

高雄榮總經人體研究倫理審查委員會審查通過之 人體研究計畫主持人 Clinical Trials 登入流程

步驟1：醫師確實填寫以下資料後，傳至受試者保護中心：

irb@vghks.gov.tw

步驟2：由受試者保護中心向IRB 確認此計畫案件是否經 IRB 審核通過並協助轉由臨床試驗科申請帳號。

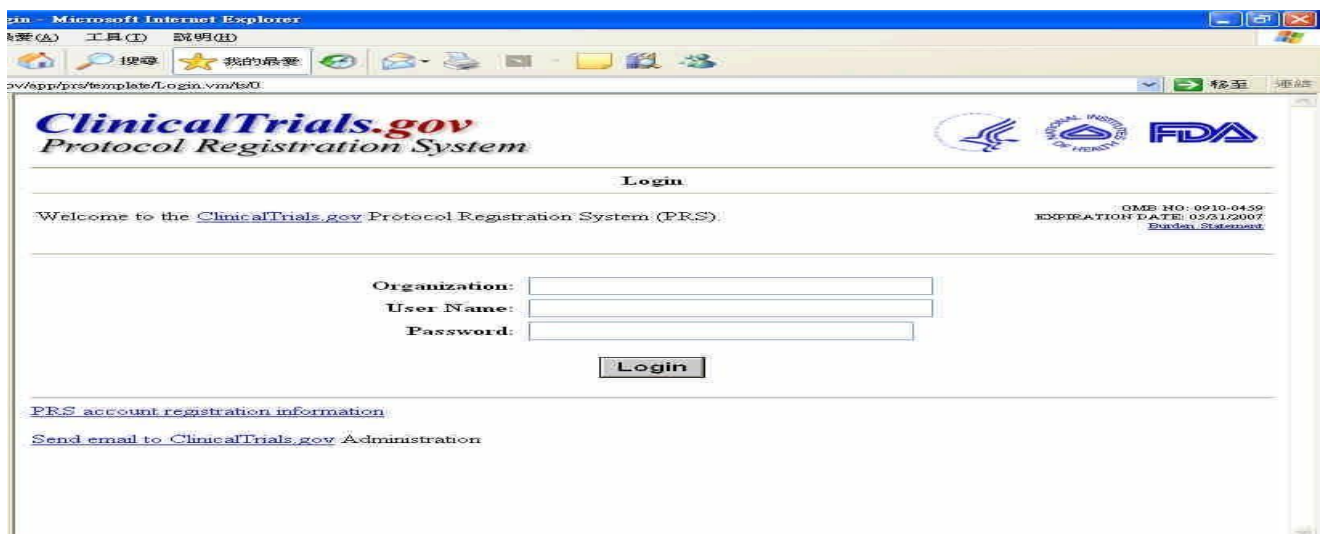
步驟3：再進入<https://register.clinicaltrials.gov/>將計畫資料填寫完整。

中文姓名		英文姓名	
IRB計畫編號 (同意函)			
中文計畫名稱			
英文計畫名稱			
聯絡電話			
E-mail			

(針對計畫內容進行的撰寫如需協助可洽教研部臨床試驗科姜茜如小姐，分機71542)

PI登錄流程

當收到 clinicaltrials.gov 給之 Organization、User name、Password 的信件時，請 PI 至以下網址 <https://register.clinicaltrials.gov/app/prs/template/Login.vm/ts/0> 登錄您的資料，畫面如下。於此網頁輸入後



The screenshot shows the login page of the ClinicalTrials.gov Protocol Registration System (PRS) in a Microsoft Internet Explorer browser. The page title is "ClinicalTrials.gov Protocol Registration System". The main heading is "Login". Below the heading, there is a welcome message: "Welcome to the ClinicalTrials.gov Protocol Registration System (PRS)". To the right, there is a small box containing "GMS NO: 0910-0459", "EXPIRATION DATE: 09/31/2007", and "Prada, Shantou". The login form consists of three input fields: "Organization:", "User Name:", and "Password:". Below these fields is a "Login" button. At the bottom of the page, there are two links: "PRS account registration information" and "Send email to ClinicalTrials.gov Administration".

