

NCCU IRB Online System

2021



Contents (1/3)

- Procedures for Examining Research Ethics
- How to Access the NCCU IRB Website
- Introduction To The User Interface of NCCU IRB Website
- Curiculum Vite (CV) and IRB Training Certification
- Application and Review Process
- Research Ethics Review Application
- Project Abstract



Contents (2/3)

- Research Proposal
- Principal Investigator's Affidavit
- Informed Consent Form(s) for Research Participant(s)
- Case Reports, Surveys, and Interview Summaries
- Promotional Materials for Recruiting Research Participants
- Research Team Affidavit on the Completion of Ethics Training
- Others



Contents (3/3)

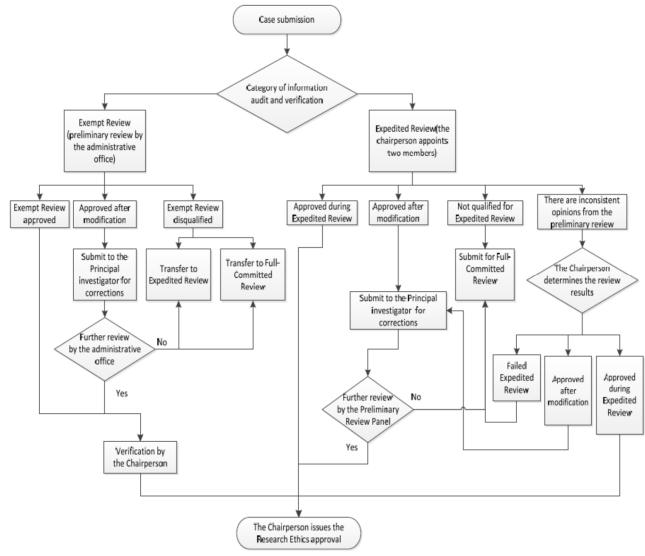
- Tracking the Application Progress
- Responding to Review Board Opinion
- Amendment of Research
- Interim Report
- Completed/Final Report
- NCCU IRB Office Contact Information
- Other Information



Procedures for Examining Research Ethics

Procedures for examining research ethics





Procedures for Examining Research Ethics



The required materials for IRB are as follows:

	Full-board review	Expedited review	Exempt review
Research ethics review Application	V	V	V
Project abstract	V	V	V
Research proposal	V	V	V
Informed consent form(s) for research participant(s)	V	V	
Curriculum Vita (CV)	V	V	V
Promotional materials for recruiting research participants	V	V	
Principal investigator's affidavit	V	V	V
Research ethics training certificates	V	V	V
Others	V	V	V







nccu.edu.tw 的其他相關資訊»

Google, and click "線上審查系





Step 3: Enter the "線上審查系統" Online review system



線上審查系統



National Chengchi University IRB application Review system website:

http://rec.nccu.edu.tw/app/super_pages.ph
p?ID=page111

Step 4: Enter "前往校內人士帳號登入口 (Login to iNCCU online system)"







Step 8: This is the user interface of NCCU IRB application review system.





Introduction to the User Interface of NCCU IRB
Website

Introduction to the NCCU IRB Website Interface

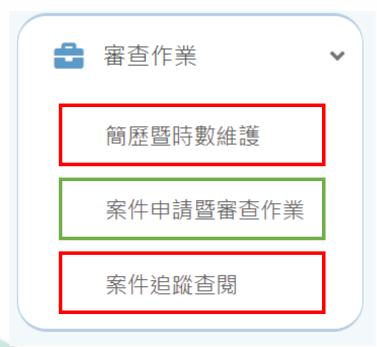


Step1: Enter "審查作業" ("Review Process") area



Introduction to the NCCU IRB Website Interface





- CV and IRB Training Certification: The principle investigator must fill in basic personal information and certification of IRB training hours.
- Application and review process: New application.
- **Application tracking:** Track application progress.







Step 1: Enter " 簡歷暨時數維護 (CV and IRB Training Certification)"







簡歷暨時數維護 » 管理維護個人簡歷及課程時數







Individual training hours (Please upload proof of research ethics training hours or Collaborative Institutional Training Initiative (Citi Program) certificate completed within the last two years)



Step 9: Click on the "儲存" to save your information







Step 1: Click on the "案件申請暨審查作業" (Application and Review Process)





Q 計畫系	紧查詢介面			
roject nun	nber計畫案號			
	Applic	cation Type		
	案件類別	顯示全部	•	
	北京大士	顯示全部		
	排序方式	新案		New Application
		變更案		Amendment of research
		期中報告		Interim report
		結案報告		Completed/Final report
		撤案		Withdrawn
■計畫案	查詢結果	實地訪查		Onsite Review
項次	計畫案號	嚴重不良事件報告		Serious adverse events report
		暫停/終止報告		Suspension/Termination
				*



Q 計畫案查詢介面		
Project number計畫案號		
Project name 計畫名稱		
Application type案件類別	顯示全部	
Sort by 排序方式	依日期	
	依日期	Sort by date
	依計畫案號	Sort by application number

NATIONAL CHENGCHI UNIVERSITY

Step 2: Click on "新增計畫案" (Add new project)

案件申請暨審查作業»提供計畫案管理





與計畫案關係: 請選擇 計畫名稱: 計畫主持人帳號: 如尚無計畫主持人帳號請留空 Step 3: Please choose your role in this project (more details in the next slide)

Step 4: Project title

Step 5: PI's account number

Cancel

🗙 取消



Step 6: Save



Step 7: Please choose your role in this project Principal investigator's interface

