Operations Update Edition	Topics
Update 42 – (Oct 26)	Changing the lead site: What does Bellberry need to know? Want the HREC to review or comment on a document? Before you submit: give you PICF a final proof read Completing the Study Sites page in eProtocol Wednesday is the cut-off, not the target
Update 41 – (Sep 2026)	Why does Bellberry ask for a clinical trial registration number? PICF Pathways: Choosing the right approach Getting HREC indemnities right the first time Protocol Clarification Letters: What they are for Demystifying HRECs Webinar series with MJA
Update - Special Edition (Sep 2026)	New Bellberry website launch Bellberry document name updates
Update 40 - (Aug 2026)	Bellberry expands HREC capacity with four new committees New Bellberry website Submit early and avoid delays Supporting non-English speaking participants: HREC expectations TGA GCP Inspection Program 2025: Key Findings for research sites and sponsors National Mutual Acceptance (NMA) and NHMRC Certification
Update 39 – (Jul 2026)	End of Year Submission and Meeting Dates Serious Breach or Important Protocol Deviation? Why the Distinction Matters ICH GCP: Don’t Forget the Agreements Behind the Agreement Stop Before You Submit: A reminder for Sponsors and CROs Registration in eProtocol

Update 38 – (Jun 2026)	Common Reasons for Administrative Return of Participant Documents When does an 'approved' drug still need an Investigator's Brochure? Submission Tips: Keeping eProtocol Tidy During Review Cycles Bellberry at the SCRS Australia & New Zealand Site Solutions Summit
Update 37 – (May 2026)	Using lay-person language in PICFs When to submit your Final Report in eProtocol Fee for reactivating expired applications Update to review of Clinical Study Reports (CSRs) Bellberry guidance document updates: • BA G1 Submission Requirements and Responsibilities • BA G2 Registrations • BA G6 Application Fees • BA G15 Insurance & Indemnities • MAR G1 Amending approved research – general overview • MAR G4 Progress and Final Reports • BA F1.1.1 Submission requirements checklist
Update 36 – (Apr 2026)	Upholding Participants' Rights: Complaints to the HREC Website Refresh Coming Soon Consent Updates and Re-Consent: How should changes be presented? Investigator's Brochure & Annual Safety Report New documents: • LER G2 AI Research Guidance • BA G18 Participant Information Card Guidance Bellberry guidance document updates: • BA F1.1.17 PICF Submission Pathways • BA G12 Version Control & Document Naming Conventions

Update 35 – (Mar 2026)	Third-Party & Electronic Documents: What the HREC Requires FDA draft guidance on NAMs HREC composition listings – What's changed? NHMRC guidance on PICFs Protocol number changes: What you need to know Bellberry guidance document updates: • BA G1 Submission Requirements & Responsibilities • BA G5 Participant Information & Consent Form Development • BA F5.1.2 Sample Consent Form • BA G15 Insurance & Indemnities
Update 34 (33 void) – (Feb 2026)	Principal Investigator CVs- What HRECs need to see Reminder: All study related submissions must be lodged via eProtocol Bellberry guidance document updates: • BA G14 Pregnancy & Sexual Health • BA F14.1.2 Pregnancy & Pregnant Partner Data Release Template • BA G8 CVs and Investigator Qualifications
Update 32 - (Jan 2026)	Completing the Sponsor page in eProtocol Inclusion of Side effects in Study Documentation GCP R3 Update Bellberry guidance document update: • BA F1.1.12 Site-Specific Clauses Template
Update 31 - (Dec 2025)	Guidance update – PICF development & optional objectives Participant notification of incidental findings Race-based recruitment strategies Address for Indemnities Fees

	Bellberry guidance document updates: • BA G5 Participant Information & Consent Form Development • BA F1.1.1 Submission Requirements Checklist
Update 30 - (Nov 2025)	Process Update: HREC Response Timeframes Is your Clinical Trial Site ready for the unexpected? Common HREC Queries End of year meeting dates and closure period
Update 29 - (Oct 2025)	Categorising Risk in Research: Harm Beyond Discomfort Waivers of Consent in Research Bellberry guidance document update: • BA G5 Participant Information & Consent Form Development New – Operations Update Register End of Year Meetings and Submission Deadlines
Update 28 - (Sep 2025)	New Bellberry Office Address New eProtocol Registrations Contact Email Bellberry User Satisfaction Survey End of Year Meeting and Submission Deadlines Digital Scribes National Statement 2025 Update When the Study is Full: What about the next screened participant?
Update 27 - (Aug 2025)	A Smarter, Simpler PICF for Participants: CT:IQ InFORMed PICF Consent is More than a Form Timely Submissions and Amendment Review Updates:

