - Assigned to two primary reviewers OR
  - Redirected to appropriate SREC OR
  - Returned to applicant if there is missing information
- 5th-16th Reviews submitted by PRs
- 17th-20/25th Online committee endorsement and decision
- By 28th-30th – response by Chair/Dep Chair with notification
- It can take 4-8 weeks depending on time of year and availability of reviewers
- **No committee in August**

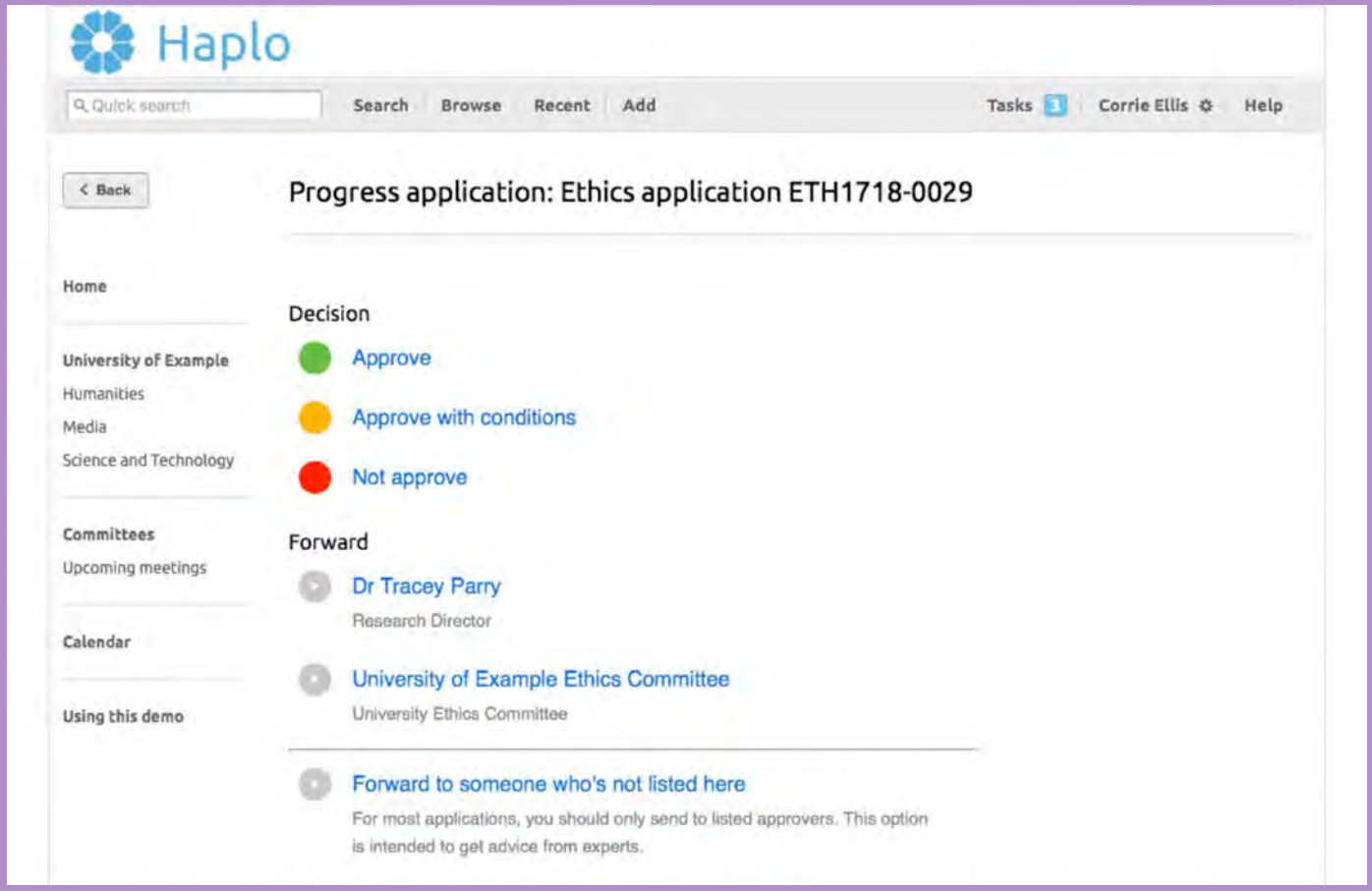
Online recommendations made with comments and discussion between the members. A meeting can be called if needed.



