



**Instructions:** Complete this form if:  
 (1) You intend to carry out a **Clinical Case Study**;  
 (2) You wish your project to be registered by the GCHHS – HREC, and;  
 (3) You intend to publish your findings from the project.  
**Submit the completed form as an attachment to the Exemption form via Ethics Review Manager (ERM)**

**Do not complete this form if you intend carrying out a research project.**

Preliminary Check		
Will the project:	Yes	No
Seek to gather new knowledge?		
Involve the use of data that is not from an existing collection of data or records that contain only non-identifiable data?		
Involve any clinically significant departure from the routine clinical care provided?		
Involve a comparison of cohorts?		
Be conducted externally to the Gold Coast Hospital and Health Service?		
Involve any staff or patients external to the Gold Coast Hospital and Health Service?		

***If you answered YES to any of the items above, please contact the HREC Coordinator to discuss whether this application is suitable for your project.***

<b>Applicant (Principal Investigator on Exemption form) details:</b>	
Name of Primary Applicant:	
Service / Work Location:	
Contact Number:	
Email:	
<b>1(a) Project title:</b>	
<b>1(b) Project timeframe:</b>	
Anticipated Start Date:	Anticipated Finish Date:
<b>1(c) Project team:</b>	
<b><i>Please list each member of the project team, including their position (under "profession/post") and department in section 4a of the Exemption Form via ERM</i></b>	



2. Nature of the project:

Retrospective (assess activity/process carried out in the past)

Prospective (assess activity/process to be carried out in the future)

3(a) Project background (briefly review the current literature relating to the focus of the clinical case study, include citations):

3(b) Please provide a complete list of references here:

4. Project aims (why is it important to carry out the clinical case study?):



## *Clinical Case Study and the Human Research Ethics Committee (HREC)*

5. Describe the participant(s) that will be included in this project (number, age, gender, staff, patient):

6. Describe the investigations carried out (if relevant):

7. Differential diagnosis (if relevant):

8. Has consent been sought?

Yes

No - If not, why?

9(a) Please provide details of how you plan to collect your data (including what data will be collected from what source/s):

9(b) How and where will data be stored?



10. What results are expected (including learning points/take home messages)?

11. What will happen to the results?

Internal report	Yes	No	Conference presentation	Yes	No	Publish in professional literature	Yes	No
-----------------	-----	----	-------------------------	-----	----	------------------------------------	-----	----

12. Indicate why this is a clinical case study project rather than a research study

13. Documents:

**Please attach a copy of the following in the Exemption Form:**

- a. Information and consent form
- b. Questionnaire/s to be used (if relevant)
- c. Data collection tools to be used (if relevant)

14(a) Applicant declaration:

**Please sign the Exemption Form - signatures and declarations**

14(b) Head of Department declaration (if the Head of Department is a member of the project team, then the 'one up' rule applies)

I would like to advise my support for this project to be undertaken at the Gold Coast Hospital and Health Service. I certify that I have discussed this project and the resource implication for this Department with the Applicant. I certify that there are suitable and adequate facilities and resources for the project to be conducted at this site. My signature indicates that I support this project being carried out using such resources.

**Name (PRINT):**  **Position:**

**Signature:**  **Date:**

**INSTRUCTIONS FOR SUBMITTING COMPLETED AND SIGNED APPLICATION FORM:**

1. Log in to [Ethics Review Manager \(ERM\) Applications](#).
2. Select the tile *Create Project* from the list of Actions on the left-hand side
  - Enter the Project Title, choose *Queensland Health* as the jurisdiction and *Exemption Form* as the Main Form type, then select *Create Project*.
3. Complete the questions as prompted
  - For question 2, please choose the *Gold Coast Hospital and Health Service Human Research Ethics Committee (EC00160)* to ensure that the project is submitted to the GCHHS HREC for review
  - Please ensure ALL members of the project team are listed under question 4a. The Primary Applicant should be listed as the *Principal Investigator* and must be a GCHHS staff member. Additional members of the project team should be listed as *Associate Investigators*.
4. Upload the completed and signed Clinical Case Study and the Human Research Ethics Committee application form under question 6a (select *Study Plan / Project design*) along with any other supporting documents.
5. Once the Exemption Form is completed and all supporting documents are uploaded, the Principal Investigator should complete the *Signatures and Declarations* page and sign the form. This can be done electronically (recommended) or alternatively, print the form, obtain the "wet-ink" signature, and upload this page to the Exemption Form.
6. To submit the application, select the *Submit* tile from the list of Actions on the left-hand side and follow the prompts. This will submit your application to the GCHHS Ethics Office for processing.