

試驗登錄clinicaltrials.gov 操作說明

臨床試驗中心 製作

更新日期 113.07.10

帳號申請表

本中心官網申請辦法

Email至 tcvghcrc@vghtc.gov.tw

Email 主旨：【ClinicalTrials.gov帳號申請】

The image is a screenshot of an email from ClinicalTrials.gov. The header shows the email subject as "ClinicalTrials.gov PRS Account Created" with a "收件匣 x" (Inbox x) icon. The email is addressed to "ClinicalTrials.gov Registration <register@clinicaltrials.gov>" and is marked as "寄給我" (Sent to me). There is a button to "翻譯成中文 (繁體)" (Translate to Chinese (Traditional)). The main body of the email states: "Message generated by ClinicalTrials.gov Protocol Registration and Results System". It then says: "A PRS user account has been created for you." followed by "The PRS URL is <https://register.clinicaltrials.gov>. To login, you will need the following information:" and lists the account details: Organization: C, User Name: Lannanrang, and Password: u72h7iyf. It then instructs the user to "Please login and change your password as soon as possible." and "Also verify that correct." The email also shows the "Full Name:" field and the "E-Mail:" field with the address "lyyang0111@gmail.com". At the bottom, it says: "If you have questions about the system or have trouble logging in, please contact your organization's PRS administrator (troublefup6@cgmh.org.tw)."

帳號申請成功通知信

ClinicalTrials.gov 帳號申請表	
計畫主持人資料	
Investigator Name 完整英文姓名(First Name & Last Name)	
Email Address	
Phone Number	
登錄案件之 IRB 編號	
使用者資料	
User Login Name	
Full User Name	
Other User Information (請填聯絡電話)	
User Email (Login information, including initial password, is sent to this address.)	

首次申請帳號者

對臨床試驗中心提出申請

- Email至：tcvghcerc@vghtc.gov.tw
- Email 主旨：【ClinicalTrials.gov帳號申請】

臨床試驗中心
寄出信件
(帳號申請表)

- 申請人回覆ClinicalTrials.gov帳號申請表
- 需填寫計畫主持人資料及使用者資料

臨床試驗中心
收到PI資料後
開立帳號權限

- 申請人收到ClinicalTrials.gov網站提供的
Organization、Username、Password的信件後，至
ClinicalTrials.gov網站登錄試驗資料

登入

ClinicalTrials.gov PRS Protocol Registration and Results System

Login

Welcome to the [ClinicalTrials.gov](#) Protocol Registration and Results System (PRS).

- **Organization: TaichungVGH**
(本院專用帳號，勿改)

Organization:

One-word organization name assigned by PRS (sent via email when account was created)

Username:

Password:

[Forgot password](#)

Login

- 需先申請帳號才能登入網站
- 如有登錄上的問題可以撥4780來電詢問喔！

新增新研究案 Create a new record

- 輸入帳密後點選 **New Record**後即可開始編輯

ClinicalTrials.gov PRS
Protocol Registration and Results System

Quick Links

[New Record](#)

[Quick Start Guide](#)

[Problem Resolution Guide](#)

Records ▼ Accounts ▼ Help ▼

新增新研究案 Create a new record

✓

* Organization's Unique Protocol ID:

輸入IRB number

✓

* Brief Title:

研究案名稱(不超過3百字)

Special Characters

[*] Acronym:
(if any)

If specified, will be included at end of Brief Title in parentheses.

