

POLICYI021 COMMUNICATION WITH INVESTIGATORS/SPONSORS

| | | |
|------------------------------|---------------------------|-----------------------------------|
| Manual: Policies | Document ID: PI021 | Date Created: Jan 10 |
| Section: Investigator | No. Pages: 1 | Review Date: Aug 17 |
| | | Future Review Date: Aug 19 |

PURPOSE

To outline the Bellberry procedure for engagement with investigators/sponsors as outlined in the National Statement. Section 5.2.13 – 5.2.15

Bellberry encourages open and informal communication with researchers/sponsors in the following ways:

- Bellberry staff are committed to providing a professional, high quality and efficient service to the research community. Staff are readily accessible to assist researchers/sponsors and their staff through the review process on a daily basis.
- Researchers may be invited by the Committee to attend review meetings to present their study, or answer concerns in regard to specific issues either in person or via telephone.
- If questions are received regarding the review process the Committee Chair will consider face to face meetings to resolve issues that have been unresolved by written or telephone communication.
- In the event that issues are unresolved, refer to Bellberry PolicyI006 Complaints Related to the Review Process.
- Communication 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 are able to 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. National Statement 5.2.20