臺大醫院臨床試驗計劃案登錄
Clinical Trial Registration

臨床試驗中心 統計諮詢小組

2023/02/01

Objectives

* Background for Registration
* Procedures for registering your Clinical Trial
* Frequently Asked Question

Background for Registration

Why Clinical Trial Registration?

* **Required by Law**

  Section 801 of the Food and Drug Administration Amendments Act (FDAAA801) requires Responsible Parties to register and submit summary results of clinical trials with ClinicalTrials.gov. The law applies to certain clinical trials of drugs (including biological products) and medical devices.

* **Required for Journal Publication**

  International Committee of Medical Journal Editors (ICMJE) requires trial registration as a condition for the publication of research results generated by a clinical trial.

Why Clinical Trial Registration?

In 2005, the International Committee of Medical Journal Editors (ICMJE) initiated a policy requiring investigators to deposit information about trial design into an accepted clinical trials registry before the onset of patient enrollment.

2005年國際醫學雜誌編輯委員會之投稿規定

* **經倫委會核准之臨床試驗，需於招募第一位受試者參與前，將臨床試驗計劃資料登錄於臨床試驗公開網站。**
* **未完成臨床試驗登錄之計畫案，ICMJE有權不接受其文章發表。**

Name	Type	Intervention Type	Registration Policy Scope	Results Submission Policy Scope
Section 801 of the Food and Drug Administration Amendments Act (FDAAA 801) (PDF)	U.S. Federal law enacted in 2007	Drugs, biologics, and devices	Controlled clinical investigations of an FDA-regulated drug, biologic, or device, other than Phase 1 (drugs/biologics) or small feasibility studies	Same scope as registration, but interventional studies of FDA approved drugs, biologics, or devices
2013 Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects	International policy initially adopted by the World Medical Association (WMA) General Assembly in 1964; last amended in 2013	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	"Every research study involving human subjects must be registered in a publicly accessible database before recruitment of the first subject." (Para 35)	"Researchers have a duty to make publicly available the results of their research on human subjects... Negative and inconclusive as well as positive results should be published or otherwise made publicly available." (Para 36.)
Clinical Trials Directive (2001/20/EC), Article 11 (and associated Regulations and Guidelines)	European Union directive adopted in 2001	Drugs and biologics	Phase 2–4 adult trials and Phase 1–4 pediatric trials	Same scope as registration (includes products without marketing authorization applications)
WHO International Clinical Trials Registry Platform	International policy initiated in 2006	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	"The registration of all interventional trials is a scientific, ethical and moral responsibility."	N/A
ICMJE Statement	Publication policy initiated in 2004	Any (includes drugs, biologics, devices, surgical procedures, and behavioral treatments)	All interventional studies, including Phase 1 studies; defines criteria for "acceptable registries"	N/A
Section 113 of the Food and Drug Administration Modernization Act	U.S. Federal law enacted in 1997	Drugs and biologics	Efficacy trials for "serious or life threatening diseases or conditions" regulated by FDA	N/A

Why Clinical Trial Registration?

Registry Purpose	Group That Benefits
Fulfill ethical obligations to participants and community	Patients, general public, research community
Provide information to potential participants and referring clinicians	Patients, clinicians
Reduce publication bias	Users of the medical literature
Help editors and others understand the context of study results	Journal editors, users of the medical literature
Promote more efficient allocation of research funds	Granting agencies, research community
Help institutional review boards (IRBs) determine appropriateness of a research study	IRBs, ethicists

Source: Zarin DA, Keselman A. Registering a clinical trial in ClinicalTrials.gov. *Chest*. 2007;131(3):909-12. [Full Text]

What is a Clinical Trial?

World Health Organization Definition

* A clinical trial is ' *Any research project that prospectively assigns human participants or groups to one or more health-related interventions to evaluate the effects on health outcomes.*‘

Interventions include but are not restricted to drugs, cells and other biological products, surgical procedures, radiological procedures, devices, behavioural treatments, process-of-care changes, preventive care, etc.

對任何受試者進行與健康有關的介入措施以評估對健康影響的計畫。

What is a Clinical Trial?

International Committee of Medical Journal Editors, ICMJE Definition(2007)

* **WHO's Definition:** A clinical trial is "Any research study that prospectively assigns human participants or groups of humans to one or more health related interventions to evaluate the effects on health outcomes."