會出現下面畫面如下，在此畫面按 "Create "



The screenshot shows the main menu of the ClinicalTrials.gov Protocol Registration System (PRS) in a Microsoft Internet Explorer browser. The page title is "ClinicalTrials.gov Protocol Registration System". The main heading is "Main Menu". Below the heading, there is a link to "Quick Start Guide (for first-time users)". The main content area is a table with four sections: "Protocol Records", "User Account", "Help", and "Session". Each section contains a list of links. The "Protocol Records" section includes "Create", "Modify", "View", and "Undelete". The "User Account" section includes "Change password". The "Help" section includes "What's New", "User's Guide", "Data Element Definitions", "Registration Requirements", and "FDAMA 113 Requirements". The "Session" section includes "Logout".

當您按下"Create"後會出現下面畫面

The screenshot shows the 'Create New Protocol Record' page on the ClinicalTrials.gov website. The page header includes the site logo and navigation links. A red-bordered box contains important instructions: 'Especially for multi-site trials, data submitters must coordinate with all of their partners such that trial information is submitted only once to ClinicalTrials.gov.' and 'All studies submitted to ClinicalTrials.gov must have approval from a human subjects review board, such as an Institutional Review Board, ethics committee or equivalent group.' Below this, a note states: 'NOTE: In the PRS data entry screens that follow, data elements (fields) required by ClinicalTrials.gov, and those additional data elements associated with WHO/ICMJE policy, are identified.' The form has two input fields: 'Unique Protocol ID: *' and 'Brief Title: *'. At the bottom, there are 'Continue' and 'Cancel' buttons. A legend indicates that '*' denotes 'Required' fields, and 'WHO' and 'WHO/ICMJE' refer to specific policy requirements.

點選藍色框框字體會出現小對話視窗說明資料之填寫，如下：

This screenshot shows the same 'Create New Protocol Record' page as before, but with a tooltip window open over the 'Unique Protocol ID' field. The tooltip, titled 'https://register.clinicaltrials.gov - Cli...', provides a definition: 'Organization's Unique Protocol ID * Definition: Unique identification assigned to the protocol by the sponsoring organization, usually an accession number or a variation of a grant number. Multiple studies conducted under the same grant must each have a unique number. Examples: CC-99-H-0020, R01-102456-1, R01-102456-2'. The background page remains the same, showing the instructions and the form fields.

填寫完後按左下角” Continue”

The screenshot shows the 'Create New Protocol Record' page on the ClinicalTrials.gov website. The page header includes the site logo and navigation links. A red box highlights the instruction: 'Please specify both a Brief Title and a Unique Protocol Id'. Below this, a note states: 'Especially for multi-site trials, data submitters must coordinate with all of their partners such that trial information is submitted only once to ClinicalTrials.gov. All studies submitted to ClinicalTrials.gov must have approval from a human subjects review board, such as an Institutional Review Board, ethics committee or equivalent group.' A second note explains that data elements required by ClinicalTrials.gov and WHO/ICMJE policy are identified. The form contains two input fields: 'Unique Protocol ID: *' and 'Brief Title: *'. At the bottom, there are 'Continue' and 'Cancel' buttons. A legend indicates that '*' denotes 'Required', 'WHO' denotes 'WHO', and 'WHO/ICMJE' denotes 'WHO/ICMJE'.

Microsoft Internet Explorer

愛(A) 工具(T) 說明(H)

搜尋 我的最愛

rv/app/prs/action/CreateStudy/ts/6/uid/U00008&N

ClinicalTrials.gov
Protocol Registration System

Create New Protocol Record

Please specify both a Brief Title and a Unique Protocol Id

Especially for multi-site trials, data submitters must coordinate with all of their partners such that trial information is submitted only once to ClinicalTrials.gov.