與計畫案關係:	計畫主持人	Principal investigator
計畫名稱:		
	Cancel × 取消 儲存	Save



Step 8: Please choose your role in this project Non-principal investigator's interface

與計畫案關係: 請選擇 請選擇 計畫名稱: 助理 共同主持人 計畫主持人帳號: 協同主持人 ×取消 Save Cancel

Research Assistant Co-principal investigator **Sub-investigator**



案件申請暨審查作業»提供計畫案管理

After completing the above information, the following information will appear in the IRB system

3 案件資訊	Application information	
計畫案號	Application No.	
案件類別	新案 Project category: New Review	
案件名稱	test Project title	
計畫主持人	^{主持人} Principal investigator	
案件狀態	^{待提交} Project review status: Ready to submit	

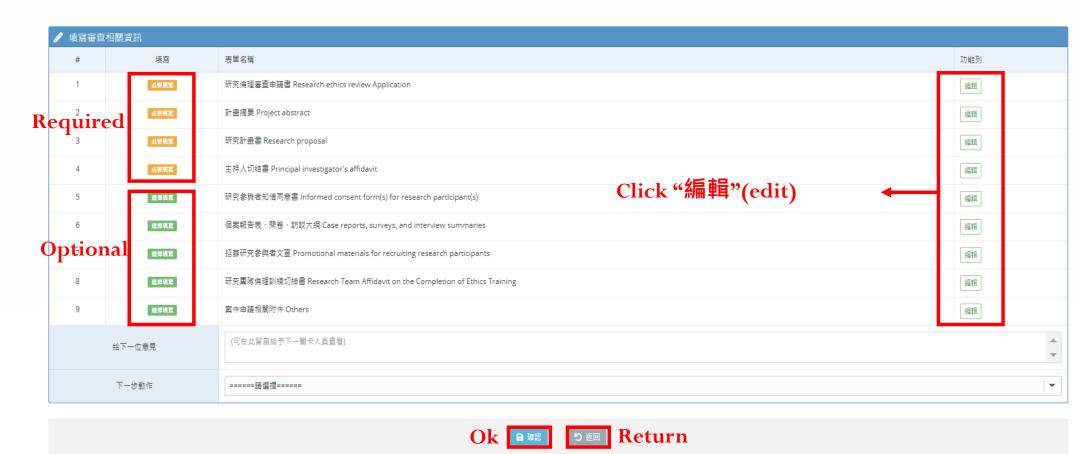








See the next slide for more information about the review documents





給下一位意見	(可在此留言給予下一關卡人員查看)		
下一步動作	=====請選擇=====		
	=====請選擇=====		
	初審送出【將送至行政人員】		
	Step 8: Ok		

Step 9: Preliminary review (send to administrative staff)
***Fill in the "required" information in the previous steps before submitting the IRB file



5	選擇填空	研究參與者知情同意書 Informed consent form(s) for research participant(s)		
6	選擇填皂	個案報告表、問卷、訪談大綱 Case reports, surveys, and interview summaries		
7	選擇填富	招募研究參與者文宣 Promotional materials for recruiting research participants		
8	選擇填富	研究團隊倫理訓練切結書 Research Team Affidavit on the Completion of Ethics Training		
9	選擇填包	案件申請相關附件 Others		
###				
× [王持人切結書] 尚未填寫				
□ 確認 5 返回				

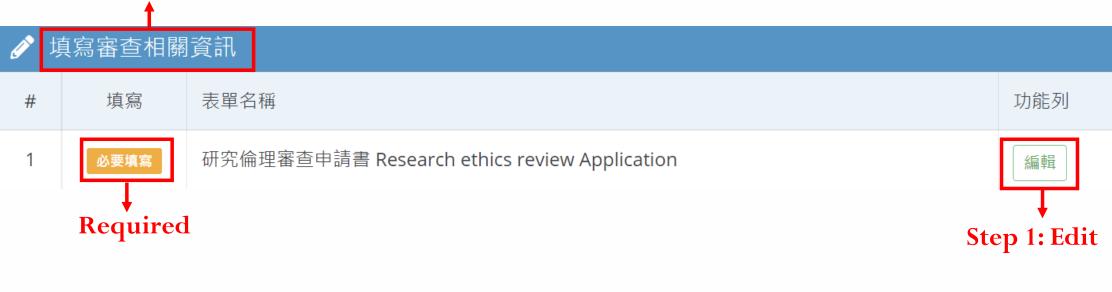


Research Ethics Review Application

Research Ethics Review Application



Fill in the other related information for review



Research Ethics Review Application



National Chengchi University Research Ethics Review Board New Review Application

國立政治大學人類研究倫理審查委員會 研究倫理審查申請書

審查類別	Project type	Step 2: OFull-board review O Expedited review O Exempt review
○ 一般審查 ○) 簡易審查 (請勾選一項)	(Please check one option)
○ 校內案件 ○	校外案件 學生論文 (請勾選一項)	Step 3: OIn-campus project O Off-campus project O Thesis
1.計畫名稱	Project title	(Please check one option)
中文: test	Project title (Chinese)	→Step 4: Fill in the Chinese project title
英文:	Project title (English)	Step 5: Fill in the English project title



2. Principal investigator + Co-principal investigator + Sub-investigator + Research Assistant



When you click "帶入資訊", the number of research ethics training hours or Collaborative Institutional Training Initiative (Citi Program) certification of will appear. If not complete, submit the "Research Team Affidavit on the Completion of Ethics Training" form).



Step 8: 3. Project type (check all that apply): If the project only needs NCCU IRB

→ review and does not require foreign or other off-campus IRB review, please check

"domestic single-center".

