ClinicalTrials.gov 資料登錄說明

- 依據國際醫學雜誌編輯委員會(International Committee of Medical Journal Editors, ICMJE)之投稿規定：經人體試驗委員會核准之臨床試驗，需於**招募第一位受試者前**，將臨床試驗計畫資料登錄於美國國衛院(National Institutes of Health)臨床試驗網站(ClinicalTrials.gov-Protocol Registration System)，完成登錄作業後，ICMJE 始接受研究結果之發表。
- 另 WHO 對「臨床試驗研究計畫」之定義為：「對任何受試者或特定族群進行一個或多個健康有關的**介入措施**(如藥物、外科手術、器材、行為治療、飲食介入或照護過程改變)以評估對健康影響之計畫。」倘非屬上述定義之臨床試驗計畫，是否登錄，可由計畫主持人自行決定。
- 本院計畫主持人如需此項登錄請洽人體試驗委員會暨行政中心提出帳號申請，相關流程如下

1. 請填妥下列資料寄至 D9065@cch.org.tw，行政中心將協助開啟您的帳號。

Email 主旨：ClinicalTrials.gov 帳號申請

User Login Name	
Full User Name	
Other User Information	(請填寫分機號碼 或 MVPN)
User Email	(請務必填寫正確)
Phone	

2. 提出申請的 PI 收到 ClinicalTrial.gov 提供的 Organization、User name、Password 的信件後，請至 https://register.clinicaltrials.gov/app/prs/template/Login.vm/ts/0 網址登錄您的資料。

3. 填寫說明

Study Identification	
Organization’ s Unique Protocol ID	請填寫 IRB 編號
Brief Title	請填寫計畫簡短名稱(限制

	120 字元)
Official Title	請填寫計畫完整名稱

4. 操作說明 (https://prsinfo.clinicaltrials.gov/prs-users-guide.html#createanewrecord)：

4.1 How to Create a New Record

- New Record
  From the PRS home page, use either the **"New Record"** Quick Link or select **"New Record"** under the Records menu. Both will take you to the Create New Record page.
- Enter the Unique Protocol ID, Brief Title, and Study Type
  Enter the Unique Protocol ID, Brief Title, and Study Type (interventional, observational, or expanded access) for your record on the Create New Record page.
- Click Continue
  Click **"Continue"** to save data and proceed to the next module.
- Repeat data entry and click Continue for each module
  Repeat data entry and click **"Continue"** for each module. When you get to the Edit Arms page, click on **"+ Add Arm"** and fill in the data for each arm of the study. Click **"Continue"** after adding the last arm.
- Click Continue and then Quit on the next module
  To create a record and save for completion at later sessions, click **"Continue"** and then **"Quit"** on the next module. Data is saved only after you click on Continue. To continue editing your record, follow the steps in 4.2 Modifying a Record.
- Follow instructions in 4.3
  After clicking **"Continue"** on the final data entry page (Edit References), follow the instructions in 4.3 Preparing, Approving, and Releasing a Study Record to PRS.

4.2 Modifying a Record

There are two methods by which you can edit a record. You can either select Edit All to make changes in multiple modules at once, or edit specific modules.

(i) Edit All: Module Walk-Through

To walk through your entire record and make changes as needed:

a. In the Record List on your Home page, select "**Open**" next to the record you wish to edit.
b. Select "**Open**" next to the section of the record (Protocol, Results, or Delayed Results) to be modified on the Record Summary page.
c. Select "**Edit All**" to start the step-by-step walk-through.
d. Make changes as needed on each module.
e. Select "**Continue**" to save the changes and move to next module. Select "**Quit**" to save changes and exit the walk-through at any time.
f. Follow the steps to release your record.

(ii) Edit a Module

To edit specific modules in your record:

a. In the Record List on your Home page, select "**Open**" next to the record you wish to edit.
b. Select "**Open**" next to the section of the record (Protocol, Results, or Delayed Results) to be modified on the Record Summary page.
c. Locate the data field to be modified and select "**Open**" or "**Edit**" for the corresponding module.
d. Make changes on the data entry page.
e. Select "**Save**" to save the changes and return to the section page. Repeat steps c-f for all modules to be modified.
f. Update the Record Verification Date data field to the

current date.

g. Follow the steps to release your record.

4.3 Preparing, Approving, and Releasing a Study Record to PRS

Before releasing a record to PRS Staff for review, read it over carefully to make sure it is accurate, complete, and free of errors. Here are steps to follow and tools you can use to prepare and release your record.

- Draft Receipt

  Look your record over carefully to ensure that it does not contain spelling or other mistakes, and check that it is formatted correctly and clearly. The following links and features available from the Record Summary page can help with this process:

  (i) Draft Receipt

  The Draft Receipt function provides a copy of your record as it currently appears in the PRS. You can download the Draft Receipt as either an Adobe PDF or RTF (rich text format) file. The format of the draft receipt reflects the PRS content order.

