

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。

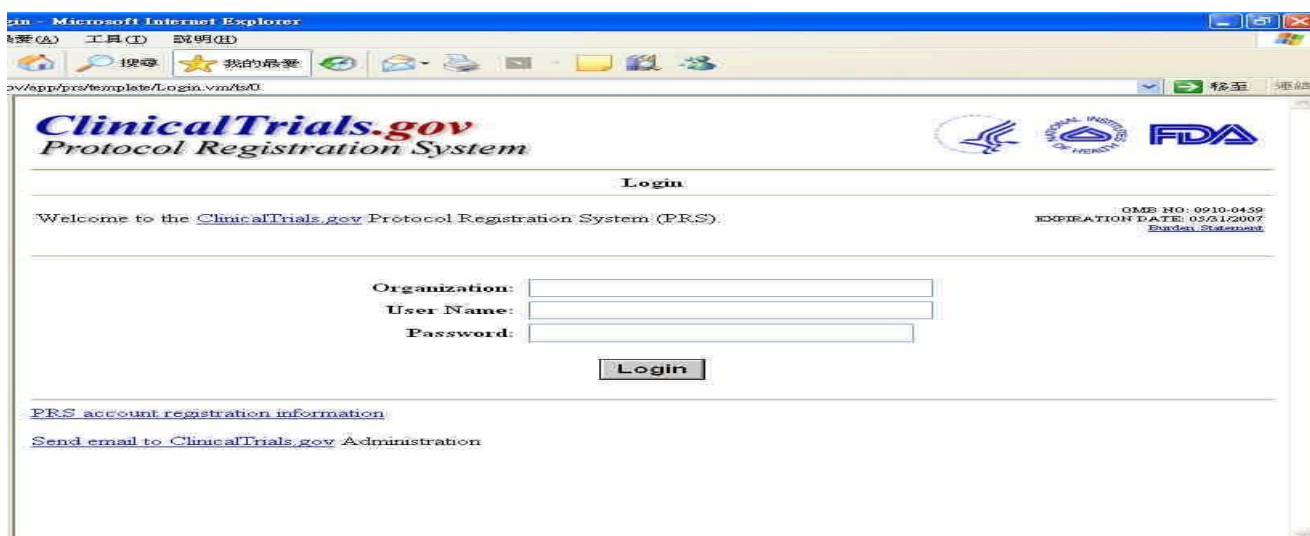
步驟3：再進入<https://register.clinicaltrials.gov/>將計畫資料填寫完整。

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

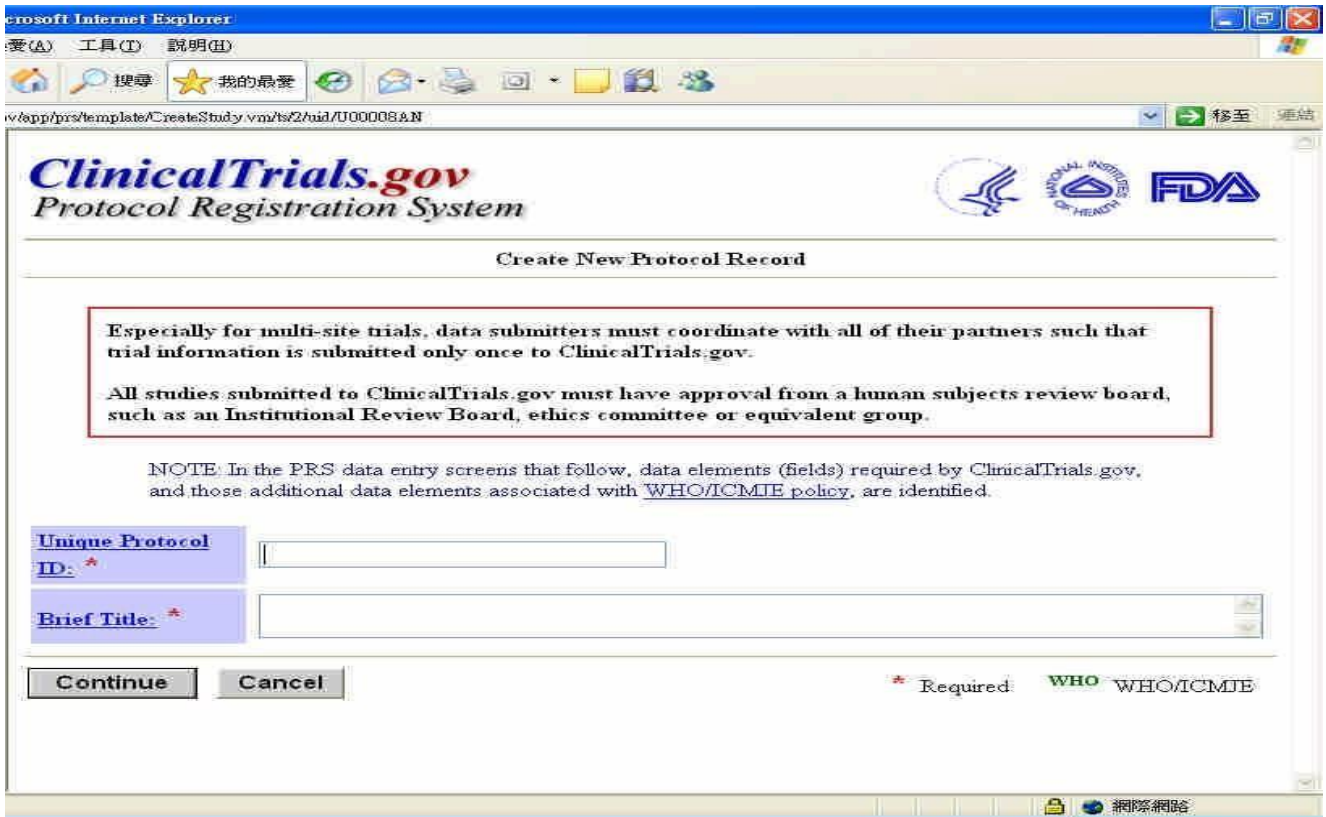
當收到 clinicaltrials.gov 給之 Organization、User name、Password 的信件時，請 PI 至以下網址 <https://register.clinicaltrials.gov/app/prs/template/Login.vm/ts/0> 登錄您的資料，畫面如下。於此網頁輸入後



