



Melbourne Health Post Approval Summary Sheet

AMENDMENTS:

When Melbourne Health is the reviewing HREC:

- All amendments should be submitted for review by the HREC

When Melbourne Health is an accepting site

- Amendments should be submitted after ethics approval is obtained from the reviewing HREC. The amendment should be submitted with a copy of the approval letter from the reviewing HREC

CORRESPONDENCE:

When Melbourne Health is the reviewing HREC:

- All correspondence should be submitted for review

When Melbourne Health is an accepting site

- Concurrent submission to the HREC and local governance office should occur. The Office for Research does not require the lead HREC approval unless the correspondence impacts on the overall conduct of the trial or the patients enrolled.

SERIOUS ADVERSE EVENTS:

When Melbourne Health is the reviewing HREC:

- All 'related' serious adverse events should be submitted for review within 24 hours of the event or as soon as possible thereafter

When Melbourne Health is an accepting site

- Concurrent submission to the HREC and local governance office should occur. The Office for Research does not require the lead HREC approval unless the event impacts on the overall conduct of the trial or the patients enrolled. All 'related' serious adverse events that occur in patients from Melbourne Health should be concurrently submitted to governance office for review.

SUMMARY ADVERSE EVENTS:

When Melbourne Health is the reviewing HREC:

- All summary adverse events should be submitted for review as required by the study sponsor

When Melbourne Health is an accepting site

- If the summary information impacts upon the conduct of the trial, lead HREC approval should be submitted along with the governance submission of these documents.

PROGRESS REPORTS:

When Melbourne Health is the reviewing HREC:

- Annual progress reports should be submitted annually for the Melbourne Health site.. The CPI should review all site reports for which he/she and the HREC are responsible and send the Melbourne Health progress report and the CPI coversheet completed for each of the sites for which the HREC is responsible.

When Melbourne Health is an accepting site

- Site report should be submitted annually. The Office for Research does not require the lead HREC approval unless the report impacts on the overall conduct of the trial or the patients enrolled.

Only study correspondence or study related safety reports or summaries that relate to the conduct of the study at Melbourne Health or the patients of Melbourne Health require review from a governance perspective. All other study related information that is not relevant to the conduct of the study at this site need not be submitted for governance review. Lead ethics review will suffice in these cases.