3.計畫性質(複選):(說明:若計畫僅需送本校倫理審查,不需送國外或其他校外IRB審查,請勾選「本國單一中心」。)
多國多中心 本國多中心 本國第一中心
International multicenter Domestic multicenter Domestic single-center
其他(請註明):
☐ Other (please specify):
如為社區研究,請說明本研究對社區的影響與協商過程:
☐ For community studies, describe the impact on the community and the negotiation process:



4.研究計畫經費來源	Step 9: 4. Funding source(s)	
委託單位:	Consigning entity:	
○ 學術研究	☐Academic research	
教育部 利	料技部 衛生福利部 國衛院 中研院	□MOE □MOST □MOHW □NHRI □AS
其他(請註明	∄):	□Other (please specify):
其他(請註明)	:	□Other (please specify):
○ 自籌(自行研究	無獲得經費補助)請填寫計畫預算總經費為:	元
Self-funded (inde	pendent project without funding) Total bu	daet·NT\$



Step 10: 5. Project duration: yyyy/mm/dd to yyyy/mm/dd

5.研究起迄期間:		
	至	
計畫實施地點:Step 1	1: Research site:	



聪	Example 2 Contact inform			G. 42 Pl . P. 1. 1	
	帳號	Step 12: Enter account number.	帶入資訊	Step 13: Please click here.	
	聯絡人姓名	Name	單位 (校外單位請加註單位名稱)	Academic Unit	
	職稱	Title	聯絡電話	Contact number	
	手機	Phone number	傳真	Fax	
	E-mail			by the applicant who has	
	聯絡地址	Address	o his/her best knowledge y false or purposely with	e. The applicant agrees to be held held held information.	
	以上資料由本人負責填寫,已經盡力確保內容正確。若有不實或蓄意隱瞞,願負法律上應負之責任。 主持人簽章: 日期: Step 14: Principal investigator signature Date:// (yyyy/mm/dd)				
	(Click"主持人	簽草") Step 15: Save 儲存	R 閉 Closure		



Project Abstract

Project Abstract



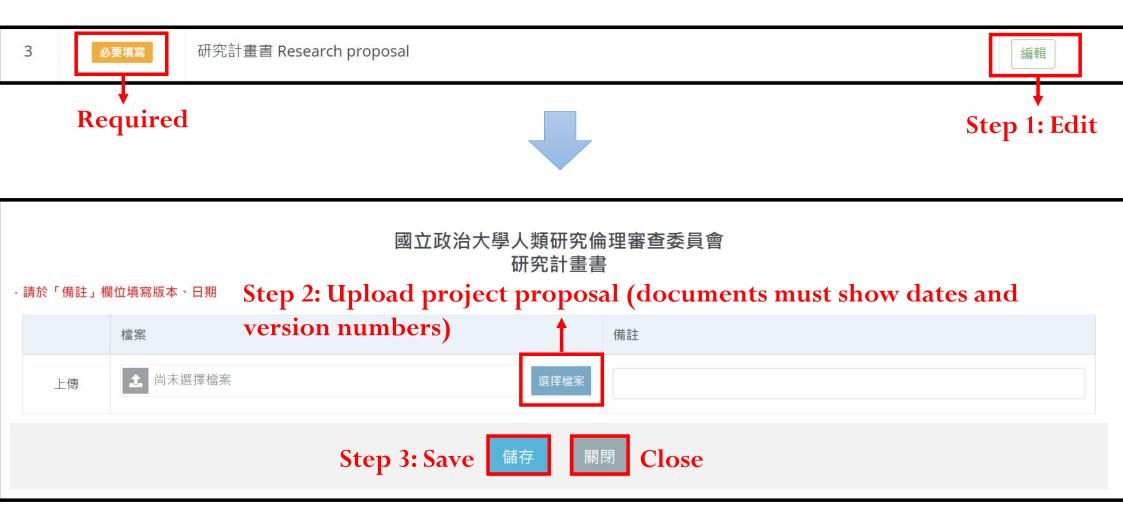




Research Proposal

Research proposal



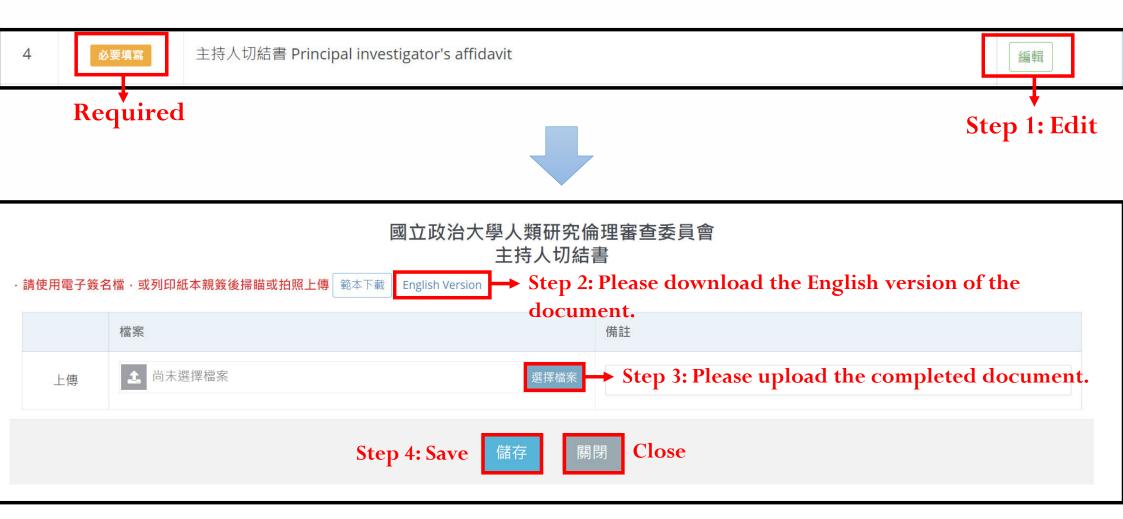




Principal Investigator's Affidavit

Principal Investigator's Affidavit







Informed Consent Form(s) for Research Participant(s)