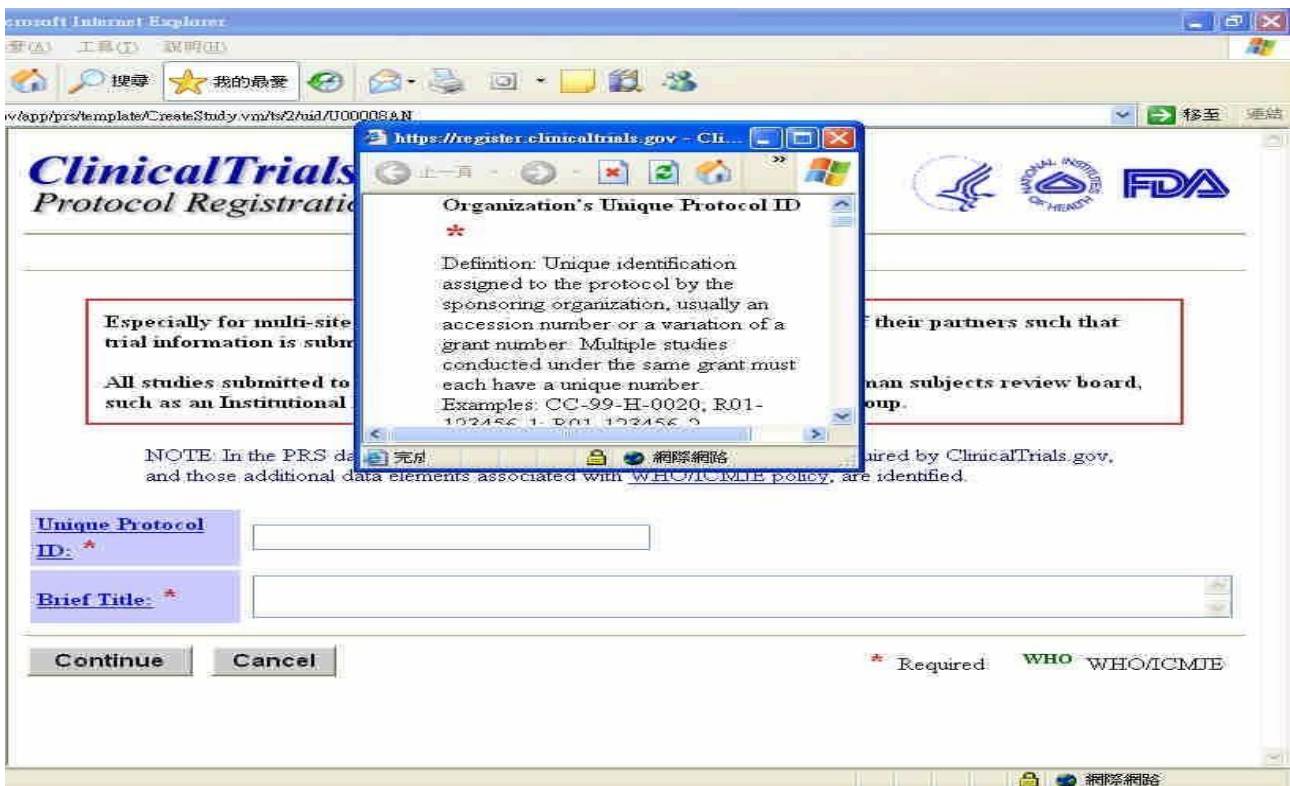
會出現下面畫面如下，在此畫面按 "Create "



