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Operations	Drug Safety Evaluation Branch
Procedure:	Management of External Evaluations - DTES
Operations:	Drug Safety and Evaluation Branch (DSEB)
Written by:	Updated by Andrew Bartholomaeus
Document Title:	DSEB SOP – Number will be allocated by SOP Coordinator - Evaluation Reports
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Signature:	
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1. PURPOSE

This SOP outlines the procedure to be followed when allocating evaluation work to external evaluators.

2. RESPONSIBILITY

DTES Stream Leaders and Section Head.

3. BACKGROUND

DTES is not resourced to evaluate the peak flow of product applications in house. Peak work loads are therefore accommodated by utilising external evaluators under contract. In order to ensure that the letting of contracts complies with all relevant Government, Departmental and TGA guidelines, this SOP outlines the key steps to be undertaken from the point of decision that external work is required through to payment of the contractor on completion.

4. PROCEDURE

4.1 Identification of applications requiring external evaluation

Section Executive in Committee

1. During the fortnightly work allocation meeting the section executive (section head and stream leaders) in committee, will identify applications which are unable to be completed in a timely manner, within the available resources of the section. This consideration will take the following factors into account:
 - a. Number of unallocated applications on the section work list and in filter
 - b. Time lapsed since the application was accepted for evaluation
 - c. Due date for availability of internal evaluators
 - d. Size of the application package (number of pages/volumes/studies)
 - e. Nature of the application and its suitability for external evaluation
 - i. New or existing class of drug
 - ii. Complexity of the pharmacology & toxicology

- iii. Need for reference to previous evaluations
- f. Priority status of the application
- g. Target ADEC meeting date
- h. Progress of other evaluation units (PCE, Clinical, etc)

4.2 Selection of external consultant

Stream 6 EL2

- 2. The Stream 6 EL2 will compile a list of external evaluators currently able to take on an evaluation.

Section Head

- 3. The section head will select an external evaluator to assign the identified application to, taking into account the following factors;
 - a. Amount of work allocated to each external evaluator over the previous 6 month period,
 - b. Quality and timeliness of assessment reports completed by each external evaluator
 - c. Nature and complexity of the evaluation and suitability of each evaluator to undertake the work,
 - d. Any potential conflicts of interest associated with each evaluator with respect to the specific application.
- 4. Once an external evaluator has been selected by the section head, the stream leader managing the specific application will be advised.

4.3 Assignment of work to the external evaluator & contract preparation

Stream Leaders

- 5. The stream leader completes the allocation sheet in Premier by entering the following information:
 - External evaluator: (name, phone, fax, email, organisation, location)
 - Special delivery instructions: (if any)
 - Time to complete: (generally 3 months)
 - Volumes and pages to be evaluated: (Module 4 data, plus Module 5 CYP450 data)
 - Other material to be dispatched: (nonclinical evaluation report guidance if the updated document has not been sent to the evaluator, Evaluation report template, number of volumes of Modules 1 and 2, and any other relevant material)
 - Calculate fees: (add 500 pages to the total number of pages; the total number of pages should include Module 1 and relevant pages in Module 2 (overviews, quality and nonclinical summaries, but not necessarily all of the clinical summaries). Double check the fees against the calculation using the spreadsheet, which is stored in S:\... \tox\Administration Folder\External evaluation\ External Evaluator Fee Calculator.xls).

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6. Complete "Recommendation minute for external evaluation", for approval by the Branch Director. The template is saved in S:\...\tox\Administration Folder\External evaluation\Recommendation minute for external evaluations (final).doc.

Fill in the following details:

• *Details of consultancy*

Name of consultant: (to appear on the contract and for the public record)	(preferably the business name)
Address:	
ABN:	
Title of consultancy: (eg. Clinical evaluation of a new chemical entity)	Non-clinical evaluation of a new chemical entity (if it is an NCE) (Do not write the drug name here. This information will appear in the Gazette)
Contract value (GST-inclusive):	\$

• *Procurement*

(tick the second box)

- This procurement is a direct engagement of a consultant who is a recognised and pre-eminent expert; or
- This procurement is a direct engagement of a consultant who is known to have the requisite skills where the value of the project did not justify the expense or delay associated with seeking tenders.

• *Regulation 10*

(tick the appropriate box)

- The consultancy is over \$25,000 and involves the payment of funds in a future financial year. An application for Regulation 10 authorisation is required and is attached; or
- The consultancy does not involve a payment in a future financial year of more than \$25,000. An application for Regulation 10 authorisation is not required.

7. Attach Forward the Minute and allocation sheet to the Tox file, and forward them to the Branch Director for approval. Give the Tox file directly to the Branch EA.

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Branch EA

8. Once it is approved by the Branch Director, the minute and allocation sheet and Tox file are sent to the Branch EA, who will raise a contract. The Branch EA also needs the Tox file.
9. The contract is sent to the external evaluator by the EA for signature.

10. When the signed contract is received, the contract is signed by the section head and sent to the contractor. The EA advises the DSEB Data to dispatch data to the evaluator.
11. The Branch EA completes the DTES External Evaluator Excel spreadsheet record at S:CO\TGA\DSEB\Tox\Administration Folder\External Evaluation\External Evaluations from 2005.xls

4.3 Completion of the evaluation

External evaluator

12. On completion of the initial evaluation of the application, the external evaluator will provide a working draft (electronic copy) for advice and/or discussion on issues, concerns and/or deficiencies.
13. Following review of the working draft by the stream leader it is sent back to the evaluator for corrections and/or additions.
14. After making corrections to the working draft, the evaluator sends TGA a printed copy and an electronic copy of the evaluation report, and an invoice.

4.4 Finalisation of the evaluation and contractor payment

Following completion by the External Evaluator

15. The stream leader reviews the evaluation report before authorisation by the DTES head.
16. After authorisation, the DTES head forwards the Tox file and evaluation report to the EA.
17. The EA advises the DSEB Finance staff of payment to the evaluator and DSEB Data to pick up data, sends the report to the sponsor, and forwards the Tox file to the stream leader.
18. The stream leader fills in the “Evaluation report authorisation” form (S:\..\tox\Management\Proforma - Evaluation Report Authorisation - 23-08-06.doc), and places it in the Tox file before giving the Tox file to the clinical unit head.

5. REFERENCES

Nil

6. ATTACHMENTS

Nil