Informed Consent Form(s) for Research Participant(s)







Case Reports,
Surveys, and
Interview
Summaries

Case Reports, Surveys, and Interview Summaries







Promotional
Materials for
Recruiting
Research
Participants

Promotional Materials for Recruiting Research Participants





國立政治大學人類研究倫理審查委員會 招募研究參與者文宣

· 招募文宣請於「備註」欄位填寫版本、日期 Promotional materials must show dates and version numbers





Research Team Affidavit on Completion of Ethics Training

Research Team Affidavit on the Completion of Ethics Training







Others

Others













案件追蹤查閱 »提供計畫案歷程

計畫案號	NCCU-REC-202106-I068	Project application No.
審查類型	簡易審查案件	Review category
案件類別	新案	New Application
案件名稱		Project title
計畫主持人		Principal investigator's name
證明書	審查證明書	Ethics review approval
追蹤審查頻率	N/A	Follow-up review frequency
歷次審查結果	審查結果▼	Results of previous review
歷次會議結果	會議結果▼	Results of previous meetings
表單	表單資訊▼	Document Information (details see page 62.)







	表單一表單一表單資訊▼	N	ATIONAL	CHENGCH	II UNIVERSI
項次	表單名稱	:	初審	複審1	
1	申覆申請表 Application form's reply	Click this symbol to vi	ew th	e conte	nt of the
2	免審結果通知書 Notice of Exemption Results	information submitted	l in th	e past	
3	未符合簡易審查條件通知書 Notification of failure to meet the requirements of exp	pedited review			
4	審查相關附件 Review related attachments				
5	審查意見回覆單 Review opinion reply form			Q	
6	研究倫理審查申請書 Research ethics review application		Q		
7	計畫摘要 Project abstract		Q		
8	研究計畫書 Research proposal		Q		
9	主持人切結書 Principal investigator's affidavit		Q		
10	研究參與者知情同意書 Informed consent form(s) for research participant(s)				
11	個案報告表、問卷、訪談大綱 Case reports, surveys, and interview summaries		Q	Q	
12	招募研究參與者文宣 Promotional materials for recruiting research participants		Q	Q	
13	研究團隊倫理訓練切結書 Research Team Affidavit on the Completion of Ethics Train	ning			
14	案件申請相關附件 Others				





Step 1: Click the "案件申請暨審查作業" (Application and review work)









Responding to Review Board Opinion 國立政治大學人類研究倫理審查委員會 審查意見回覆單

送審編號: REC-202106-I068			
主持人:胡仁	送審次數	第1次審查	
計畫名稱:臺灣五大人格特質量表常模調查計畫			
審查委員一意見: 網路問卷,不簽署同意書. 建議在covering letter 加上一句: 你回答問卷代表同意參與此研究 類似	以之說明		→ Reviewer's opinion
申請者回覆: 感謝審查委員的建議。我們於covering letter新增「若您閱讀完上述說明本次修改新增第二部分:與直屬主管的互動狀況,共計12個題項,請參求 修改前:		8問卷階段。」	Step 6: Applicant's response Step 7: Content before modification
修改後: 若您閱讀完上述說明並同意參與研究,請按下「開始」,將進入填寫問款 修改文件:□ 參與者同意書 □ 計畫書 ✓ 其他 研究問卷(含covering (備註:請申請人修正時·將任何修改過的文件·以色塊標記修改處後再	letter) 再行上傳·以利加快審查速度。)		(if available) → Step 8: Modified content → Step 9: Please check the files that have been modified
consent form Research pro	oject 🗌 others		

Remarks: When making amendments, please highlight or change text color of any modified sections to make the review process more efficient.



After modifying the content of the file, please upload the updated file.