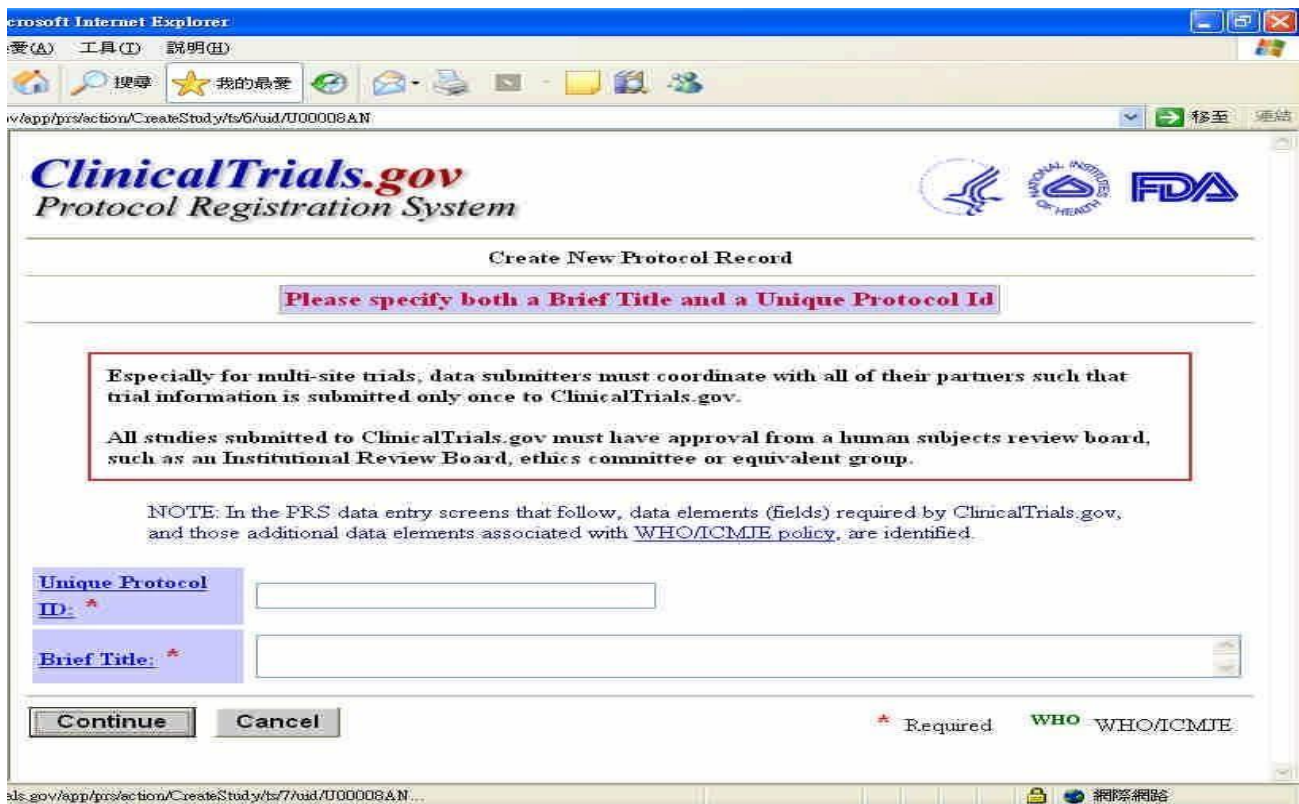
當您按下"Create"後會出現下面畫面



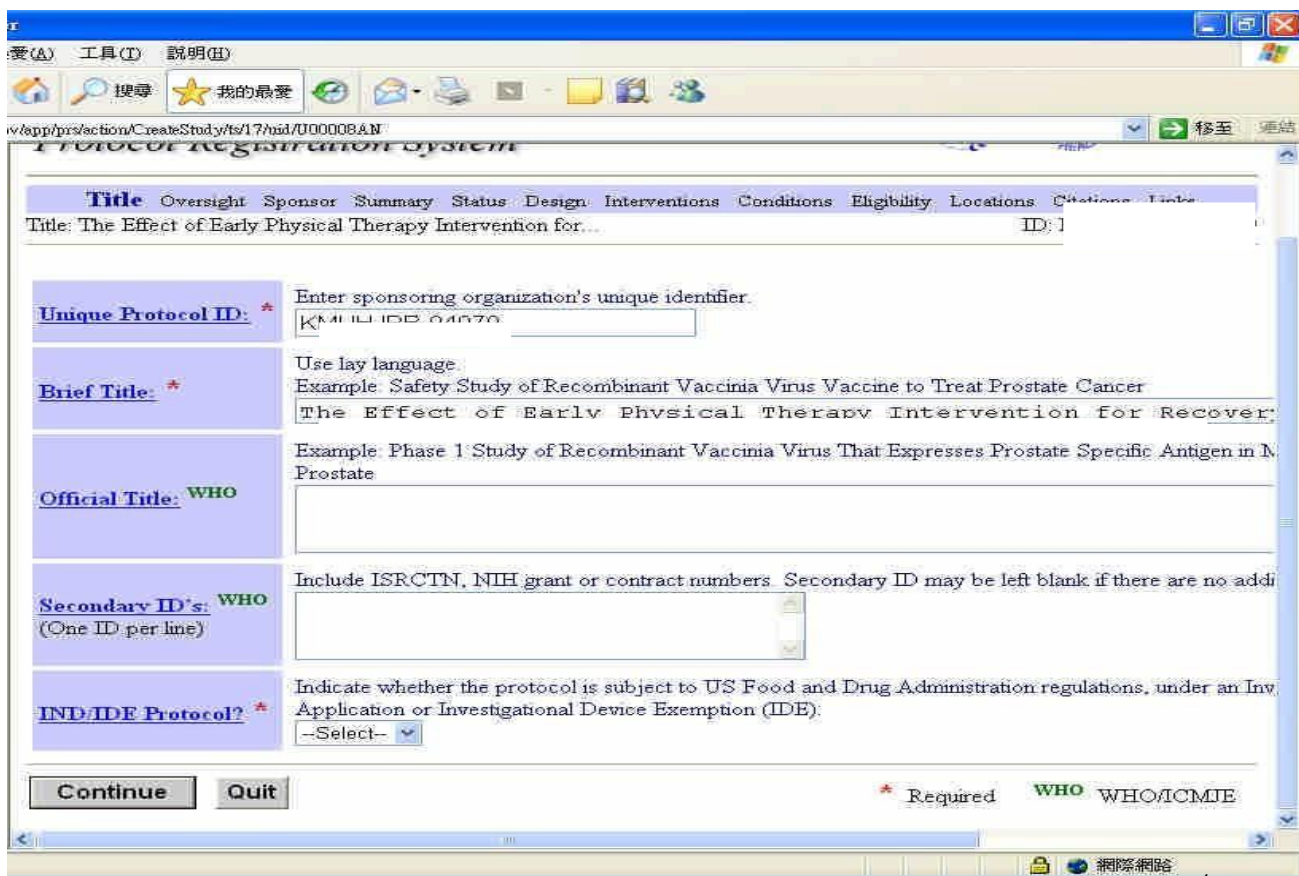
點選藍色框框字體會出現小對話視窗說明資料之填寫，如下：



填寫完後按左下角” Continue”



” Continue”



” Continue”

plorer

愛(A) 工具(T) 說明(H)

搜尋 我的最愛

w/app/pr/action/EditTitle/ts/19/aid/U00008&N/sid/S00000PG

Protocol Registration System

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