✓

* Study Type:

☐ Interventional (or clinical trial) — participants assigned to intervention(s) based on a protocol

☐ Observational participants not assigned to intervention(s) based on a protocol; typically in context of routine care

☐ Expanded Access availability of an experimental drug or device outside of a clinical trial protocol

Continue

Cancel

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

新增新研究案 Create a new record

ClinicalTrials.gov **PRS**
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Identification

ID: Test123	Protocol Title Phase I Study	Edit Study Identification
Help Definitions		
* Organization's Unique Protocol ID:	<input type="text" value="Test123"/>	
* Brief Title:	<input type="text" value="Protocol title Phase I study"/>	
[*] Acronym: (if any)	<div><input type="text" value="Phase I"/> <small>If specified, will be included at end of Brief Title in parentheses.</small></div>	
* § Official Title:	<input type="text"/>	
[*] Secondary IDs: (if any)	<div><input type="button" value="+ Add Secondary ID"/></div>	

Ex :
Brief Title: Women's Health Initiative
Acronym: WHI (可自行定義)
Displayed on ClinicalTrials.gov as: Women's Health Initiative (WHI)

新增新研究案 Create a new record

ClinicalTrials.gov *PRS*
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Status

ID: Test123 Protocol Title Phase I Study

Edit Study Status

[Help](#) [Definitions](#)

* Record Verification Date: Month: Year:

* Overall Recruitment Status:
Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: Day: Year: Type:
Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date: Month: Day: Year: Type:
Final data collection date for primary outcome measure.

* § Study Completion Date: Month: Day: Year: Type:
Final data collection date for study.

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Definition:
The date on which the responsible party last verified the clinical study information in the entire ClinicalTrials.gov record for the clinical study, even if no additional or updated information is being submitted.

新增新研究案 Create a new record

ClinicalTrials.gov PRS Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Status

ID: Test123

Protocol Title Phase I Study

[Edit Study Status](#)

[Help](#) [Definitions](#)

* Record Verification Date:

Month: Year:

* Overall Recruitment Status:

Before selecting Suspended, Terminated or Withdrawn see the [Overall Recruitment Status definition](#).

Tip: Day is not required for Anticipated dates.

* § Study Start Date:

Month: Day: Year: Type:

Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date:

Month: Day: Year: Type:

Final data collection date for primary outcome measure.

* § Study Completion Date:

Month: Day: Year: Type:

Final data collection date for study.

[Continue](#)

[Back](#)

[Quit](#)

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed (last participant's last visit has occurred)
- Suspended
- Terminated
- Withdrawn (Study halted prematurely, prior to enrollment of first participant)

新增新研究案 Create a new record

Sponsor/Collaborators

Sponsor/Collaborators

Sponsor: Taichung Veterans General Hospital

Responsible Party: Principal Investigator

Investigator: **IIT研究，此項目需填寫PI本人！！（很重要）**

Official Title: **送審後PI才會再次收到確認信件**

Affiliation: Taichung Veterans General Hospital

Collaborators:

新增新研究案 Create a new record

Oversight

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Oversight

ID: Test123

Protocol Title Phase I Study

[Edit Oversight](#)

[Help](#) [Definitions](#)

* § U.S. FDA-regulated Drug: --Select--

Studying one or more U.S. FDA-regulated drug or biologic products?
For more information see the "Elaboration" in the [Applicable Clinical Trial \(ACT\) Checklist](#) (PDF).

* § U.S. FDA-regulated Device: --Select--

Studying one or more U.S. FDA-regulated device products?
For more information see the "Elaboration" in the [Applicable Clinical Trial \(ACT\) Checklist](#) (PDF).

* U.S. FDA IND/IDE: --Select--

(Not public)

Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

預計向美國FDA申請新藥或新醫療技術登記，才需填YES

* Human Subjects Protection Review:

Board Status: Submitted, approved

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded by the NIH, or IDE. [This information is not made public.]

Approval Number:

本院IRB或TFDA

Board Name:

Board Affiliation:

Board Contact: Phone: Extension:

Email:

Address:

Data Monitoring Committee: --Select--

FDA Regulated Intervention: --Select--

[Continue](#)

[Back](#)

[Quit](#)

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

新增新研究案 Create a new record

Oversight

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Oversight

ID: Test123

Protocol Title Phase I Study

[Edit Oversight](#)

[Help](#) [Definitions](#)

* § U.S. FDA-regulated Drug:

Studying one or more U.S. FDA-regulated drug or biologic products?
For more information see the "Elaboration" in the [Applicable Clinical Trial \(ACT\) Checklist \(PDF\)](#).