All studies submitted to ClinicalTrials.gov must have approval from a human subjects review board, such as an Institutional Review Board, ethics committee or equivalent group.

NOTE: In the PRS data entry screens that follow, data elements (fields) required by ClinicalTrials.gov, and those additional data elements associated with WHO/ICMJE policy, are identified.

Unique Protocol ID: *

Brief Title: *

Continue Cancel

* Required WHO WHO/ICMJE

ds.gov/app/prs/action/CreateStudy/ts/7/uid/U00008&N...

網際網路

” Continue”

The screenshot shows the 'Protocol Registration System' page on the ClinicalTrials.gov website. The page header includes the site logo and navigation links. A red box highlights the instruction: 'Please specify both a Brief Title and a Unique Protocol Id'. Below this, a note states: 'Especially for multi-site trials, data submitters must coordinate with all of their partners such that trial information is submitted only once to ClinicalTrials.gov. All studies submitted to ClinicalTrials.gov must have approval from a human subjects review board, such as an Institutional Review Board, ethics committee or equivalent group.' A second note explains that data elements required by ClinicalTrials.gov and WHO/ICMJE policy are identified. The form contains several input fields: 'Unique Protocol ID: *', 'Brief Title: *', 'Official Title: WHO', 'Secondary ID's: WHO (One ID per line)', and 'IND/IDE Protocol? *'. At the bottom, there are 'Continue' and 'Quit' buttons. A legend indicates that '*' denotes 'Required', 'WHO' denotes 'WHO', and 'WHO/ICMJE' denotes 'WHO/ICMJE'.

Microsoft Internet Explorer

愛(A) 工具(T) 說明(H)

搜尋 我的最愛

rv/app/prs/action/CreateStudy/ts/17/uid/U00008&N

Protocol Registration System

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: The Effect of Early Physical Therapy Intervention for... ID: 1

Unique Protocol ID: * Enter sponsoring organization's unique identifier.
K44445564576

Brief Title: * Use lay language.
Example: Safety Study of Recombinant Vaccinia Virus Vaccine to Treat Prostate Cancer
The Effect of Early Physical Therapy Intervention for Recover...

Official Title: WHO Example: Phase 1 Study of Recombinant Vaccinia Virus That Expresses Prostate Specific Antigen in N Prostate

Secondary ID's: WHO (One ID per line) Include ISRCTN, NIH grant or contract numbers. Secondary ID may be left blank if there are no addi

IND/IDE Protocol? * Indicate whether the protocol is subject to US Food and Drug Administration regulations, under an Inv Application or Investigational Device Exemption (IDE).
--Select--

Continue Quit

* Required WHO WHO/ICMJE

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” Continue”

plorer

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搜尋 我的最愛

iv/app/prs/action/EditTitle/ts/18/aid/U00008&N/sid/S00000PG

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Protocol Registration System

Title Oversight **Sponsor** Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: The Effect of Early Physical Therapy Intervention for... ID: II

Provide information for the human subjects review board, such as an Institutional Review Board (IRB), ethics committee or equivalent group, that is responsible for the review and monitoring of this protocol. For studies involving multiple review boards, provide information only for a single board.

If review board approval has been granted, enter the approval number below.
Please send a signed board approval letter to ClinicalTrials.gov ([address and instructions](#)).

Board Approval: *

Status: Submitted, approved Approval Number:

Board Name: *

Board Affiliation: *

Board Contact: *
(Not made public)

Business Phone: Extension:

Business Email:

Business Address:

Overview Enter in English country followed by organization name

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” Continue”

plorer

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搜尋 我的最愛

iv/app/prs/action/PopulateStudy/ts/19/aid/U00008&N/sid/S00000PG

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ClinicalTrials.gov Protocol Registration System

Title Oversight **Sponsor** Summary Status Design Interventions Conditions Eligibility Locations Citations Links

Title: The Effect of Early Physical Therapy Intervention for... ID: 1...