Application can be progressed or returned



Options


Haplo
Quick search
Search
Browse
Recent
Add
Tasks 3
Corrie Ellis
Help
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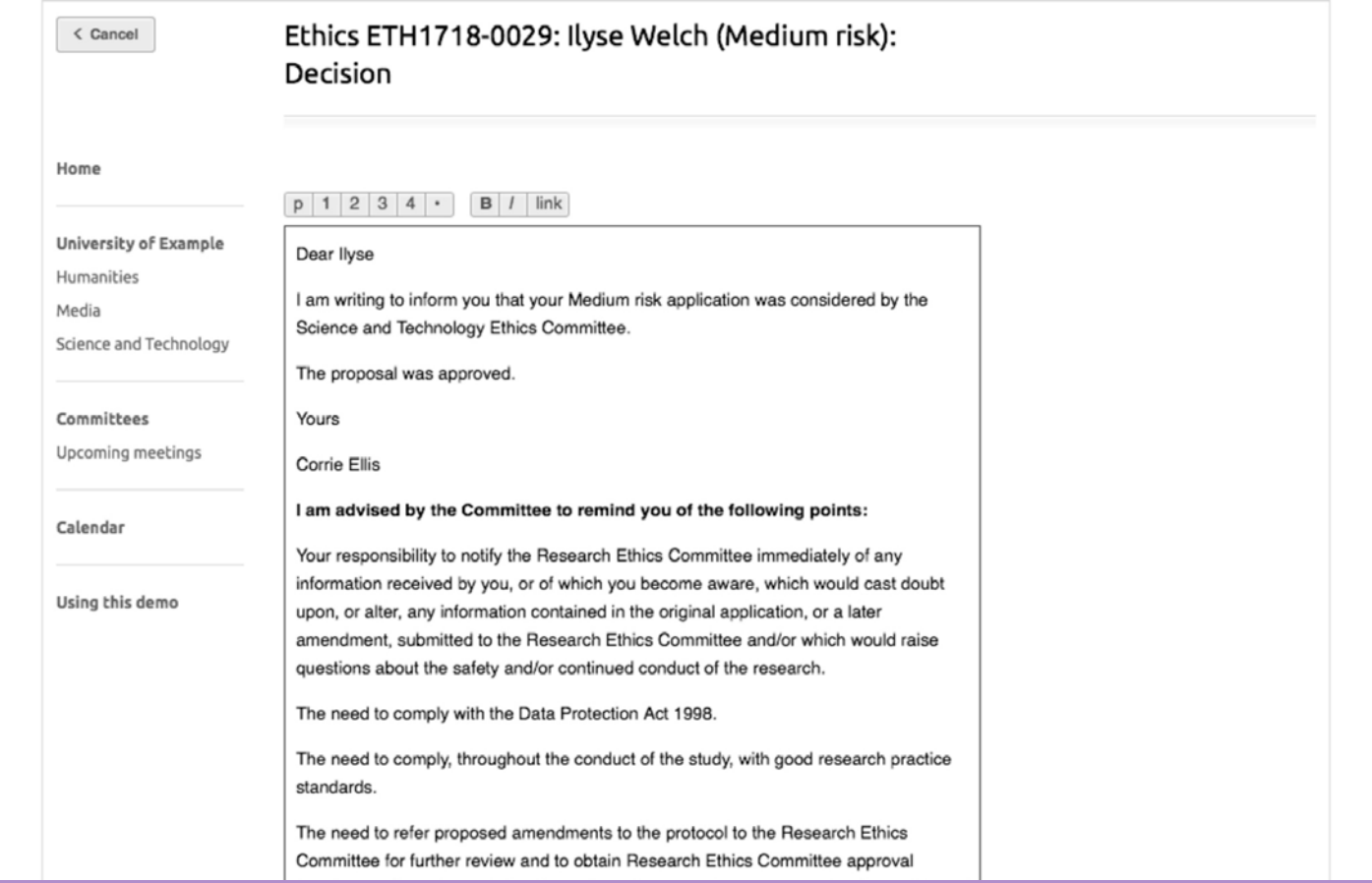
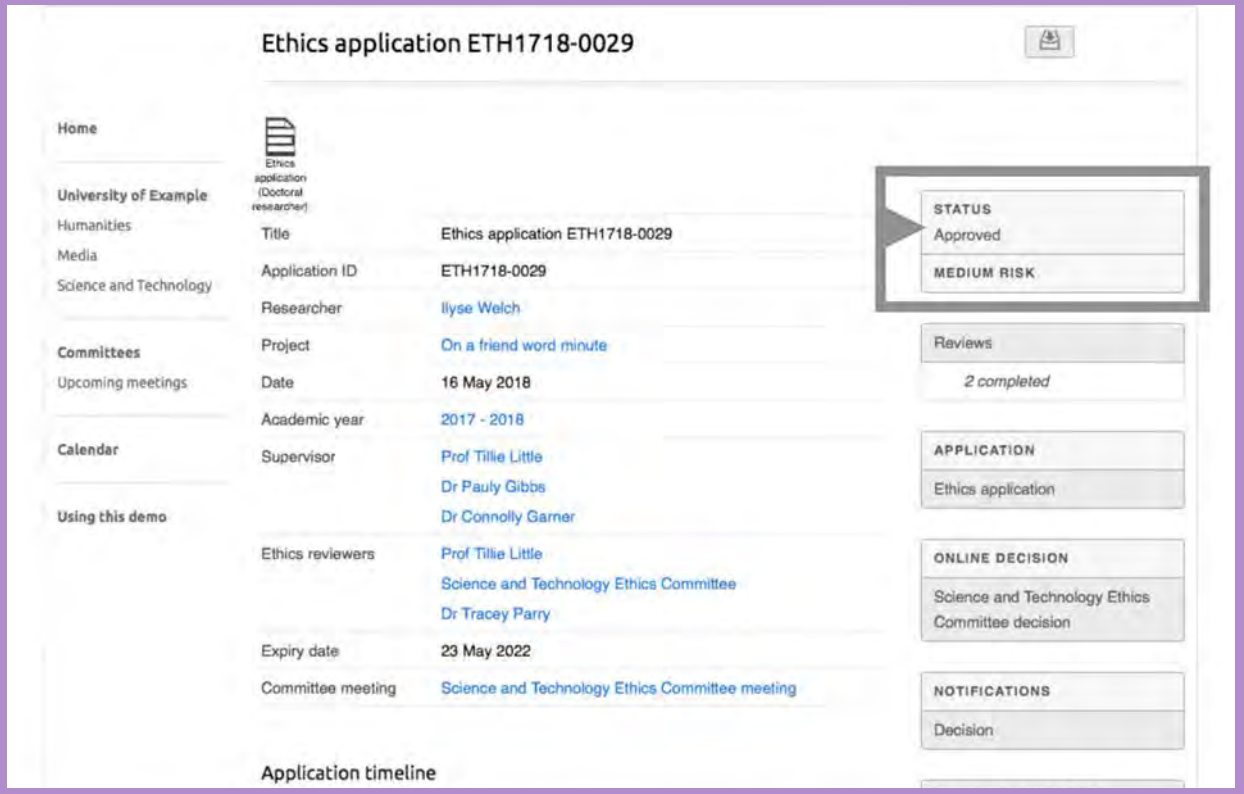
Progress application: Ethics application ETH1718-0029
Home
University of Example
Humanities
Media
Science and Technology
Committees
Upcoming meetings
Calendar
Using this demo
Decision
Approve
Approve with conditions
Not approve
Forward
Dr Tracey Parry
Research Director
University of Example Ethics Committee
University Ethics Committee
Forward to someone who's not listed here
For most applications, you should only send to listed approvers. This option is intended to get advice from experts.

