

Documentation changes

Key points:

- There are several changes to Bellberry documentation. Many documents that you previously knew as policies are now sitting in an updated structure of 'guidance' and 'forms' (table below)
- This list is not exhaustive; it contains only references to the former policies.

Levels of Ethical Review (LER)

This area contains documents that aim to give a brief overview of the review pathways available to those seeking ethical review for human research, quality assurance (QA) activities, and low and negligible risk (LNR) research. There are also self-reflection checklists for QA and LNR activities.

Old document ID & title	New document ID	New document title
POLICYI016 Low Risk or Negligible Risk Review	LER G1	Review Pathways - Quality Assurance, Low and Negligible Risk, Full HREC Review
POLICYI026 Quality Assurance and Ethical Review	LER G1	Review Pathways - Quality Assurance, Low and Negligible Risk, Full HREC Review
POLICYI028 Taking Over Ethical Oversight of Approved Research	LER G1	Review Pathways - Quality Assurance, Low and Negligible Risk, Full HREC Review

Bellberry Applications (BA)

Once you have determined your research pathway, you are ready to apply to Bellberry. This area includes guidance and forms that cover most facets of what is required for your application.

Old document ID & title	New document ID	New document title
POLICYI001 Administration Fees	BA G6	Application fees
POLICYI002 Participant Payment and Reimbursement	BA G10	Participant payment & reimbursement
POLICYI003 Conflict of Interest	BA G7	Conflict of interest
POLICYI007 Ionising Radiation	BA G13	Ionising radiation
	BA F13.1.1	Standard clauses – ionising radiation
	BA F13.1.2	Standard clauses – ionising radiation
	BA F13.1.3	Standard of care declaration - template
POLICYI008 Advertising	BA G9	Advertising
POLICYI011 Data Storage and Retention	BA G11	Researcher data storage and retention
POLICYI013 Pregnancy and Sexual Health	BA G14	Pregnancy and sexual health
	BA F14.1.1	Standard clauses – pregnancy & sexual health
POLICYI014 Compensation	BA F5.1.6	Standard clauses - compensation for injury
POLICYI015 Investigator Qualifications	BA G8	Investigator qualifications
POLICYI017 Multi Centre Applications	BA G1	Submission requirements and responsibilities
POLICYI018 Adult Photographic Release Form	BA F5.1.1	Adult photographic release consent
POLICYI021 Communication with Investigators / Sponsors	BA G1	Submission requirements and responsibilities
POLICYI023 Timeliness of Ethical Review	BA G1	Submission requirements and responsibilities
POLICYI025 Confidentiality/Privacy	BA G11	Researcher data storage and retention
	BA F11.1.1	Standard clauses - confidentiality and privacy
POLICYI029 National Approach to Single Ethical Review of Multi-Centre Research (National Approach)	BA G1	Submission requirements and responsibilities
	BA F1.1.7	HREC Process Flowchart

Monitoring Approved Research (MAR)

After you have received approval, Bellberry has ongoing monitoring requirements. This area has guidance and forms related to areas such as progress & final reports, safety, protocol violations, site monitoring.

Old document ID & title	New document ID	New document title
POLICYI004 Adverse Event and Safety Reporting	MAR G2	Safety Reporting
POLICYI009 Monitoring of Approved Trials	MAR G6	Site monitoring and desktop auditing
POLICYI009a Site Monitoring	MAR G6	Site monitoring and desktop auditing
POLICYI010 Monitoring - Progress Reports	MAR G1	Progress and Final Reports
POLICYI019 Monitoring – Protocol Violations	MAR G3	Protocol Violations and Serious Breaches
	MAR F3.1.1	Serious Breaches Report Form - Sponsor
	MAR F3.1.2	Serious Breaches Report Form - Third Party
POLICYI020 Monitoring – Withdrawal/Suspension of Ethical Approval	MAR G1	Withdrawal or Suspension of Ethical Approval
POLICYI022 Governance of the Review of Research	Retired	

Corporate Governance (CG)

This area contains relevant public policies relating to research, privacy, complaints and terms of references.

Old document ID & title	New document ID	New document title
POLICYI005 Complaints related to the conduct of a research project	CG P9	Complaints
POLICYI006 Complaints related to the review process	CG P9	Complaints
POLICYI024 HREC Member Details	CG P8	HREC ToR
POLICYA006 Privacy Policy	CG P5	Privacy Policy

Information Technology (IT)

This area has guidance on the Bellberry's management and retention of data and records and the use and acceptance of e-Signatures.

Old document ID & title	New document ID	New document title
POLICYI027 Electronic Signatures	IT G4	eSignatures
POLICYA003 Information Security Policy	IT G1	Information Security