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

網際網路

” Continue”

plorer

愛(A) 工具(T) 說明(H)

搜尋 我的最愛

w/app/pr/action/PopulateStudy/ts/19/aid/U00008&N/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: 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

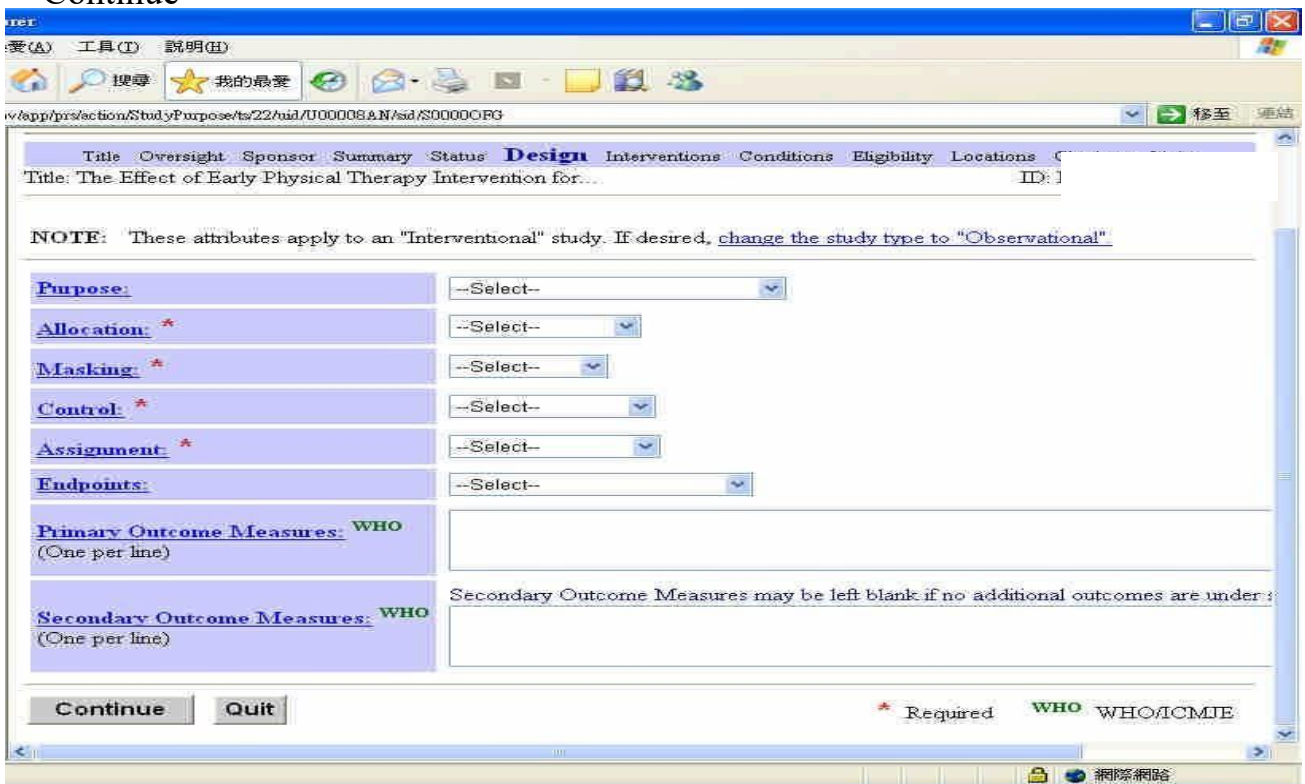
” Continue”