Health-related interventions *include any intervention used to modify a biomedical or health-related outcome (for example, drugs, surgical procedures, devices, behavioral treatments, dietary interventions, and process-of-care changes).*

Health outcomes *include any biomedical or health-related measures obtained in patients or participants, including pharmacokinetic measures and adverse events.*

藥物動力學、不良事件反應

What is a Clinical Trial?

ClinicalTrials.gov Definition

A clinical study involves research using human volunteers (also called participants) that is intended to add to medical knowledge. There are two main types of clinical studies: clinical trials and observational studies. ClinicalTrials.gov includes both interventional and observational studies.

* **Interventional:** studies in human beings in which individuals are assigned by an investigator based on a protocol to receive specific interventions. Subjects may receive diagnostic, therapeutic or other types of interventions. The assignment of the intervention may or may not be random. The individuals are then followed and biomedical and/or health outcomes are assessed.

* **Observational:** studies in human beings in which biomedical and/or health outcomes are assessed in pre-defined groups of individuals. Subjects in the study may receive diagnostic, therapeutic, or other interventions, but the investigator does not assign specific interventions to the subjects of the study.

What is a Clinical Trial?

醫療法第八條:

* 本法所稱人體試驗，係指醫療機構依醫學理論於人體施行新醫療技術、新藥品、新醫療器材及學名藥生體可用率、生體相等性之試驗研究。

Who is Responsible for Registering?

* 由研究者自行發起之研究案且責任歸屬於Principal investigator(PI)，應由計畫主持人於取得倫委會同意函後完成登錄。

* 有廠商贊助(Sponsor)之計畫，贊助者應主動完成登錄。

When is Timing for Registration?

* 21 days after 1st patient is enrolled (PL 110-85)
* Prior to enrollment of 1st patient (ICMJE)

Web Site Registry

* 臺大醫院已向美國國家衛生研究院(National Institutes of Health, NIH) clinicaltrials.gov網站申請本院專用帳號。

* 供本院研究者自行發起研究案之計畫主持人(PI)登錄其臨床試驗研究計劃。

* 帳號密碼請詳見倫委會核准函。

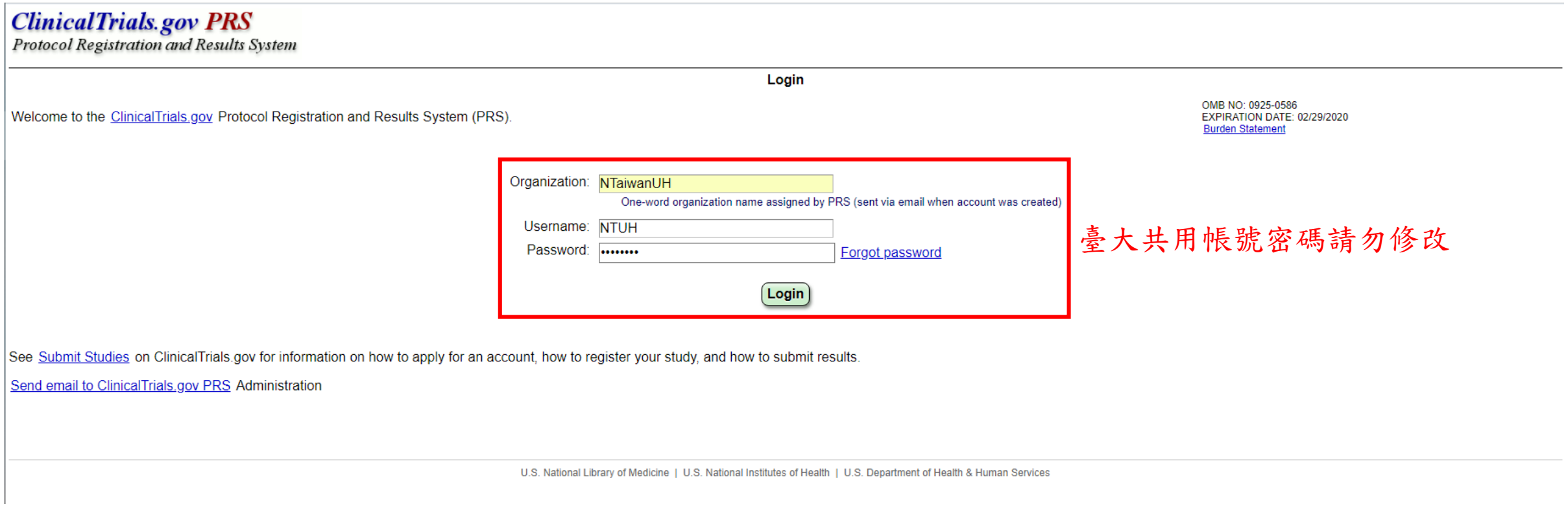
Procedures for registering your Clinical Trial

How to Register?