  You can import the RTF file into a word processing program, such as Microsoft Word. This is useful for editing and sharing a record with co-workers or colleagues who don't have a PRS User account. Note that changes made to the RTF file will need to be entered back into the PRS system into the appropriate modules.

  To download a Draft Receipt, open your record from your Record List, find Draft Receipt option on the Record Summary page, and select link to either PDF or RTF below the Record Status box.

  (ii) Preview

Use the Preview feature to see approximately how the text will appear on ClinicalTrials.gov. Once your entry is complete, select Preview to see how your record will appear on the public website.

a. Select "**Preview"** on the Record Summary page.
b. On the Protocol Registration Preview page, examine data for accuracy. Review the Brief Title and Brief Summary to see if language will be easily understood by website users. Check that formatting in Brief Summary and Eligibility Criteria allows for ease of reading.
c. Select "**Close"** to return to Record Summary page. Edit the record to make any changes that are needed.

(iii) Spelling and Acronym Checkers

The PRS System has a Spelling Checker that checks free-text data elements, such as Brief Title and Detailed Description. You can access this via the Spelling link on the Record Summary page. The Spelling Checker may not recognize some words, such as newer drug names. The PRS Spelling Checker does not check certain types of words for accuracy. This includes acronyms (all uppercase or mixed-case) and chemical names (combinations of letters and numbers).

The Acronym Checker flags possible unexpanded acronyms in your record. PRS Review criteria calls for all acronyms to be spelled out on first mention in the Protocol Section and Results Section of the study record. For example, the first mention of National Institutes of Health should be followed in

parentheses by (NIH). Note that the Acronym Checker does not check the accuracy of the acronym or of the expanded term.

(iv) PRS Review Criteria

PRS Staff rely on two sets of criteria when reviewing summary protocol and results information in study records:

- ✓ ClinicalTrials.gov Protocol Review Criteria (PDF)
- ✓ ClinicalTrials.gov Results Review Criteria (PDF)

It is strongly recommended that you check these criteria against your study record

- Approving a Record

The Approval process differs depending on the Sponsor Organization or Responsible Party for the study record. If the Responsible Party is the Sponsor, an Administrator—acting as the agent of the Sponsor Organization—approves records. If the Principal Investigator or Sponsor-Investigator is the Responsible Party, the Principal Investigator must approve the record, even if he or she is not an Administrator.

A record must be approved before it can be released to the PRS for PRS Review.

(i) How to Submit a Record for Approval

When you have entered information for all the modules of the record, you are ready to submit the record to your Administrator for approval.

a. In the Record List on your Home page, select "**Open**" next to the record you wish to submit.

b. Review the record and make any necessary changes. Address any system validation messages.

c. Select "**Entry Complete**" in the Next Action area near the top of the Record Summary page. This generates an automatic email notification to the Administrator indicating that the record is complete and ready for their review.

Your Administrator will review the record. Once approved, the Administrator can also release the record to PRS Staff for review.

(ii) How to Approve a Record for Release to PRS
After users create and mark the record as Entry Complete, an automatic email notification is sent to the Responsible Party. The process is the same no matter who is responsible for approving and releasing the record:

a. Use the Record List custom filter to check for records that are Ready for Review and Approval. A system-generated email notification of completed records will also be sent.
b. Select "**Open Record**" on your Record List.
c. Review the record by following steps described in "**Draft Receipt**".
d. Update Record Verification Date to the current month and year.
e. Select "**Approve**" on the Record Summary page.

- Releasing a Record
  After the record is approved, the last step is for the Responsible Party to release it for PRS Review.

When a Principal Investigator or Sponsor-Investigator is designated as the Responsible Party for a record, it is the Principal Investigator or Sponsor-Investigator who must Release the record for PRS Review. When the Sponsor is designated as the Responsible Party for a record, an Administrator must Release the record.

The steps are the same whether an Administrator, Principal Investigator, or Sponsor-Investigator must release the record:

(i) In the Record List on your Home page, select "**Open**" next to the record you wish to submit.
(ii) Review the record for accuracy and make changes if needed.
(iii) Select "**Release**" on the Record Summary page.
(iv) Check the box to update Verification Date automatically.
(v) Select "**Release**" to submit the record to ClinicalTrials.gov for PRS Review.

After a record is released, it undergoes PRS Review. If the PRS team requires further changes, the record is returned so changes can be made and the Release process must be repeated. If the record meets PRS Review criteria, it is posted on the ClinicalTrials.gov website and is available to the public.

Note: If an Administrator makes changes to an Approved record, it does not need to be Approved again. However, the record must still be Released