The screenshot shows the ClinicalTrials.gov Protocol Registration System interface. The browser window title is "plorer". The address bar shows the URL: [www/app/prs/action/PopulateStudy/1s/20/aid/U00008&N/sid/S00000PG](http://www.app/prs/action/PopulateStudy/1s/20/aid/U00008&N/sid/S00000PG). The page header includes the ClinicalTrials.gov logo and the National Institutes of Health (NIH) and FDA logos. The navigation menu includes: Title, Oversight, Sponsor, **Summary**, Status, Design, Interventions, Conditions, Eligibility, Locations, Citations, Links. The title is "The Effect of Early Physical Therapy Intervention for..." and the ID is "JPMUH-IRB-94079". The main content area has two sections: "Brief Summary:" with a "(Formatting tips)" link and a text area containing the instruction "Use lay language. Include a statement of the study hypothesis."; and "Detailed Description:" with another "(Formatting tips)" link and an empty text area. The browser status bar at the bottom shows "網際網路".

” Continue”

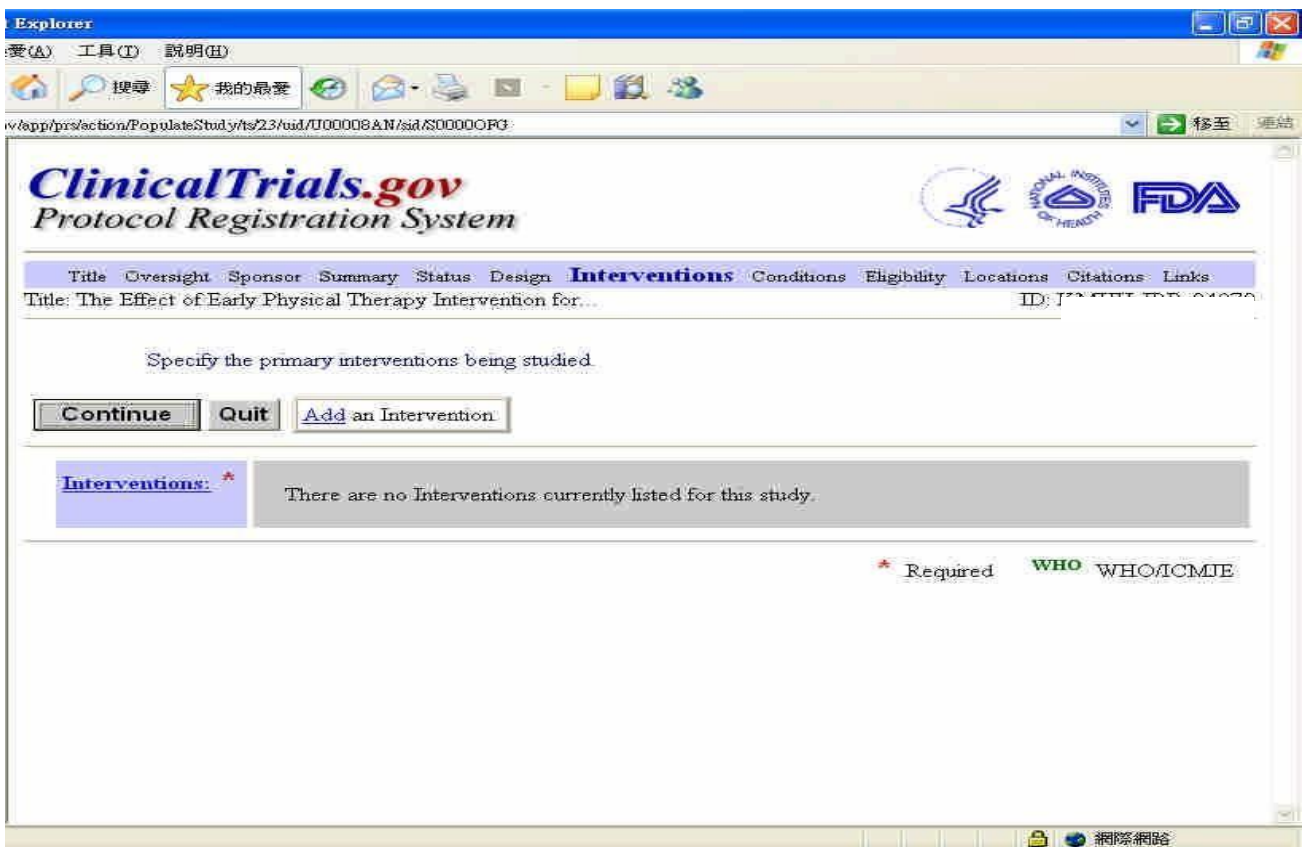
The screenshot shows the ClinicalTrials.gov Protocol Registration System interface. The browser window title is "ter". The address bar shows the URL: [www/app/prs/action/PopulateStudy/1s/21/aid/U00008&N/sid/S00000PG](http://www.app/prs/action/PopulateStudy/1s/21/aid/U00008&N/sid/S00000PG). The page header includes the ClinicalTrials.gov logo and the National Institutes of Health (NIH) and FDA logos. The navigation menu includes: Title, Oversight, Sponsor, Summary, **Status**, Design, Interventions, Conditions, Eligibility, Locations, Citations, Links. The title is "The Effect of Early Physical Therapy Intervention for..." and the ID is "KMUH-IRB-94079". The main content area contains several form fields: "Study Phase:" with a dropdown menu set to "--Select--"; "Study Type:" with radio buttons for "Interventional" (selected) and "Observational"; "Overall Recruitment Status:" with a dropdown menu set to "--Select--"; "Record Verification Date:" with a dropdown menu set to "--Select--" and a "Year:" input field; "Key Trial Dates" section with "Study Start Date:" (marked with a "WHO" icon), "Last Follow-Up Date:", "Data Entry Closure Date:", and "Study Completion Date:", each with a dropdown menu set to "--Select--" and a "Year:" input field. At the bottom, there are "Continue" and "Quit" buttons. A legend indicates "* Required" and "WHO WHO/ICMJE". The browser status bar at the bottom shows "網際網路".