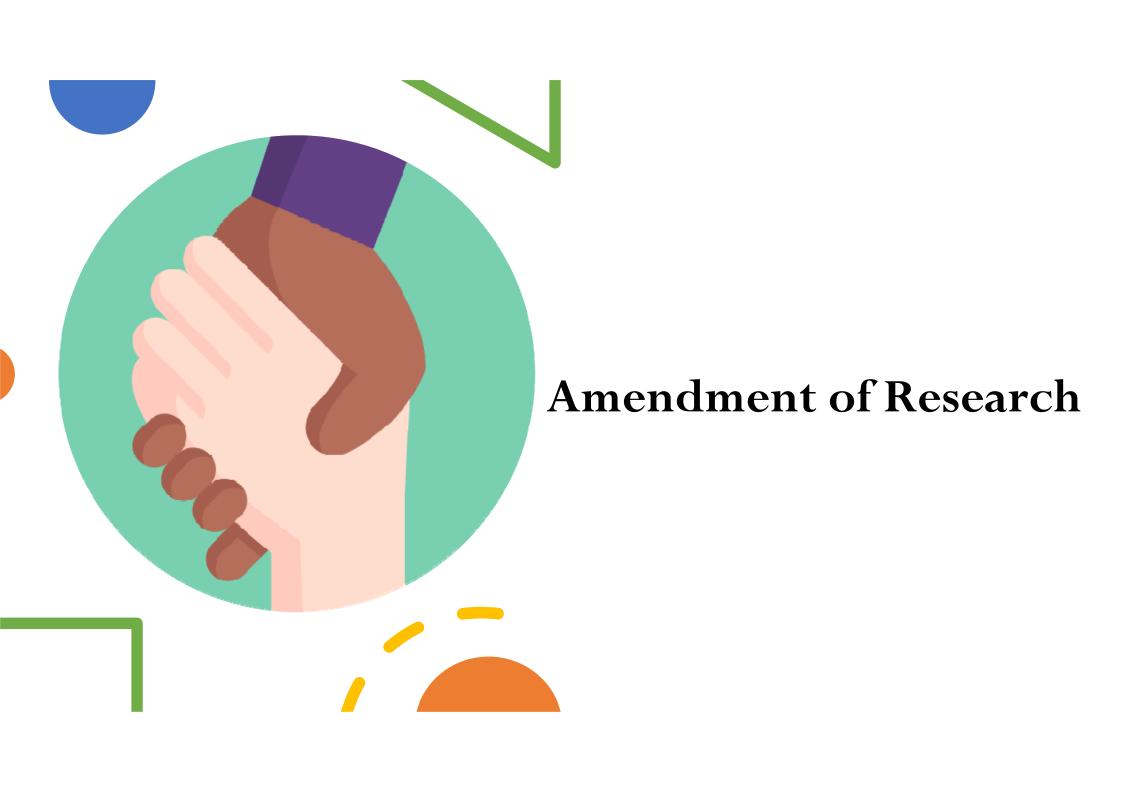
The upload procedure is the same as the new review application process.

This step requires you to pay special attention to each file's requirements and the deadline date.

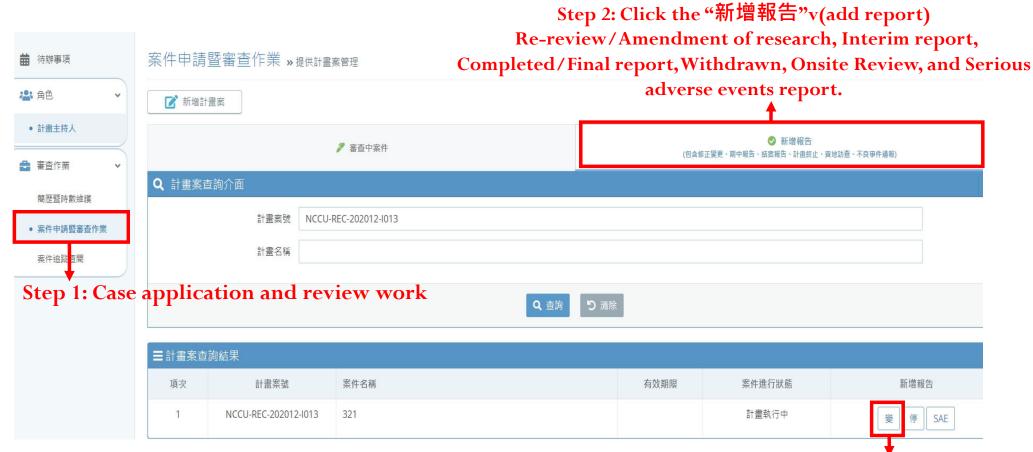
	審查相關資訊		本案歷次相關案件追蹤~
#	填寫	表單名稱	功能列
1	必要填寫	研究倫理審查申請書 Research ethics review Application	編輯
2	必要填寫	計畫摘要 Project abstract	編輯
3	必要填寫	研究計畫書 Research proposal	編輯
4	必要填寫	主持人切結書 Principal investigator's affidavit	編輯
5	必要填寫	審查意見回覆單	編輯
6	選擇填寫	研究參與者知情同意書 Informed consent form(s) for research participant(s)	編章
7	選擇填寫	個案報告表、問卷、訪談大綱 Case reports, surveys, and interview summaries	編輯
8	選擇填寫	招募研究參與者文宣 Promotional materials for recruiting research participants	編輯
9	選擇填寫	研究團隊倫理訓練切結書 Research Team Affidavit on the Completion of Ethics Training	編輯
10	選擇填寫	案件申請相關附件 Others	編章



給下一位意見	比留言給予下一關卡人員查看)
下一步動作	Step 10: Send to administrative staff
	=請選擇=====
初審送と	出【將送至行政人員】



Amendment of Research



Step 3: Re-review/Amendment of research

Amendment of Research





Amendment of Research



Step 2: Click the "修正/變更申請表" (Re-review application) Basic information of the project

政治大學人類研究倫理審查委員會 修正/變更申請表 **Step 4: The times of** 原送審編號: NCCU-REC-202101-I003 修正次數:第 revise/update 計畫名稱(中文): 321 計畫名稱(英文):ewge 主持人 中文姓名 主持人 英文姓名 user01 測試01機構/測試01單位 單位 職稱 主持人 聯絡電話 0987654321 E-mail user01@test.com 研究起訖期間:2020-02-02至2020-02-20

Amendment of Research



Step 2: Click the "修正/變更申請表" (Revise/update application)

修正/變更原因及內容(請詳述)

Step 5: Please explain the reason and content of the Revise/update in detail.

