

Sponsor access to eProtocol

Key points:

- Sponsors and CROs that wish to access studies in eProtocol can now liaise with the site Principal Investigator to obtain access.
- Sponsors can assist with all parts of the application but cannot press 'submit'. This is the responsibility of the Principal Investigator.
- Principal Investigators retain control of all persons that they wish to allow access.

Sponsors, CROs and SMOs are permitted to access their studies in eProtocol. Once decided upon between the Sponsor, CRO, SMO and site, a request for eProtocol access occurs through submission of BA F2.1.3 Nominated contact authorisation. The Principal Investigator at the site is then responsible for adding the representative to their application in eProtocol. After the representative has access to the study in eProtocol, they can assist in all areas of the research application for the life of the study, including uploading documentation. Importantly, only the Principal Investigator or their site delegate can use the 'submit' function in eProtocol, as it is the Principal Investigator that holds ultimate responsibility for the conduct of the research at the site. The declaration for all submissions within eProtocol acknowledges the responsibilities of the Principal Investigator. The Principal Investigator may also choose to remove the sponsor representative from their application.

Communication (by phone or email) between Bellberry administration and sponsors will be restricted to matters of an administrative nature e.g. general policy or procedure questions. Any other communication from the Sponsor should be received via the Principal Investigator through eProtocol. Bellberry staff can assist Investigators with minor scientific or ethical matters (i.e. clarification of a Committee question). All other matters will be directed to the HREC and be dealt with between the Committee and the Investigator.

See related documents:

Bellberry Applications

[BA G1 Submission requirements and responsibilities](#)

[BA F2.1.3 Nominated contact form](#)