Notification letter is generated



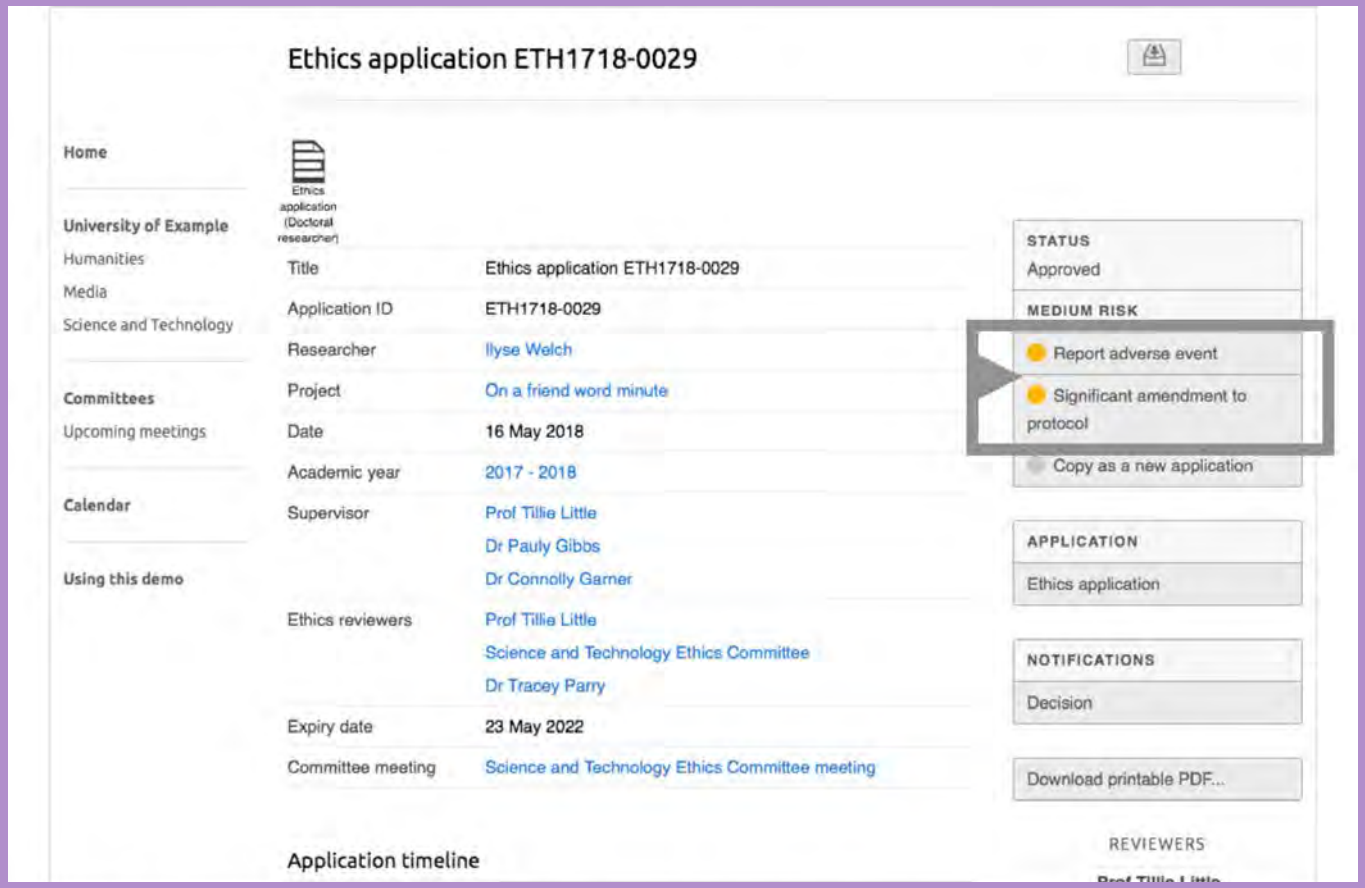
Once approved the final status will show or it will show as returned to applicant for amendments