* § U.S. FDA-regulated Device:

Studying one or more U.S. FDA-regulated device products?
For more information see the "Elaboration" in the [Applicable Clinical Trial \(ACT\) Checklist \(PDF\)](#).

* U.S. FDA IND/IDE:
(Not public)

Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational Device Exemption (IDE)?

* Human Subjects Protection Review:

Board Status:

The following information is required if the study meets each of these criteria: not required to be registered under 42 CFR Part 11, not funded by the U.S. government, or IDE. [This information is not made public.]

Approval Number:

Board Name:

Board Affiliation:

Board Contact: Phone: Extension:

Email:

Address:

Data Monitoring Committee:

FDA Regulated Intervention:

Choose "YES" or "NO" from the drop down.
計畫案來源或經費與美國FDA有關才需填YES

[Continue](#) [Back](#) [Quit](#)

* Required

* § Required if Study Start Date is on or after January 18, 2017

[*] Conditionally required (see Definitions)

新增新研究案 Create a new record

Study description/ Conditions

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Description

ID: Test123 Protocol Title Phase I Study

Edit Study Description

[Help](#) [Definitions](#)

* Brief Summary:

[Special Characters](#)

Detailed Description:

Avoid duplicating information that will be entered elsewhere, such as Eligibility Criteria or Outcome Measures.

[Continue](#) [Back](#) [Quit](#)

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Home > Record Summary > Protocol Section > Conditions

ID: Test123 Protocol Title Phase I Study

Edit Conditions

[Help](#) [Definitions](#)

* Conditions or Focus of Study:

[x Delete](#)

[Search MeSH](#), the National Library of Medicine's Medical Subject Headings, for valid condition terms.

If there are no conditions under study, enter brief description of focus of study instead.

[+ Add Condition](#)

Keywords:

[+ Add Keyword](#)

[Continue](#) [Back](#) [Quit](#)

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

新增新研究案 Create a new record

Study design

會依前面所選的
研究類型自動帶出

ClinicalTrials.gov PRS
Protocol Registration and Results System

Home > Record Summary > Protocol Section > Study Design

ID: Test123 Protocol Title Phase I Study

Edit Interventional Study Design

Help Definitions (前瞻型)

Study Type: Observational

* Observational Study Model: Cohort

* Time Perspective: Prospective

Biospecimen Retention: None Retained

* Enrollment: Number of Subjects: 300 Type: Anticipated

* Number of Groups/Cohorts: 1

Help Definitions (介入型)

* Study Type: Interventional

* § Primary Purpose: Select

* Study Phase: --Select--

Use "N/A" for trials that do not involve drug or biologic products.

* § Interventional Study Model: --Select--

Model Description:

* § Number of Arms:

Treatment
Prevention
Diagnostic
Supportive
Care
Screening
Health
Services
Research
Basic
Science
Device
Other

Single Group
Parallel
Crossover
Factorial
Sequential

Note: "Arm" means a pre-specified group or subgroup of participant(s) in a clinical trial assigned to receive specific intervention(s) (or no intervention) according to a protocol.

新增新研究案 Create a new record

Study design

* § Masking:

- ☐ Participant
- ☐ Care Provider
- ☐ Investigator
- ☐ Outcomes Assessor
- ☐ None (Open Label)

Check all roles that are masked or check None (Open Label).

Masking Description:

* § Allocation:

Select N/A for single-arm studies.

* § Enrollment: Number of Participants: Type:

* Required
* § Required if Study Start Date is on or after January 18, 2017
[*] Conditionally required (see Definitions)

Definition: The method by which participants are assigned to arms in a clinical trial.

- N/A (not applicable)
- Randomized
- Nonrandomized

Definition: The estimated total number of participants to be enrolled (target number) or the actual total number of participants that are enrolled in the clinical study.