Sponsor: *

Kaoshing Medical University Chung-Ho Memorial Hospital

Collaborators: WHO
(Enter up to 10 agencies, one agency per line)

Include all additional funding sources. Collaborators may be left blank if the lead sponsor has sole responsibility sole funding source

Continue **Quit**

* Required WHO WHO/ICMJE

網際網路

Internet Explorer

http://www.clinicaltrials.gov/ct2/show/study?term=...

ClinicalTrials.gov
Protocol Registration System

[Title](#)
[Oversight](#)
[Sponsor](#)
[Summary](#)
[Status](#)
[Design](#)
[Interventions](#)
[Conditions](#)
[Eligibility](#)
[Locations](#)
[Citations](#)
[Links](#)

Title: The Effect of Early Physical Therapy Intervention for... ID: NCT00000000

Brief Summary: [\(Formatting tips\)](#)

Use lay language. Include a statement of the study hypothesis.

Detailed Description: [\(Formatting tips\)](#)

網路網路

[Home](#)
[Help](#)
[My Favorites](#)
[Refresh](#)
[Print](#)
[Back](#)
[Forward](#)
[Stop](#)

[http://www.clinicaltrials.gov/](#)
[移至...](#)

ClinicalTrials.gov Protocol Registration System





[Title](#)
[Oversight](#)
[Sponsor](#)
[Summary](#)
[Status](#)
[Design](#)
[Interventions](#)
[Conditions](#)
[Eligibility](#)
[Locations](#)
[Citations](#)
[Links](#)

Title: The Effect of Early Physical Therapy Intervention for... ID: KMH-IRB-94079

Study Phase: * --Select--

Study Type: *
 ☒ [Interventional](#)
☐ [Observational](#)

Overall Recruitment Status: * --Select--

Record Verification Date: * --Select-- Year:

Key Trial Dates

Study Start Date: WHO --Select-- Year:

Last Follow-Up Date: --Select-- Year:

Data Entry Closure Date: --Select-- Year:

Study Completion Date: --Select-- Year:

* Required WHO WHO/ICMJE

” Continue”

Continued

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v/app/pr/action/StudyPurpose/ts/22/sid/U00008&N/sid/S00000ORG

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Title Oversight Sponsor Summary Status **Design** Interventions Conditions Eligibility Locations

Title: The Effect of Early Physical Therapy Intervention for... ID: J

NOTE: These attributes apply to an "Interventional" study. If desired, [change the study type to "Observational"](#)

Purpose: --Select--

Allocation: --Select--

Masking: --Select--

Control: --Select--

Assignment: --Select--

Endpoints: --Select--

Primary Outcome Measures: WHO
(One per line)

Secondary Outcome Measures: WHO
(One per line)

Secondary Outcome Measures may be left blank if no additional outcomes are under:

Continue Quit

* Required WHO WHO/ICMJE

網路網路

” Continue”

The screenshot shows the ClinicalTrials.gov website interface. At the top, there is a navigation bar with the site name and a search bar. Below this, a breadcrumb trail shows the path: Home > Search > Study Results > Study Details > Interventions. The main content area displays the study title 'The Effect of Early Physical Therapy Intervention for...' and a table with columns for 'Intervention', 'Description', and 'Status'. The table is currently empty, with a message stating 'There are no Interventions currently listed for this study.' The bottom of the page features a footer with the text 'ClinicalTrials.gov' and 'U.S. Department of Health and Human Services'.

” Continue”

explorer

http://www.clinicaltrials.gov/ct2/show/study/summary?term=The+Effect+of+Early+Physical+Therapy+Intervention+for+...&rank=1

ClinicalTrials.gov
Protocol Registration System

Title Oversight Sponsor Summary Status Design Interventions **Conditions** Eligibility Locations Citations Links

Title: The Effect of Early Physical Therapy Intervention for... ID: 1

Specify the primary condition or disease being studied.