	- Submission deadline - Post approval amendments - Complex amendments End of Year Meetings and Submission Deadlines HREC Audits: Supporting Researchers, Protecting Participants: - Top three trends and tips from audits in recent years We're Moving (Bellberry Adelaide Headquarters)
Update 26 - (Jul 2025)	Registering for eProtocol: Important Guidance - Nominate the correct organisation - Use a professional email address - Do not use a residential address or PO box - Submit an OVOP promptly How to manage Admin Changes to PICFs Help Us to Help You: Submit Early, Avoid Delays Share your Opinion on HREC services – Upcoming Engagement Survey
Update 25 - (Jun 2025)	ICH Good Clinical Practice (GCP) E6(R3) Update Friendly Reminder: Please submit Applications earlier on Wednesdays Participant Reimbursement: Spotlight on Travel Costs for Rural and Regional Participants Austin Health Now Accepts Bellberry for All Phases of Commercially Sponsored Clinical Trials Bellberry Website Feedback Survey
Update 24 - (May 2025)	Bellberry 2024 Clinical Trials Activity Report Quality of Information in Serious Breach Reports and Significant Safety Issue (SSI) Reports:

	- Submission tips - What to include Bellberry guidance document update: - BA G9 Advertising and Social Media guidance document updates: • Generic advertising • Study-specific advertising • Generic vs study specific advertising New eProtocol Interface Update and Outstanding Issue: - Error message due to characters exceeding 1999 Bellberry Website Feedback Survey
Special Operations Update (May 2025)	eProtocol Software Update: - eProtocol version 2 application template from Saturday 10 May 2025 Further Reading on: Provision of Personal Health Information Before or Without Consent - Further information provided related to Operations Update 23 - Best practice - Creating a generic pre-screening PICF
Update 23 - (Apr 2025)	eProtocol Interface Update: - Saturday, 10 May 2025 Screening in Clinical Trials – Why You Cannot Ask a Participant to Fast Before Consent: - Relevant GCP and National Statement references - Real-world example - What you can do instead Provision of Personal Health Information Before or Without Consent:

	- Breach of confidentiality - Breach of Good Clinical Practice - Regulatory and ethical consequences Why Version Control Matters in Research Submissions
Update 22 - (Mar 2025)	Clarifying eProtocol questions: Getting Page 1 and Page 2 right for Consent and Recruitment The Importance of Keeping Emergency Contact Details Up to Date in PICFs
Update 21 - (Feb 2025)	Bellberry guidance document updates: • MAR G1 Amending Approved Research – General Overview • LER G1 Review Pathways – Higher Risk and Lower Risk Research o Letters stating that research is exempt from review are no longer provided o Applications requesting review via the lower risk pathway must include completed LER F1.1.16 Application for Lower Risk Review in the eProtocol application Understanding the Impact of Changes to the Principal Investigator or Organisation on HREC Approval Levels of Ethical Review: Lower Risk Review and Exemption from Review Update Application Fees – FAQs Upcoming Improvements to eProtocol: - Project to update and enhance eProtocol o Phase 1 – refreshed system interface, functionality remains the same o Phase 2 – improvement of functionality and introduction of new modules

Update 20 - (Jan 2025)	Site Monitoring (audits): - Percentage of studies audited by state, phase and therapeutic area - Common findings across sites, suggestions for improvement on findings - Percentage of Studies Audited by Therapeutic Area
Update 19 - (Dec 2024)	Data Cleaning in eProtocol: - Administrative edits eProtocol Application Page 5 – Workaround for Question 2 Fees Update: - Multi-centre vs. multi-site/decentralised/satellite site - New multi-site/decentralised/satellite site fee
Update 18 - (Nov 2024)	Change to HREC Composition Lists Christmas and New Year Meeting Submission Deadlines Bellberry guidance document update: • BA G5 PICF development including eConsent
Update 17 - (Oct 2024)	eProtocol Application Changes Reminder - Communication with Bellberry - Reference the eProtocol application ID DSMB/SMC/DMC Submission Requirements Screening in Clinical Trials - Fasting for screening blood tests