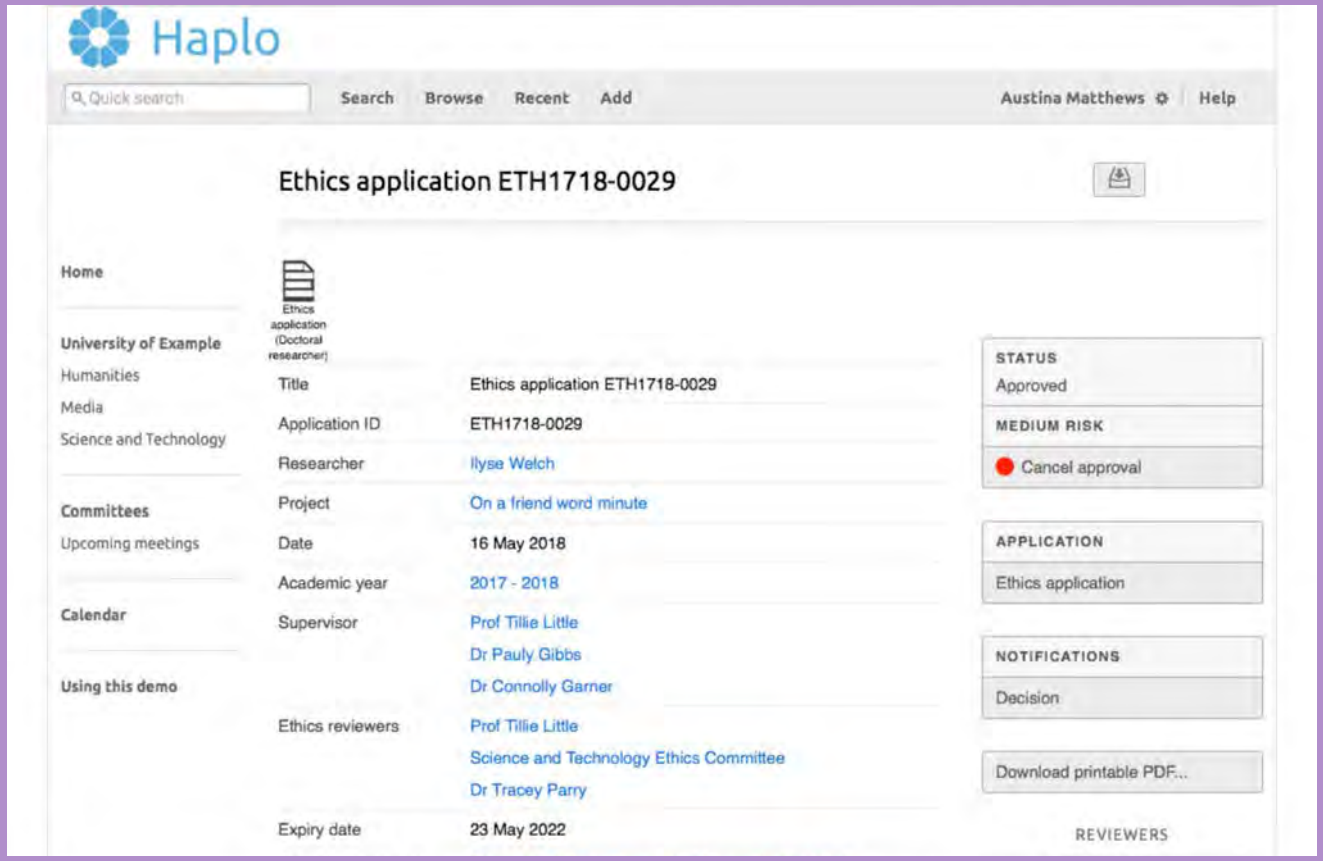
Adverse events and significant amendments

Ethics Monitor

Amendments can be made via Haplo



If there are adverse events or other factors, approval can be cancelled



Top issues in the last year

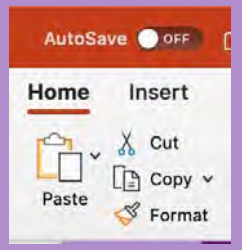
1. Start dates too soon to allow for review period – stalled system

   Default now is 2 months from submission
2. Ticking wrong boxes – Health-related findings (HRF), Participant cohorts
3. Not uploading the required documents
4. HoD not approving and submitting the application before 1st
5. Problems with notifications
6. Not removing previous versions of documents when submitting revised documents
7. Research proposals should be focused with emphasis on methods and ethical issues. **Do NOT** submit your full registration document and/or report.

Top tips to avoid ‘conditions’

1. Participant information sheet and consent forms
   - Omission of EHU required statements or information
   - Not clearly written
   - Too long or complicated – lay language

2. Missing information/documents or lack of clarity in responses



3. Not providing evidence of collaboration/gate keepers or DBS

Request the templates from the research support team FHSCM-ResearchOffice-Admin@edgehill.ac.uk

PPI or colleague review

Clarify any queries with Chair/Dep Chair before submitting

It may feel like the system or committee are……

but we're here to help you proceed from proposal to getting started in an ethical and EHU 'sponsored' way ☺

Please get in touch if you have any questions before you submit

FHSCM-ResearchOffice-Admin@edgehill.ac.uk