Conditions are checked against the National Library of Medicine's Medical Subject Headings (MeSH).
[Search MeSH](#) for a specific condition term.

Conditions: *
(Enter 1 to 5 conditions, one per line)

Keywords:
(One per line)

Continue **Quit**

* Required WHO WHO/ICMJE

” Continue”

explorer

http://www.clinicaltrials.gov/ct2/show/study/summary?term=The+Effect+of+Early+Physical+Therapy+Intervention+for+...&rank=1

ClinicalTrials.gov
Protocol Registration System

Title Oversight Sponsor Summary Status Design Interventions Conditions **Eligibility** Locations Citations Links

Title: The Effect of Early Physical Therapy Intervention for... ID: 1

Eligibility Criteria: *

(Formatting tips)

Gender: * --Select--

Age Limits: * Minimum: --Select-- Maximum: --Select--

Participants: Healthy Volunteers? --Select--

Target Number of Subjects: WHO

Continue **Quit**

* Required WHO WHO/ICMJE

” Continue”

The screenshot shows a web browser window titled "plorer" displaying the "ClinicalTrials.gov Protocol Registration System" interface. The browser's address bar shows the URL: `iv/app/prs/action/PopulateStudy/ts/26/uid/U000008&N/sid/S000000PG`. The page features a navigation menu with tabs: Title, Oversight, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, **Locations**, and Citations. The "Locations" tab is active, showing the title "Title: The Effect of Early Physical Therapy Intervention for..." and the ID "ID: 1". Below the navigation menu, there are three instructions: "Specify the Central Contact * with overall recruiting responsibility for this study.", "Specify the Study Officials/Investigators * with overall scientific responsibility for this study.", and "Add a location to this Study.". To the left of these instructions are two buttons: "Continue" and "Quit". Below the instructions, there is a section labeled "Locations: *" with a message: "There are no Locations currently listed for this study.". At the bottom right, there are links for "* Required", "WHO", and "WHO/ICMJE". The browser's status bar at the bottom shows "網際網路" (Internet).

” Continue”

The screenshot shows the same web browser window as the previous one, but now displaying the "Citations" tab. The address bar shows the URL: `iv/app/prs/action/AddLocation/ts/27/uid/U000008&N/sid/S000000PG`. The navigation menu is the same, but the "Citations" tab is now active. The title "Title: The Effect of Early Physical Therapy Intervention for..." and the ID "ID: 1" are still visible. Below the navigation menu, there is a prompt: "Provide Citations of publications related to the protocol, background or results.". To the left of this prompt are two buttons: "Continue" and "Quit". To the right of the buttons is a link: "Add a Citation to this study, if applicable.". Below the prompt, there is a section labeled "Citations:" with a message: "There are no Citations currently listed for this study.". The browser's status bar at the bottom shows "網際網路" (Internet).

” Continue”

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http://www.clinicaltrials.gov/ct2/addLinkItem.jspx?ts/29/uid/U00008AN/sid/S00000PG

ClinicalTrials.gov
Protocol Registration System

Title Oversight Sponsor Summary Status Design Interventions Conditions Eligibility Locations Citations **Links**

Title: The Effect of Early Physical Therapy Intervention for... ID: J290008AN/S00000PG

Use this screen to provide pointers to web pages directly relevant to the protocol. Provide up to 5 suggested links.

Links to educational, research, government, and other non-profit Web pages are acceptable. All submitted links are subject to review by ClinicalTrials.gov.

Links: There are no Links to related web pages currently listed for this study.

網際網路

” Continue”

Microsoft Internet Explorer

愛(A) 工具(T) 說明(H)

http://www.clinicaltrials.gov/ct2/addLinkItem.jspx?ts/29/uid/U00008AN/sid/S00000PG

ClinicalTrials.gov
Protocol Registration System

Protocol Record Completed

Title: The Effect of Early Physical Therapy Intervention for... ID: J290008AN/S00000PG

You have reached the last data entry screen. Proceed to the next screen (Edit Protocol) to review the entire record.