此次修正/變更是否須重新簽署同意書:	Step 6: Is this re-review required to re-sign the consent form? O No
	O Yes
預期修正/變更後帶來的風險 修正/變更後面臨的風險與原計畫相當	•
○ 修正/變更後面臨的風險比原計畫高,	但明顯地可增進參與者的福祉。
○ 修正/變更後面臨的風險比原計畫高,	雖然沒有明顯地增進參與者的福祉,但對於研究主題可得到有價值的結果。
	<u> </u>

Step 7: Anticipate the risks of re-review

- OThe risks of the revision/update are the same as the original project.
- OAfter the revision /update process, the risk is higher than the original project, but it can obviously improve the well-being of participants.
- OAfter the revision /update process, the risk is higher than the original project. Although there is no obvious way to improve the well-being of participants, valuable results can be obtained for the research topic.

Amendment of research



Step 2: Edit "修正/變更申請表 (Re-review application)"

聯絡人資料 Contact info	rmation		
聯絡人姓名	主持人	單位	測試01機構/測試01單位
職稱	主持人	聯絡電話	0987654321
手機		傳真	
E-mail	user01@test.com		
聯絡地址			

以上資料由本人負責填寫,已經盡力確保內容正確。如有不實或蓄意隱瞞,願負法律上應負之責任。



Amendment of research



Step 3: Click the "修正/變更變更前後對照表" (Before-and-after revision / update process comparison table)

國立政治大學人類研究倫理審查委員會 修正/變更前後對照表

Step 10: Download the Chinese template

→ Step 11: Click the "新增"

(add the file)

▼ Step 12: Click the "選擇檔案"

(choose the file)

Step 13: Save 儲存 開閉 Close

Amendment of research



Step 3: Click the "修正/變更變更前後對照表" (before-and-after revision / update process comparison table)

修正/變更前後對照表

1. 原送審編號: Application No.

2. 計畫名稱: Project title

3. 修訂文件: Revised documents

項次	修訂項目	修訂前內容	修訂後內容	修訂理由
1	Revised item	Content before	Modified content	Reason for
2		modification -		revision
3				
4				
5				
6				

本表若不敷使用,請自行延伸,或另紙繕附。





Step 3: Interim report

苗 待辦事項▲ 角色	案件申請 乙 新增計	暨審查作業。提供計畫	畫案管理	Re-review	//Amendment o l report,Withd	增報告" (add re of research, Inter rawn, Onsite Rev ents report.↑	
計畫主持人			🎤 審查中案件		(包含修		實地訪查、不良事件通報)
審查作業 ▼ 簡歷暨時數維護	Q 計畫案查	查詢介面 					^
● 案件申請暨審查作業		計畫案號					
案件追蹤 查閱		計畫名稱					
Step 1: Case ap	plicatio	n and review v	vork	Q 查詢	り清除		
	■計畫案查	詢結果					
	項次	計畫案號	案件名稱		有效期限	案件進行狀態	新增報告
	14	NCCU-REC-202012-I013	321			計畫審查中	期 億 炷 CAE

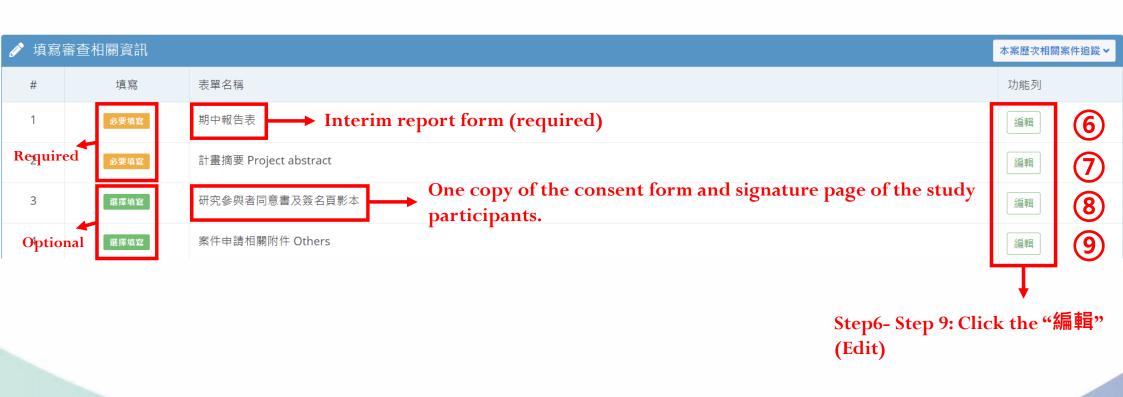


Delete



						<u> </u>
■計畫案查詢結果						
項次	計畫案號	案件類別	案件名稱	案件狀態	日期	功能列
1	NCCU-REC-202012-I013	期中報告	321	待提交	2021-10-20	編輯刪除
						\







Step 6: Interim report form (required)



編輯





政治大學人類研究倫理審查委員會 期中報告表

一、送審編號:NCCU-REC-202012-I013		Application No.	
二、主持人:主持人		Name of principal investigator	
三、計畫名稱	321	Project title	
m ++14 m	bac		
四、核准日期:~		Approval date Reason for interim report:	
五、期中報告原因:		\bigcirc 1.The project has been implemented for one year. \bigcirc 2.The project has collected	
六、期中報告說明:		50% of the samples. () 3.This is a high-risk project. Interim report description	