” Continue”



This screenshot shows the 'Design' tab of a study record on ClinicalTrials.gov. The title is 'The Effect of Early Physical Therapy Intervention for...'. A note indicates that the following attributes apply to an 'Interventional' study, with a link to change the study type to 'Observational'. The form includes several required fields (marked with an asterisk) for selection: Purpose, Allocation, Masking, Control, and Assignment, each with a dropdown menu currently set to '--Select--'. There are also fields for Primary Outcome Measures (WHO) and Secondary Outcome Measures (WHO), both with text input areas. At the bottom, there are 'Continue' and 'Quit' buttons, and a legend for the asterisk and WHO/ICMJE logos.

” Continue”



This screenshot shows the 'Interventions' tab of the same study record. The title is 'The Effect of Early Physical Therapy Intervention for...'. The page features the ClinicalTrials.gov logo and logos for the National Institutes of Health and the FDA. The 'Interventions' section is currently empty, with a message stating 'There are no Interventions currently listed for this study.' Below this message are 'Continue', 'Quit', and 'Add an Intervention' buttons. A legend at the bottom right explains the asterisk and WHO/ICMJE logos.

” Continue”

The screenshot shows the 'Conditions' page in the ClinicalTrials.gov Protocol Registration System. The browser window title is 'explorer'. The address bar shows the URL: `http://www.clinicaltrials.gov/ct2/show/study/summary?rank=1&term=ts/24/uid/U000008&n/sid/S000000PG`. The page header includes the 'ClinicalTrials.gov Protocol Registration System' logo and the logos of the National Institutes of Health and the FDA. The navigation menu includes: Title, Oversight, Sponsor, Summary, Status, Design, Interventions, **Conditions**, Eligibility, Locations, Citations, and Links. The current study title is 'The Effect of Early Physical Therapy Intervention for...' and the ID is '1'. The main content area contains the following text: '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.' Below this text are two text input fields: 'Conditions: * (Enter 1 to 5 conditions, one per line)' and 'Keywords: (One per line)'. At the bottom of the form are 'Continue' and 'Quit' buttons. A legend at the bottom right indicates that '*' denotes 'Required' and 'WHO' denotes 'WHO/ICMJE'.