Note that the data that you have entered are automatically validated by the system. Messages describing problems of varying severity (Errors, Alerts, or Notes) are included on the Edit Protocol screen, beneath the relevant fields. Review each message and take the appropriate action.

Once the record is ready for review by your administrator, click on the "Complete" link near the top of the Edit Protocol Record screen to mark the record as completed. Your administrator must then "Approve" and "Release" the record, in order for the record to be submitted for final Quality Assurance review and publication on the ClinicalTrials.gov web site.

網際網路

當您按下 ok 時,會出現以下畫面

Internet Explorer

愛(A) 工具(T) 說明(H)

搜尋 我的最愛

移至 連結

rw/app/prs/action/Navigate/ts/30/hsd/U00008AN/sid/S00000FG

Edit Protocol Record

Errors in protocol data. See messages below.

[Main Menu](#) [Select](#) [Preview](#) [Spelling](#) [Edit All](#) [Delete](#)

Next Action: [Complete](#)

Record Status: **In Progress** | [Completed](#) | [Approved](#) | [Released](#)
Owned by: CLin (jesipt@kmu.edu.tw) Last updated: 01/11/2006 02:33
by CLin (jesipt@kmu.edu.tw)
Initial release: [not yet released]

[Edit](#) Comments: None

[Edit](#) Unique Protocol ID: 9
Secondary IDs:
ClinicalTrials.gov ID:
Brief Title: Function After Breast Surgery for Breast Cancer
NOTE: Brief Title should have no more than 120 characters.
Official Title:
IND/IDE Protocol?

ALERT: IND Protocol: data not entered.

網際網路

詳細檢視您登錄的資料, 如出現紅色字體為登入不完全, 如下:

Internet Explorer

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rw/app/prs/action/SelectProtocol/sid/S00000FG/selection/Edit/ts/30/hsd/U00008AN

[Edit](#) Collaborators:

[Edit](#) Review Board: Approval Status: Approved
Board Name:
Board Affiliation:
ALERT: Approval Number: data not entered.
ALERT: Board Name: data not entered.
ALERT: Board Affiliation: data not entered.
ALERT: Neither Board Phone nor Email was entered.

Oversight Authorities:
ALERT: Oversight Authorities not entered.

[Edit](#) Brief Summary:
ERROR: Brief Summary is a required field.

Detailed Description:
NOTE: Detailed Description: data not entered.

[Edit](#) Phase:
ERROR: Phase is a required field.

Study Type: Interventional

Overall Status:
ERROR: Overall Status is a required field.

Record Verification Date:
ERROR: Verification Date is a required field.

Study Start Date:
NOTE: Study Start Date not entered.

Last Follow-Up Date:

網際網路

若無法當次完成登錄所有資料請勿按“Complete”，請至畫面左下角按“Main Menu”
再按“Modify”畫面如下：



進入”Modify”網頁可檢視您剛剛編輯未完成的案子，確定資料以存在您帳號中，再按左下角”Main Menu”回至



按” [Logout](#)”可登出此計劃案。

如要編輯已存於您帳號內未完整的計劃案,再至”Main Menu”中按”[Modify](#)”,畫面如下:

如續編輯或修改案子,請進入”Modify”內按”[Edit](#)”即可編輯或修改案件。



若按下” [Complete](#)”,待 IRB 與 ClinicalTrials 聯繫確認所有資料無誤,數天後便可於 ClinicalTrials 網頁<http://clinicaltrials.gov/ct> 查詢到您登錄的計劃案



範例:

於 ClinicalTrials 網頁 <http://clinicaltrials.gov/ct> 的 search 框內輸入 ChimeiMC 即可查詢到您登錄的計劃案 畫面如下:



出現以下畫面時可點選欲知之案件即可