新增新研究案 Create a new record

Registration

[Edit](#)

Study Identification

Unique Protocol ID: 1

Brief Title: 1

NOTE: Titles should be in proper title case.

ERROR: A title this short cannot be sufficiently descriptive.

Official Title:

ERROR: Official Title has not been entered.

Secondary IDs:

[Edit](#)

Study Status

Record Verification:

Overall Status:

Study Start:

Primary Completion:

Study Completion:

Information is required

若要繼續編輯或修改，
選擇Edit繼續編輯

※輸入完成後詳細檢視您登錄的資料，
如出現紅色字體(ERROR)為登錄資料不完全

新增新研究案 Create a new record

Registration

ClinicalTrials.gov PRS
Protocol Registration and Results System

[Contact ClinicalTrials.gov PRS](#)

User: davidhk.ma [Logout](#)

[Home](#) > Record Summary

ID: Test123

Protocol Title Phase I Study

[NCT ID not yet assigned]

Record Summary

[Home](#) [Help](#)

Record Status

In Progress → Entry Completed → Approved → Released → PRS Review → Public

Next Step: Finish Protocol section **Entry Complete** ?

Record Owner: davidhk.ma

Last Update: 05/21/2019 04:19 by davidhk.ma

Initial Release: [Not yet released]

Access List: [Edit](#)

Upload: Allowed [Edit](#)

PRS Review: [Not yet released]

Public Site: [Not yet registered]

FDAAA: Unknown (insufficient information entered) ?

[Spelling](#) [Preview](#) Draft Receipt ([PDF](#) [RTF](#)) [Download XML](#) [Delete...](#)

[Open](#) Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Test123

Brief Title: Protocol Title Phase I Study (Pase I)

Module Status: Study Identification: 1 Error 2 Notes

Study Status: 4 Errors

Sponsor/Collaborators: ✓

Oversight: 8 Errors

Study Description: Information is required

Conditions: Information is required

Study Design: 6 Errors

Arms and Interventions: Information is required

Outcome Measures: 3 Errors 1 Note

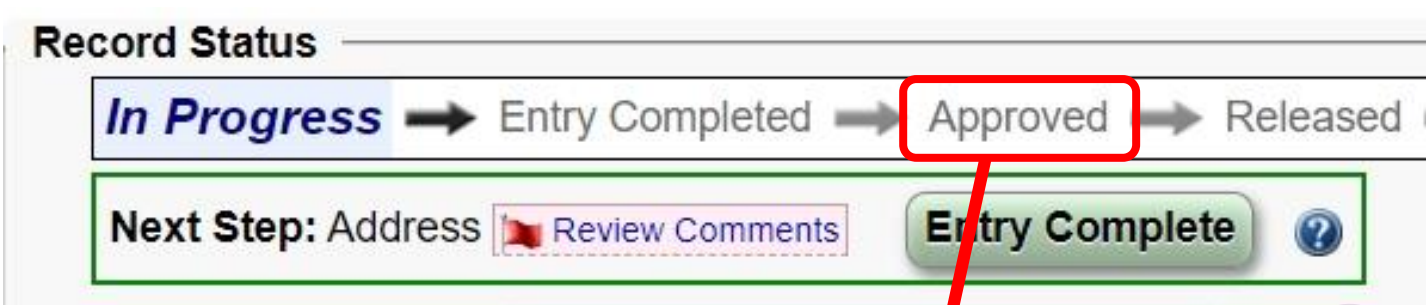
Eligibility: Information is required

Contacts/Locations: Information is required

IPD Sharing Statement:

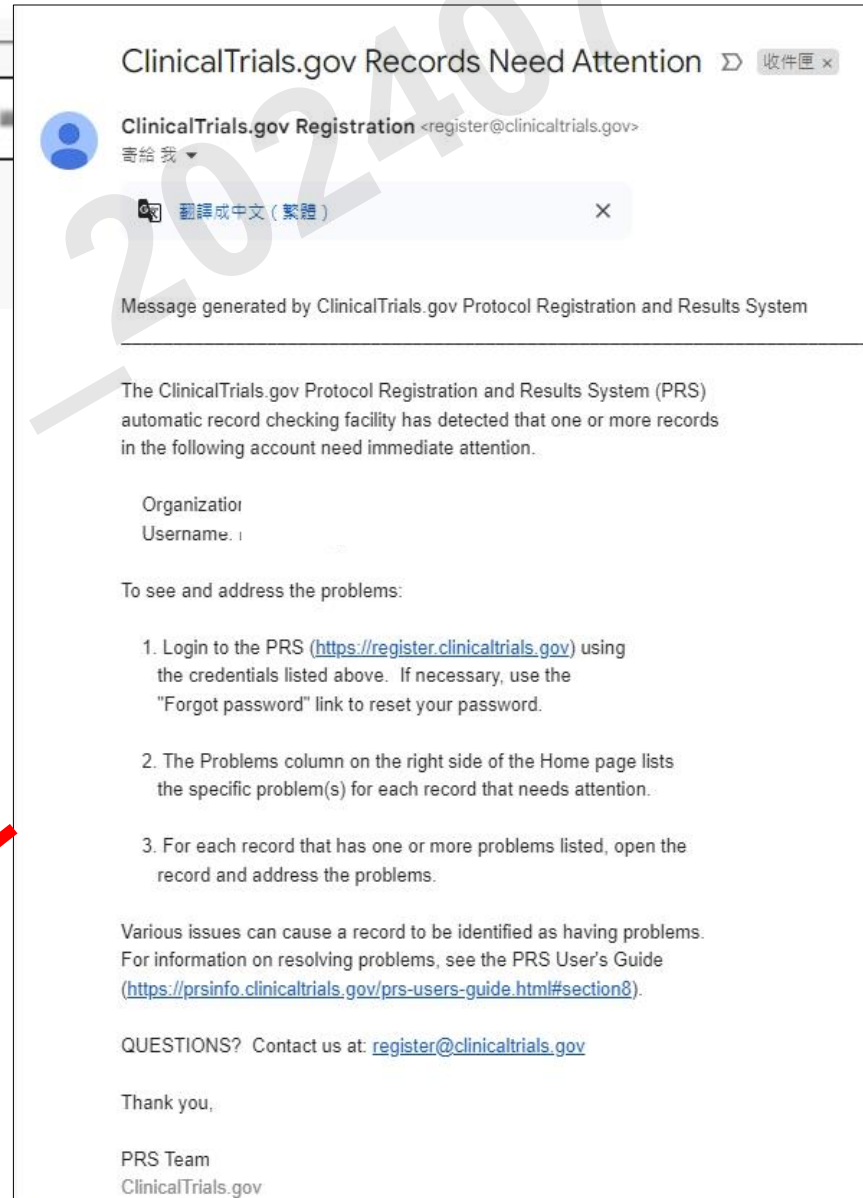
References:

新增新研究案 Create a new record



此狀態網站會寄確認信件給PI，需至信件點選“同意”才會開始進入審查階段

PI收到這封信件點選**Approved**後才會進到下一階段



新增新研究案 Create a new record

Study Result

- Results Section
 1. Participant Flow
 2. Baseline Characteristics
 3. Outcome Measures
 4. Adverse Event Information
 5. Limitations and Caveats
 6. Certain Agreements
 7. Results Point of Contact
 8. Delayed Results (Optional)

Study completion 之後再填
填寫Results Section後無法再修改變更登錄資料

總結

若沒有正確填寫試驗計畫資料，系統將拒絕此計畫登錄作業

需於招募第一位受試者前完成臨床試驗計劃登錄作業

補登容易發生邏輯錯誤以及影響科學性

進行中的臨床試驗，需每6個月更新所登錄的資料內容

已結案之臨床試驗計畫需填寫試驗結果(Result)

英文版protocol (draft可)為必備文件