POLICYI017 MULTI-CENTRE APPLICATIONS

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PURPOSE

To outline the requirements for all multi-centre applications submitted as per the National Statement Chapter 5.3. *Minimising duplication of ethical review.*

Definitions

For the purposes of an application to Bellberry, the following definitions apply to the application form:

Multi Centre Application: The study is conducted at multiple centres and a different Principal Investigator is responsible for each centre. A separate eProtocol application is required from each Principal Investigator.

Multi Site Application: The study is conducted at multiple sites, and one Principal Investigator has responsibility for the activities at all of the sites. A single application form is required.

Lead Site: The lead site is the initial application in a multi centre study taking the responsibility for responding to the Committee comments. It is a decision for the sites and sponsor to determine whether the lead site continues to take responsibility for ongoing submissions (eg generic amendments and reports) on behalf of the additional sites.

Additional Site: The other sites that will be involved in the multi centre study. Only the sites that will be undergoing Bellberry HREC review are required to be listed on the eProtocol application and submitted.

Multi-Centre Applications:

Application
An application is required to be submitted by the lead site and each additional site via eProtocol.

Lead Site
The lead site is required to submit all study related documents. The lead site will be responsible for responding to and addressing all issues raised by the Committee.

Additional Site

a) Submission prior to lead site approval

If an additional site submits an application prior to the approval of the lead site, only the application form is initially required to be submitted. All study documents are not required to be attached to the application at that time.

If the lead site application is approved by the HREC, a comment will be sent to each additional site via eProtocol to notify them that the lead site has been approved. Each site will be requested to submit their site specific documents based on the documents approved for the lead site. In addition to the PICF, this may also include any other relevant documents such as advertisements

and state specific requirements. The Insurance, Indemnities and any other outstanding documents will also be requested to be submitted.

If the lead site application is not approved by the HREC, each additional site will be notified via eProtocol and each application will then be closed.

b) Submission after lead site approval

If an additional site joins the study after the approval of the lead site, the additional site application will be required to include all of the study documents as approved for the lead site, in addition to the site specific documents as above. This is to ensure that the latest approved documents are provided, including any amendments that may have been approved since the original approval of the lead site.

Multi Site Applications:

A single application is submitted. Each site is to be listed under Section 2 of the Study Sites page of the eProtocol application. The application should outline what activities will be occurring at each site, how the Principal Investigator plans to oversee and manage the activities and Co-Investigators at the other sites.

Ongoing Lead Site Responsibilities:

It is the responsibility of the sites and sponsor to determine who will act as the lead site, and to determine what the site responsibilities are for ongoing amendments and reports.

The lead site may submit generic documents on behalf of the other site(s). This may include for example, Amendments to the Protocol, Investigator's Brochure, questionnaires and the master PICF (if being used), as well as Annual safety reports. When the lead site is submitting on behalf of another site, the Investigator and address details of the additional sites are required to be included under the multi centre question on the eProtocol submission forms.

Each site can be responsible for their own submissions for the term of the study following the initial lead site approval.

Ongoing responsibilities for all sites:

Any site specific submissions are required to be submitted by the site. This will include for example, the site specific PICF, including any time it is amended, any local advertising, SAEs and SUSARs related to the site, protocol violations, annual Progress Reports, ethics approval extension requests, and the Final Report.

Where there is a generic/master Participant Information Sheet and Consent Form (PICF) or other document, the site specific version is required to be submitted for approval.

Notification of the Committee Decision:

The Approval/Rejection letter will be generated for the lead site, and a copy will be attached for each other site application in the Attachments section via eProtocol.