” Continue”

The screenshot shows the 'Eligibility' page in the ClinicalTrials.gov Protocol Registration System. The browser window title is 'explorer'. The address bar shows the URL: `http://www.clinicaltrials.gov/ct2/show/study/summary?rank=1&term=ts/25/uid/U000008&n/sid/S000000PG`. The page header includes the 'ClinicalTrials.gov Protocol Registration System' logo and the logos of the National Institutes of Health and the FDA. The navigation menu includes: Title, Oversight, Sponsor, Summary, Status, Design, Interventions, Conditions, **Eligibility**, Locations, Citations, and Links. The current study title is 'The Effect of Early Physical Therapy Intervention for...' and the ID is '1'. The main content area contains the following text: 'Inclusion Criteria: -' and 'Exclusion Criteria: -'. Below this text are several form fields: 'Eligibility Criteria: * (Formatting tips)', 'Gender: * --Select--', 'Age Limits: * Minimum: [] --Select-- Maximum: [] --Select--', 'Participants: Healthy Volunteers? --Select--', and 'Target Number of Subjects: WHO []'. At the bottom of the form are 'Continue' and 'Quit' buttons. A legend at the bottom right indicates that '*' denotes 'Required' and 'WHO' denotes 'WHO/ICMJE'.

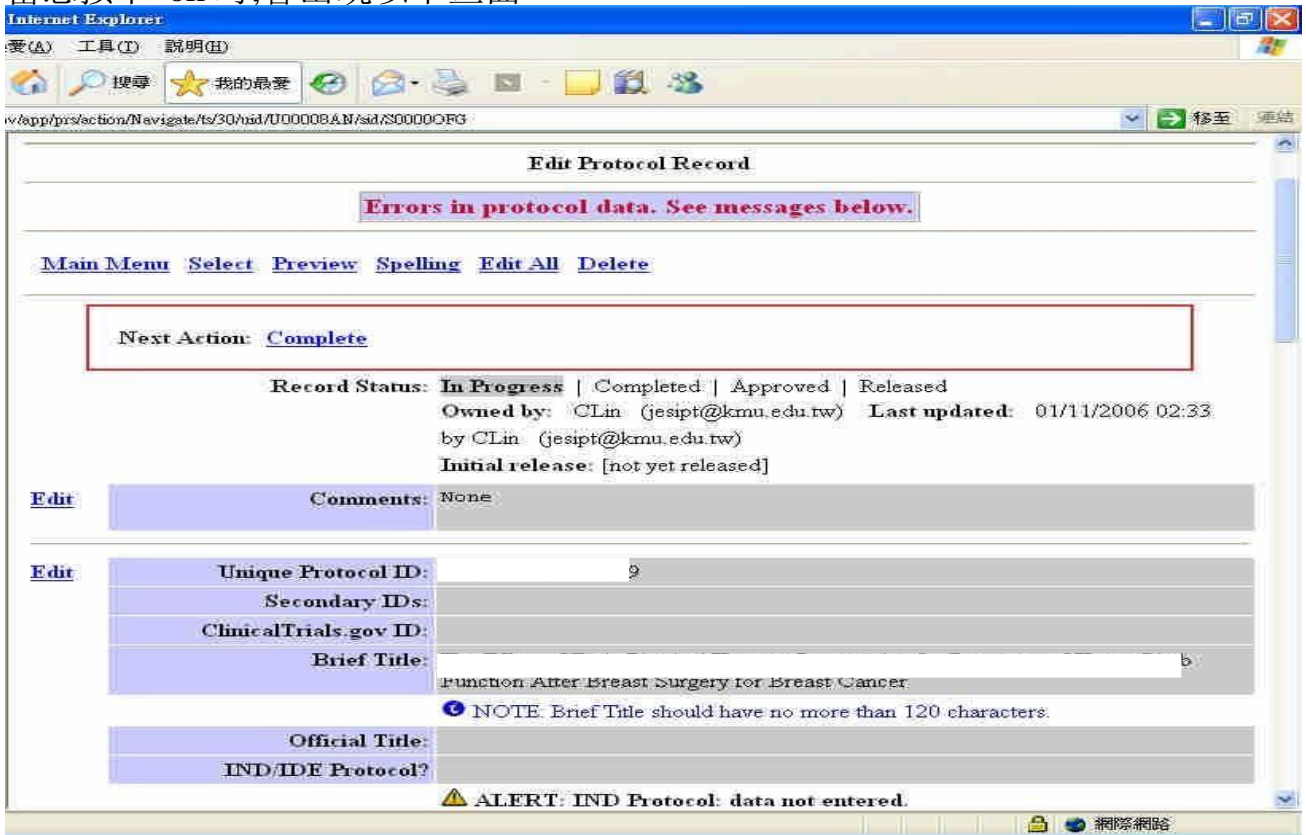
” Continue”

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 header includes the logos for the Department of Health and Human Services, the National Institutes of Health, and the FDA. A navigation menu at the top contains tabs for Title, Oversight, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, and Locations. The "Locations" tab is currently selected. Below the navigation menu, the page title is "The Effect of Early Physical Therapy Intervention for..." and the ID is "1". The main content area features a box with 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 this box are "Continue" and "Quit" buttons. Below the instructions, a "Locations:" section indicates "There are no Locations currently listed for this study.". At the bottom right, there is a legend: "* Required" and "WHO WHO/ICMJE". The browser's status bar at the bottom shows "網際網路".

