

# POLICYI028 TAKING OVER ETHICAL OVERSIGHT OF APPROVED RESEARCH

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## PURPOSE

To describe the Bellberry requirements regarding requests to take over ethical oversight of research proposals approved by another Human Research Ethics Committee.

This may occur where the original HREC is no longer going to operate, or where the Investigator/Sponsor decides to transfer the study from another HREC.

Any request by an Investigator for Bellberry to take over ethical oversight of a research proposal which has been approved by another HREC will be treated as a new application. Bellberry will require a full submission via eProtocol. It will be subject to full ethical review by a Bellberry HREC.

Bellberry will require the following:

1. (a) All documentation including Investigator Brochure, Protocol, Information Sheet and Consent Form (PICF) and any other relevant documentation pertaining to the conduct of the study;  
  
(b) All approvals and acknowledgements given to the Institution by the non-Bellberry approving HREC;  
  
(c) Any other records and/or standard matters as required by the non-Bellberry HREC.
2. A cover letter outlining which documents were originally approved documents and which are updated amendment documents.
3. Information regarding current status of recruitment (e.g. not yet commenced, ongoing, closed) and active participants (e.g. number yet to receive drug/device, number receiving drug, number in follow-up).
4. If the transfer is based on a decision of the Investigator/Sponsor, a copy of the notification from the approving HREC that they have been instructed by the Investigator/Sponsor to transfer ethical management to Bellberry. Alternatively, a copy of the correspondence requesting the transfer from the Investigator/Sponsor to the approving HREC, and the HREC response where appropriate.
5. If the transfer is due to the original HREC closing, copy of a letter to that effect from the closing HREC or institution.
6. If the submission is an additional site to a study Bellberry already has approved, all of the above documents will be required, and in addition, a tracked copy version of the PICF and any other relevant documents to show the differences between the documents as approved by the original ethics committee and the documents as approved by Bellberry.

If these tracked changes documents can be provided, with confirmation that the documents will be amended to reflect the documents as approved by Bellberry, then the review could be

undertaken as an expedited review outside a meeting.

7. Re-consent of participants will need to be considered if the PICF is changed as a result of the transfer of oversight review. Bellberry HREC will advise if participants need to be re-consented.
8. If the decision is made that the changes do not require re-consent of participants, a letter to participants noting a change of HREC and new contact details will be required. This letter will be requested to be submitted for approval following the initial HREC review.

Approval by Bellberry will not be guaranteed. Transfer of the study cannot take place until Bellberry has provided ethical approval.