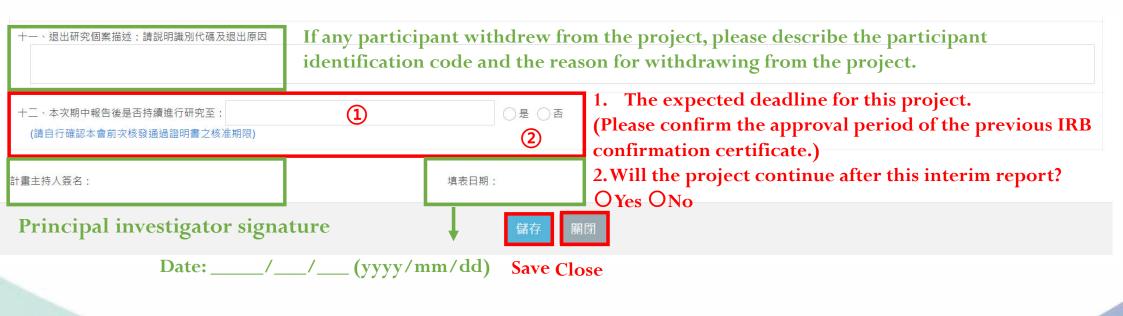
Step 6: Interim report form (required)



七、期中報告日期:為截至	之狀況		Please fill in the last date of data collection for this interim report.
八、第一位參與者收案日期:			Participation date of the first participant.
九、目前總收案人數: 人,預計收案人數	2	Д	1.The current total participants 2. Expected number of participants
十、不良事件(adverse events/AE):	2	人次	1.Total number of people with AE 2.Total number of occurrences of AE
嚴重不良事件(serious adverse events/SAE) : 事件概述及日期:	人;	人交	1. Total number of people with SAE
註:所謂不良事件是指對於研究參與者造成心理、身體或社會性傷害之事件			2.Total number of occurrences of SAE 3. Please describe the SAE incident and the date
			of occurrence.



Step 6: Interim report form (required)



Step 7: Project abstract (required)





Step 8: A copy of the consent form and signature page of the study participants.







🧳 填寫	審查相關資訊		本案歷次相關案件追蹤~
#	填寫	表單名稱	功能列
1	必要填實	期中報告表	編輯
2	必要填宣	計畫摘要 Project abstract	編輯
3	選擇填寫	研究參與者同意書及簽名頁影本	治扁車
4	選擇填寫	案件申請相關附件 Others	公無事中日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日日
	給下一位意見	(可在此留言給予下一關卡人員查看) Advice to administrative staff or reviewers	
	下一步動作	=====:請選擇=====	¥
		=====請選擇=====	
		初審送出【將送至行政人員】 Send to the IRB administrative staff.	









	案件申請	青暨審查作業 »提供計 計畫案	畫案管理	Re-review	v/Amendment o al report,Withd	增報告" (add rej of research, Inter rawn, Onsite Rev ents report.↑	
計畫主持人➡ 審查作業			審查中案件		(包含修	★ 新増報告 正 後更、期中報告、結案報告、計畫終止、到	度地訪查、不良事件通報)
	Q 計畫案	查詢介面					^
簡歷暨時數維護 家件申請暨審查作業		計畫案號					
案件追蹤查閱		計畫名稱					
Step 1: Case ap	plicatio	on and review	work	Q。查詢	り 清除		
	■計畫案函	查詢結果	11				
	項次	計畫案號	案件名稱		有效期限	案件進行狀態	新增報告
	14	NCCU-REC-202012-I013	321			計畫審查中	停結SAE

Step 3: Completed/Final report



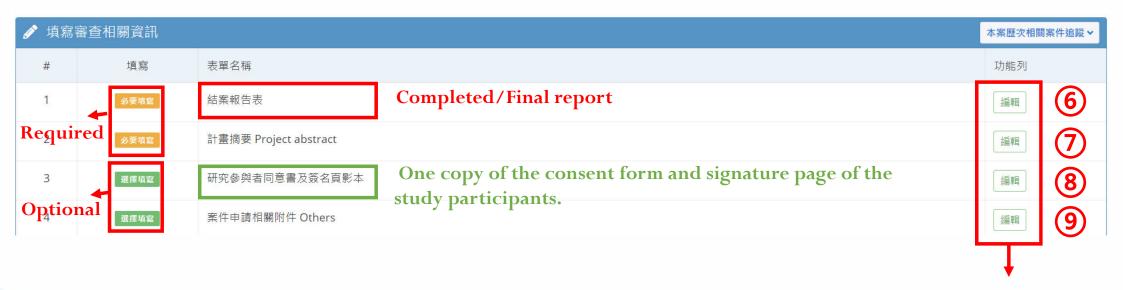
Do you want to create a completed/final report?



Step 5: Enter "編輯 (edit)"

■計畫案查	 詢結果					
項次	計畫案號	案件類別	案件名稱	案件狀態	日期	功能列
1	NCCU-REC-202012-I013	結案報告	321	待提交	2021-10-25	編輯
						▼ Delete





Step6- Step9: Enter "編輯 (Edit)"

