



## FPV HREC ADDENDUM TO COMMON APPLICATION FORM

The Department of Human Services (DHS) Common Application Form is available from:  
[www.health.vic.gov.au/ethics](http://www.health.vic.gov.au/ethics)

To submit an application, download the appropriate modules and complete them using Word.

To fill out check boxes on the Application Forms:

- view the document in Print Layout (or Page Layout) view
- fill in boxes with a cross by double-clicking on the check-box and selecting the “checked” option under the Default Value

In the interests of saving paper, you may delete questions or parts of questions that you are not required to answer in Module One, Sections D and E

**Please adjust your application for ethical approval on the DHS Common Application Form to incorporate the following amendments and additional requirements:**

### MODULE ONE

#### 1.8 PRINCIPAL RESEARCHER

The Principal Researcher is the person who has overall responsibility for the project. Please note that FPV does **not** require the Principal Researcher to be “the person **at this site** [FPV] with overall responsibility for the project”.

Whilst FPV encourages the involvement of FPV staff in research projects involving our clients, staff, database and information resources, it is not always necessary for projects conducted by external organizations/researchers to have an FPV principal or co-researcher. However, any co- or associate researchers who *are* FPV staff should be included in the application as associate researchers.

#### For Student Research:

- If the student and supervisor are taking **joint responsibility** for the project, they should both be included as principal researchers as follows:  
Principal Researcher A (Student), Principal Researcher B (Supervisor)
- For senior post graduate research (eg. Masters, PhD) it is acceptable for the student to be the sole principal researcher. The supervisor should be included in one of the ‘associate researcher’ boxes and identified as supervisor, and may also be included (at 1.10) as “Person to whom the HREC may also direct correspondence”.
- For other student research it is preferred that the supervisor be the Principal Researcher (as the person with overall responsibility for the project); the student should appear as an associate researcher in the application and can also be included (at 1.10) as “Person to whom the HREC may also direct correspondence”. However, if student and supervisor would prefer the student to be identified as the Principal Researcher, the basis for this decision needs to be included in the application (include in the ‘brief summary of relevant experience’ box).

## 1.14 (b) PROJECT PROPOSAL

Please provide copies of questionnaires and research instruments (including details of validation or other publications if instrument not well-known).

## 1.16 ADVERSE OR UNFORESEEN EVENTS

Please note that, if an adverse or unforeseen event occurs, you are required to complete an FPV HREC *Adverse Event Report*. This form can be accessed on the FPV website [www.fpv.org.au](http://www.fpv.org.au) or requested from the Secretary, FPV HREC.

## 1.39 CERTIFICATION BY PRINCIPAL RESEARCHER AND HEAD OF DEPARTMENT

### Acceptance by Head of Department

Please include completed and signed Summary Sheet of the *FPV Preliminary Acceptance of Research Proposal* form, instead of completing “Acceptance by Head of Department” section (1.39).

## 1.40 DECLARATION BY HEAD OF SUPPORTING DEPARTMENT

This item is not applicable to FPV. The signed Summary Sheet replaces this information.

## MODULE ONE: CHECKLIST

Please note the following FPV variations to the Checklist:

Is a staff member from the Institution listed as a co-researcher? <b>Not always necessary – not an absolute requirement for FPV</b>
Have you completed the form “Certification by Principal Researcher and Head of Department”? <b>Include signed Summary Sheet of FPV Preliminary Acceptance Form instead of completing ‘Acceptance by Head of Department’ at 1.39</b>
Has a completed “Declaration by Head of Supporting Department” been included for each supporting department (if applicable)? <b>This is not applicable to FPV. The signed Summary Sheet of FPV Preliminary Acceptance Form replaces this item at 1.40.</b>

## PARTICIPANT INFORMATION & CONSENT FORM TEMPLATE FOR PROJECTS *OTHER THAN* CLINICAL DRUG/DEVICE TRIALS

### CONSENT FORM

- FPV HREC does not require a ‘witness to participant’s signature’. Please delete this section from the Consent Form when modifying the template for your project.
- Please add in the following at the Researcher’s Name section: ‘Researcher/**Recruiting FPV Staff Member’s Name**’. The name & signature of the (authorized) person who will explain the project and gain consent is to be included here.

*These modifications are only applicable to the non-clinical drug/device Consent Form.*