



Research Ethics Compliance Management Software

G-Cloud 14 Service Definition Document

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Introduction

At Infonetica, we empower the world's leading researchers with an ecosystem of software products that make their lives easier, so they can focus on delivering the groundbreaking research of tomorrow.

Infonetica's products support the end-to-end lifecycle of a research project including: research grant and funding applications (Pre-Award), research governance, research ethics review, data protection impact assessments, export controls management, research project due diligence, research contracts management, clinical trial management and compliance training for researchers.

Ethics RM is Infonetica's dedicated **Cloud-based Research Ethics Review Management Solution** used by research-intensive universities, research hospitals, national ethics committees, IRBs (Institutional Review Board) and government bodies to run efficient and effective Research Ethics review and ethical compliance management processes.

It currently supports over 450,000 live research projects for 60,000 monthly active users across the UK, Europe, Canada, USA, Africa, Australia and New Zealand.

Ethics RM enables its users to:

- Realise significant cost savings from improved efficiency and accuracy
- Save time for Research Managers, Reviewers and Administrators
- Eliminate paper and email correspondence regarding Ethics Compliance
- Reduce Ethics Review and Ethics Compliance process workflow complexities
- Improve data accuracy by reducing manual data entry and duplication
- Improve the flow of information between key research stakeholders
- Reduce missed deadlines
- Have easy access to all documentation and updates
- Easily generate reports and track performance

Update ethics management and review workflow and forms any time

Summary of Functionalities

Workflow

- Configure workflows that meet the needs of any Ethics Review and ethics compliance processes with very little training and no programming knowledge
- Create multiple workflows within the same environment
- Create and configure interactive forms and workflows
- Update workflow and forms at any time
- Use logical branching to simplify research proposal completion

Project Types

Ethics RM can be configured to any type of project, study or research which is subject to ethics approval. Some of the types include:

- Clinical trials
- Animal research
- Bio-safety studies
- Environmental research
- Economics research
- Social science projects
- Defence studies

Applicant Process

- Students, staff and researchers create applications
- Students, staff, researchers, supervisors and collaborators share forms
- Supervisors and other signatories sign off on applications
- Electronic submission directly to the Committee
- Flexibility to withdraw or modify applications as required

Review Process

- Reviewers can be assigned to (or removed from) committees and applications
- Rule-based automatic application assignment to reviewers or committees can be configured
- Reviewers can be assigned based on workload
- Multiple reviewers could simultaneously work on the same application
- Reviewers can quickly and easily track changes between submissions
- Applications can be annotated by reviewers

- Reviewer annotation can be set as only visible to other reviewers
- Virtual review meetings can be held
- Applications can be escalated to a higher-level reviewer
- Reviewer comments can be moderated

Admin Process

- Applications can be reviewed
- Applications can be validated/invalidated
- Comments can be added
- Changes can be requested and reviewed
- Reviewers can be assigned
- Conflicts of interest can be registered
- Applications can be assigned to meetings
- Application types can be changed
- Applications may be re-routed to different committees/reviewers (escalate/de-escalate)
- Comments can be registered “closed”
- Comments may be moderated prior to feeding back to Applicant
- Decisions can be registered
- Forms and workflows can be created and configured
- The system can be personalised with custom role-related desktop views

Collaboration

- Set access levels for collaborators
- Researchers can collaborate on applications
- Supervisors can comment or review before submission
- Committee reviewers can collaborate on the review of submitted application

Automation

- Automated classification of application type
- Automated routing to different committees
- Automated notifications and emails when key milestones are met
- Automated alerts when deadlines are approaching or missed
- Automated version control with storage of previous application versions
- Automated collation of reviewer comments into template letters

Communication

- Standard communication templates

- Automated communication
- Editable letter and email templates
- Correspondence feature to allow applicants and reviewers to communicate within the system

Documentation

- Central repository of all applications and associated documents including:
 - Application versions
 - Amendment forms
 - Adverse event forms
 - Annual reports
 - Study closure forms
- Version control

Forms

- Configurable forms with a range of question types
- Filter questions and dependencies
- Dynamic forms
- Completeness checker
- Help, FAQ and user guide functionality

Dashboard

- Dashboards for applicants, research administrators and reviewers
- Timeline tracker
- Reporting dashboards with data and trends on KPIs
- Personalised content, showing only applications the user is involved with

Reporting

- Reporting on any data within the system
- Reporting on actions and statuses
- Reports by committee
- Output in several formats such as pdf, html, csv, word as well as via API
- Set and share standard reports
- Schedule recurring reports

Audit

- Audit trail of all activity on applications, including:
 - Applicant changes
 - Reviewer activity
 - Timestamp
 - Identity of user
 - Emails sent
 - Alerts sent
 - API calls made
 - Documents accessed by users
 - Reports run
- Page visits by user, time and date visited

Alerts & Reminders

- Automatic alerts and reminders
- Timeline recording
- Alerts for annual reports
- Alerts for overdue reviews
- Alerts for overdue resubmissions

Interfaces

- Integration with other existing systems such as HR, finance and grants systems
- Consume and output information from / to other software through APIs

System

- Choice of open or closed system
- Web-based, accessible from any device with a browser
- Supports single sign-on (SSO)

Data Protection

- GDPR compliant

Support

Training

- Training for administrators
- Train-the-trainer sessions
- Introduction training to reporting
- Provision of training environment

Helpdesk

- Support via email, telephone and Jira online ticketing system
- 9 am – 5 pm Monday to Friday excluding bank holidays
- Defined escalation and response routes
- Appointed point of contact

Data Migration

- Facility for easy data migration of research database from other systems

Infrastructure

Service

- Hosting in the cloud to comply with data protection and sovereignty
- Redundancy and overprovisioning for a reliable and uninterrupted service
- SLA (Service Level Agreement) with 99.9% uptime
- 24x7 monitoring and alerting

Integration

- Transactional and batch REST APIs
- Bulk import service for efficient data migrations
- Single Sign-On: ADFS, Azure AD and Native SAML2 iDPs such as Shibboleth

Security

- ISO 27001 certification
- Cyber Essentials Plus accreditation
- Regular independent penetration tests and audits
- Data encryption at rest and in transit

Platform

- An integrated product suite

- Fully configurable workflow engine to support the most demanding scenarios
- Comprehensive forms authoring solution
- Extensible reporting

Updates

- Regular updates driven by feedback from the Infonetica global customer community
- Optional release preview environment
- Empowered product engineering team approach going beyond agile