

Animals Humans BioSafety

General Features

21 CFR 11 Compliance			
Audit Trails			
E-Signatures			
Customizable automated emails			
User role based security			
LDAP and CAS integration			
Spell check			
Export reports to PDF, RTF, CSV			

Forms Features

User defined forms designer			
Customized form help			
User defined fields			
Conditional fields			
Rich text			
Hyperlinks and attachments			
SOP integration			
Text, multi-choice, table, date questions			
“Office use only” sections			
Specify required answers			

Protocol Creation Features

Electronic Submission			
Pre-submission peer reviews			
Pre-submission answer validation			
Amendments, renewal/continuing review			
Copy from other protocols			
Access to training/qualification records			
View comments on returned requests			
Protocol detail reports			
Attach files			
Manage all protocol associates			

Protocol Review Management Features

Automated COI check			
Flexible review routing			
Customize reviewer roles to delegate authority			
Dashboard of reviewer progress for each protocol			
Send reminder emails to reviewers			
Summarize/sanitize comments for return to PI			
PI access to monitor review progress			
Review details report			
Supports multiple committees, sub-committees			

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Protocol Review Features

- Online commenting
- Reviewers “discussion board”
- Compare different versions of the request
- View comments against previously returned request



Meetings Features

- Customizable agenda and minutes form
- Assign protocols to agenda
- Non-protocol agenda items
- Auto meeting notifications
- Record minutes in real time
- Automated check for quorum and COI



Protocol Management Features

- Automated emails for expiring protocols
- Protocol list reports
- Search for protocols using numerous criteria
- Complete protocol history covering all submissions



Animal Features

- Integration with Animal Orders and Facility Management
- Integration with Veterinary Management
- Library of procedures
- Species specific questions
- Generate AAALAC procedures report
- Automated management of animal quantities
- FDA/USDA/GLP compliant



Human Features

- Biomedical or social/behavioral/educational
- Track and search by vulnerable subjects
- Track and search by exemption/expedited categories
- Manage informed consent, brochures, etc.
- FDA/OHRP/GCP compliant



Biosafety Features

- Track and search by risk group
- Track and search by NIH Guideline section
- Track and search by BioSafety Level
- Link to animal or human protocols
- Communicate review progress with other committees
- Manage NIH and CDC compliance
- Radiation Safety Committee