Update 16 - (Sep 2024)	Bellberry guidance document updates and additional guidance:
	• BA F1.1.12 Site-Specific Clauses Template
	• MAR G2 Safety Reporting:
	  ○ Clarification on Investigator's Brochure (IB) updates
	  ○ Clarification on Significant Safety Issues (SSI)
	• BA G11 Researcher Data Storage and Retention
	• BA F1.1.1 Submission Requirements Checklist
	• MAR G4 Progress and Final Reports (updated)
	Early Phase Clinical Trial Framework Applications (via REGIS):
	- Documents requested to support submission

Update 15 - (Aug 2024)	Bellberry guidance document updates: • BA F5.1.1 Photographic and Videographic Release Content • BA G9 Advertising and Social Media • BA G12 Version Control and Document Naming Conventions • MAR G4 Progress and Final Reports ○ Administrative close-out of expired applications
Update 14 - (Jun 2024)	Bellberry guidance document updates: • BA G9 Advertising and Social Media • BA F1.1.1 Submission Requirements Checklist eProtocol Submission Fields – new/removed fields eProtocol Approval Letters (update to documents listed) CV Updates

Update 13 - (Dec 2023)	Bellberry guidance document updates: • BA F1.1.12 Site clauses • BA G5 PICF development and eConsent • BA G10 Participant payment and reimbursement • BA G11 Researcher data storage and retention Change in document area and naming: • CG P7 Research Policy is now HRO P1 Research Policy • CG P8 Terms of Reference is now HRO P2 Terms of Reference • CG P9 Complaints is now HRO P3 Complaints Electronic HREC indemnity reminders General guidance for making submissions to Bellberry Regulatory update – FDA update regarding (CAR) T cell immunotherapies
Update 12 - (Dec 2023)	eProtocol: Application questions changes (effective Q1 2024) Bellberry guidance document updates: • BA F.1.12 Site clauses • BA G2 Registrations • BA G16 eProtocol navigation guide for researchers • BA G6 Application Fees • BA G10 Participant payment and reimbursement • BA G5 PICF development and eConsent • BA G11 Researcher data storage and retention • MAR G1 Amending approved research – general overview

Update 11 - (Nov 2023)	Process change: Caveats - The HREC will now only apply a caveat in the most complex of circumstances.
Update 10 - (Jul 2023)	TGA CTN and HREC Indemnities Updates: - Clinical Trial Notification (CTN) - Bellberry contact - Emailing electronic HREC Indemnities - General advice to sites regarding HREC Indemnities Accreditation, Certification and Registration: - AAHRPP - Bellberry awarded full reaccreditation - NHMRC - Certification and Registration - OHRP Safety Reporting and Serious Breaches: - Understanding the reporting requirements of 'MAR G2 Safety Reporting' and 'MAR G3 Serious Breaches' - What does not require submission - Examples of serious breaches
Update 9 - (Jul 2022)	Quality Update: Progress and Final Reporting refresher: - Progress reporting realignment initiative - Progress and final reporting – guidance materials - Progress and final reporting – email correspondence - Progress reporting key information - Final reporting key information
Update 8 - (Mar 2022)	Progress Report Submission: - eProtocol error, some users are unable to see 'Start progress Report' as an option in eProtocol
Update 7 - (Nov 2021)	Safety Reporting Requirement Update:

	- General advice to sites regarding submissions - Example wording for the site submission
Update 6 - (Sep 2021)	Progress and Final Reporting Refresher: - Progress reporting realignment initiative - Progress and final reporting: guidance materials - Progress reporting key updates - Final reporting key updates
Update 5 - (Jul 2021)	Radiation Refresher: • BA G13 Ionising Radiation • BA F13.1.1 Standard clauses – ionising radiation • BA F13.1.2 Standard imaging – definitions • BA F13.1.3 Standard of care declaration – template • BA F13.1.4 HREC reporting flowchart – radiation
Update 4 - (May 2021)	Bellberry guidance document update: • BA F1.1.12 Site-specific clauses template o Required inclusions o Addition of examples and pre-submission checklist
Update 3 - (Mar 2021)	Process changes at Bellberry: - Table comparator of additional site start-up times 2020 to 2021 - Document updates – Summary of Changes March 2021 - FAQs relating to the process changes rolled out in late 2020
Update 2 - (Jan 2021)	Study Submission Changes: As per Operations Update 2

Update 1 - (Oct 2020)	Study Submission Changes: Summary of Changes – October 2020