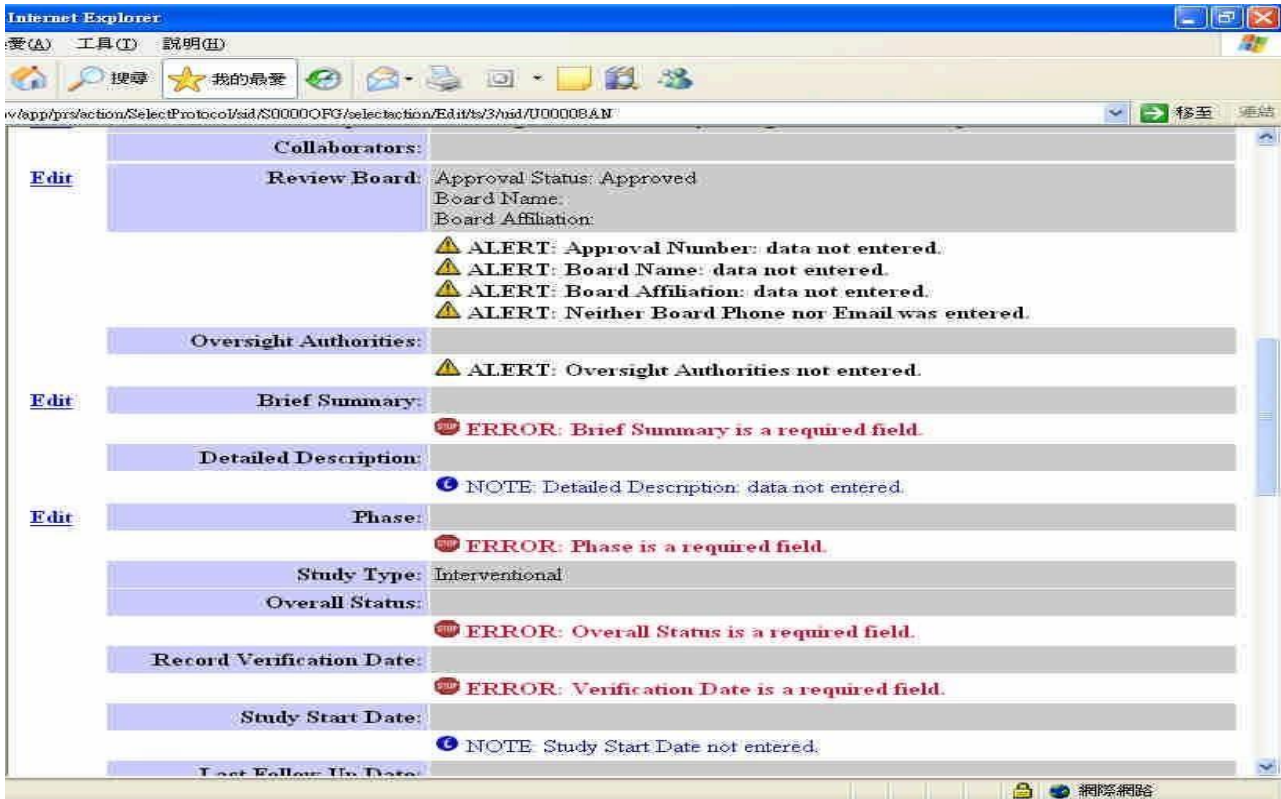
” Continue”

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/AddLocation/ts/27/uid/U000008&N/sid/S000000PG`. The page header includes the logos for the Department of Health and Human Services, the National Institutes of Health, and the FDA. A navigation menu at the top contains tabs for Title, Oversight, Sponsor, Summary, Status, Design, Interventions, Conditions, Eligibility, Locations, Citations, and Links. The "Citations" tab is currently selected. Below the navigation menu, the page title is "The Effect of Early Physical Therapy Intervention for..." and the ID is "1". The main content area features a box with instructions: "Provide Citations of publications related to the protocol, background or results.". To the left of this box are "Continue" and "Quit" buttons, and a link "Add a Citation to this study, if applicable.". Below the instructions, a "Citations:" section indicates "There are no Citations currently listed for this study.". The browser's status bar at the bottom shows "網際網路".

當您按下 ok 時,會出現以下畫面



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:



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 ClinicalTrials.gov 查詢到您登錄的
計劃案



範例:

於 ClinicalTrials 網頁 ClinicalTrials.gov 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