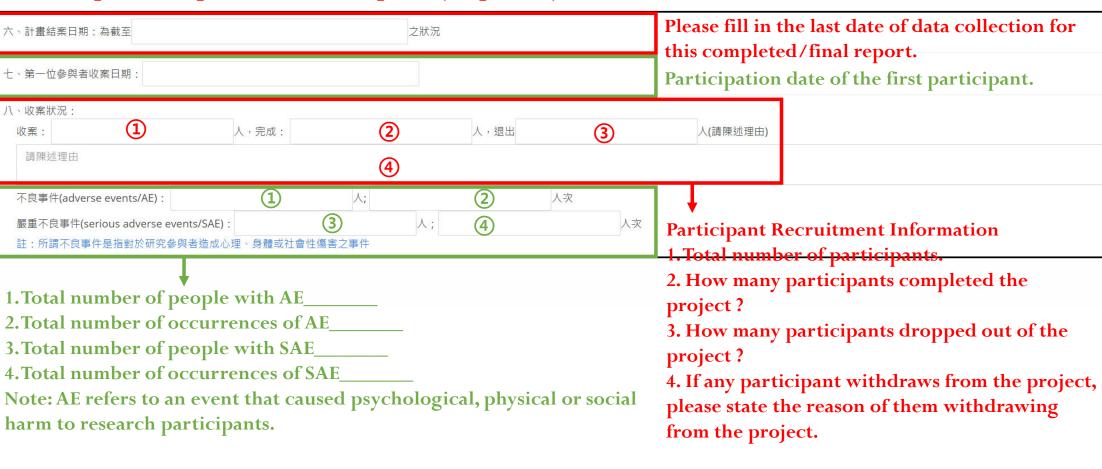


五、計畫委託者(Sponsor)





Step 6: Completed/Final report (required)





Step 6: Completed/Final report (required)

九、不良事件分析結果:	Please explain and analyze the results of AE.				
十、研究材料預計銷毀日期及方式:	The expected date and	method o	f destruction of r	esearch materials	
十一、計畫聯絡人: 電話:0987654321 傳真: 地址:			Project Contact • Phone: • Fax: • Address:		
主持人簽名:		日期:	· Principal investigat	cor signature · Date:	
單位:測試01機構/測試01單位		職稱:主持人	· Unit:	·Title:	
	Sava PH+	BB 88 C1			

Step 7: Project abstract (required)





Save





Close



Step 8: One copy of the consent form and signature page of the study participants.

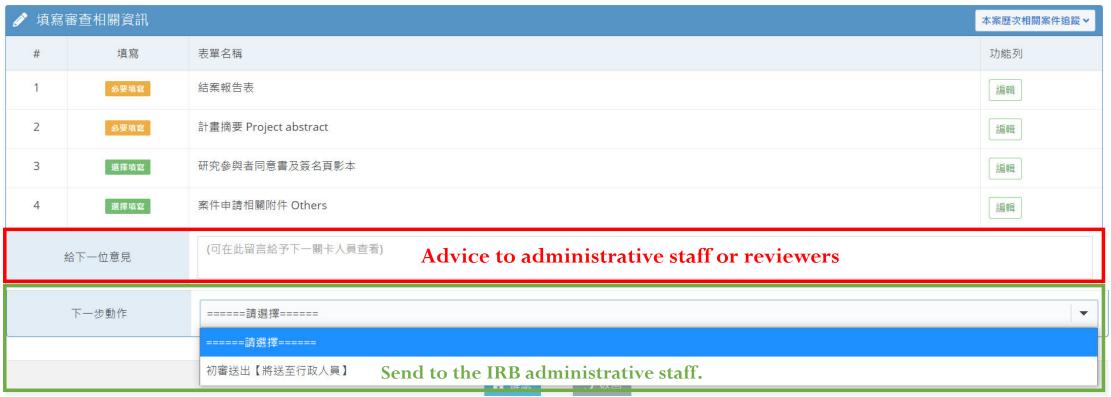


Step 9: Others



Enter "編輯 (edit)"











IRB Office Contacts



• Office of NCCU: http://rec.nccu.edu.tw/page6/super_pages.php?ID=page601

Name	黃麗秋	王心彤
Email	lchuang@nccu.edu.tw	w307@nccu.edu.tw
Extension	66015	62761

IRB Office Contact Information



- IRB file download: http://rec.nccu.edu.tw/downs1/archive.php?class=401
 - Exempt Review Application (NCCU only)
 - Expedited Review Application (NCCU only)
 - Full-Board Review Application (NCCU only)



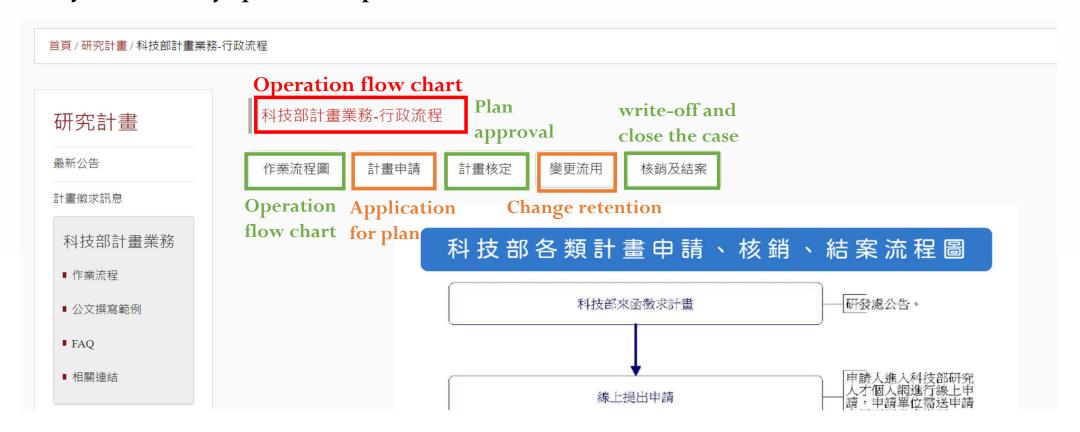
Other Information

* Planning business of the Ministry of Science and Technology of the R&D Office of NCCU:



https://ord.nccu.edu.tw/plan/super_pages.php?ID=plan1

* If you have any questions, please email: research@nccu.edu.tw





* The school provides financial reporting services for the Ministry of Science and Technology, please contact the National Chengchi University's Industry-University Operation and Innovation and Incubation Center

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