ClinicalTrials.gov Protocol Registration System (PRS)

http://register.clinicaltrials.gov

ClinicalTrials.gov Protocol Registration System Login



臺大共用帳號密碼請勿修改

Register for your Clinical Trial

ClinicalTrials.gov PRS
Protocol Registration and Results System

Quick Links
New Record
Quick Start Guide
Problem Resolution Guide

Records ▾ Accounts ▾ Help ▾
New Record
PRS Review Comments
Upload Record (XML)
Upload from NCI CTRP

Try out the new PRS beta home page, part of the ongoing ClinicalTrials.gov modernization.
New PRS Beta Home Page

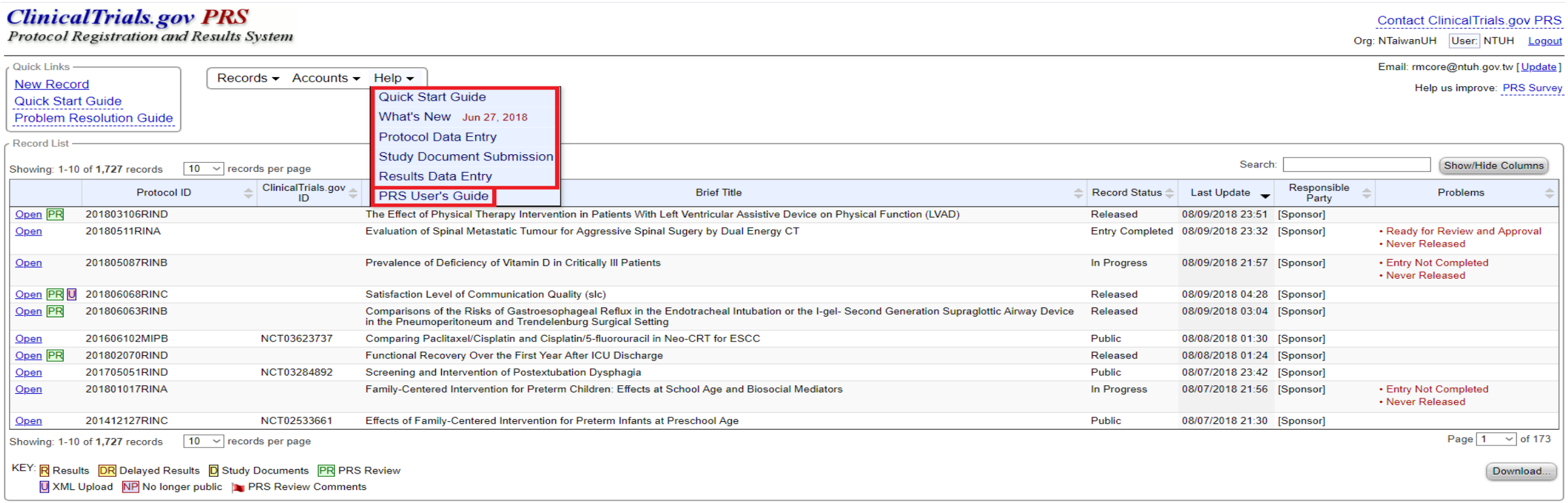
Record List

Showing: 1-10 of **2,415** records 10 records per page Search

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	P
Open PR	201802070RIND	NCT04206306	Functional Recovery Over the First Year After ICU Discharge	Released	01/30/2023 21:09	[Sponsor]
Open	202108042MIPA	NCT05286320	Phase Ib/II Trial of Combining Pembrolizumab and Lenvatinib With SBRT for HCC Patients With Portal Vein Thrombosis.	Public	01/30/2023 02:00	[Sponsor]
Open PR	202003090RINA		Atrial Fibrillation Trial To Eliminate Risk-factors (AFTTER)	Released	01/30/2023 01:31	[Sponsor]
Open PR	202111099MIPC		Immunotherapy With CCRT Followed by Surgery for Locally Advanced ESCC Patients	Released	01/30/2023 01:27	[Sponsor]
Open PR	202212021RINB		A Novel Biomarker for Response and Prognosis of HBV-related Hepatocellular Carcinoma	Released	01/30/2023 01:18	[Sponsor]
Open PR	202207146DIPB		EEG/MECG/EMG Evaluating the Severity of Aortic Stenosis, Heart Failure and Ischemic Stroke Through an Artificial Intelligenceassisted System.	Released	01/29/2023 21:38	[Sponsor]
Open PR	202211062DIND		Swallowing Evaluation by HRIM in Patients With Cervical Spondylosis	Released	01/26/2023 21:04	[Sponsor]
Open PR	202109031MIPD		Immunotherapy, Hormone Therapy, and AKT Inhibitor for Premenopausal ER Positive MBC	Released	01/26/2023 19:47	[Sponsor]
Open PR	202208053RINA		Effects of Ai Chi on Scapular Muscle Activation in Overhead Athletes With Scapular Dyskinesis	Released	01/26/2023 19:45	[Sponsor]
Open PR	201912156RIND		Impacts and Testing of the "Multi-domains Active-living Program" in Operable Non-Muscle Invasive Bladder Cancer Patients	Released	01/26/2023 19:43	[Sponsor]

台大醫院 NTUH

User's Guide


ClinicalTrials.gov PRS
Protocol Registration and Results System
Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH Logout
Quick Links
New Record
Quick Start Guide
Problem Resolution Guide
Records Accounts Help
Quick Start Guide
What's New Jun 27, 2018
Protocol Data Entry
Study Document Submission
Results Data Entry
PRS User's Guide
Email: rmcore@ntuh.gov.tw [Update]
Help us improve: PRS Survey
Record List
Showing: 1-10 of 1,727 records 10 records per page
Search:
Show/Hide Columns
Protocol ID
ClinicalTrials.gov ID
Brief Title
Record Status
Last Update
Responsible Party
Problems
Open PR 201803106RIND The Effect of Physical Therapy Intervention in Patients With Left Ventricular Assistive Device on Physical Function (LVAD) Released 08/09/2018 23:51 [Sponsor]
Open 20180511RINA Evaluation of Spinal Metastatic Tumour for Aggressive Spinal Sugery by Dual Energy CT Entry Completed 08/09/2018 23:32 [Sponsor] • Ready for Review and Approval • Never Released
Open 201805087RINB Prevalence of Deficiency of Vitamin D in Critically Ill Patients In Progress 08/09/2018 21:57 [Sponsor] • Entry Not Completed • Never Released
Open PR U 201806068RINC Satisfaction Level of Communication Quality (slc) Released 08/09/2018 04:28 [Sponsor]
Open PR 201806063RINB Comparisons of the Risks of Gastroesophageal Reflux in the Endotracheal Intubation or the I-gel- Second Generation Supraglottic Airway Device in the Pneumoperitoneum and Trendelenburg Surgical Setting Released 08/09/2018 03:04 [Sponsor]
Open 201606102MIPB NCT03623737 Comparing Paclitaxel/Cisplatin and Cisplatin/5-fluorouracil in Neo-CRT for ESCC Public 08/08/2018 01:30 [Sponsor]
Open PR 201802070RIND Functional Recovery Over the First Year After ICU Discharge Released 08/08/2018 01:24 [Sponsor]
Open 201705051RIND NCT03284892 Screening and Intervention of Postextubation Dysphagia Public 08/07/2018 23:42 [Sponsor]
Open 201801017RINA Family-Centered Intervention for Preterm Children: Effects at School Age and Biosocial Mediators In Progress 08/07/2018 21:56 [Sponsor] • Entry Not Completed • Never Released
Open 201412127RINC NCT02533661 Effects of Family-Centered Intervention for Preterm Infants at Preschool Age Public 08/07/2018 21:30 [Sponsor]
Showing: 1-10 of 1,727 records 10 records per page
Page 1 of 173
KEY: R Results DR Delayed Results D Study Documents PR PRS Review
U XML Upload NP No longer public PRS Review Comments
Download...

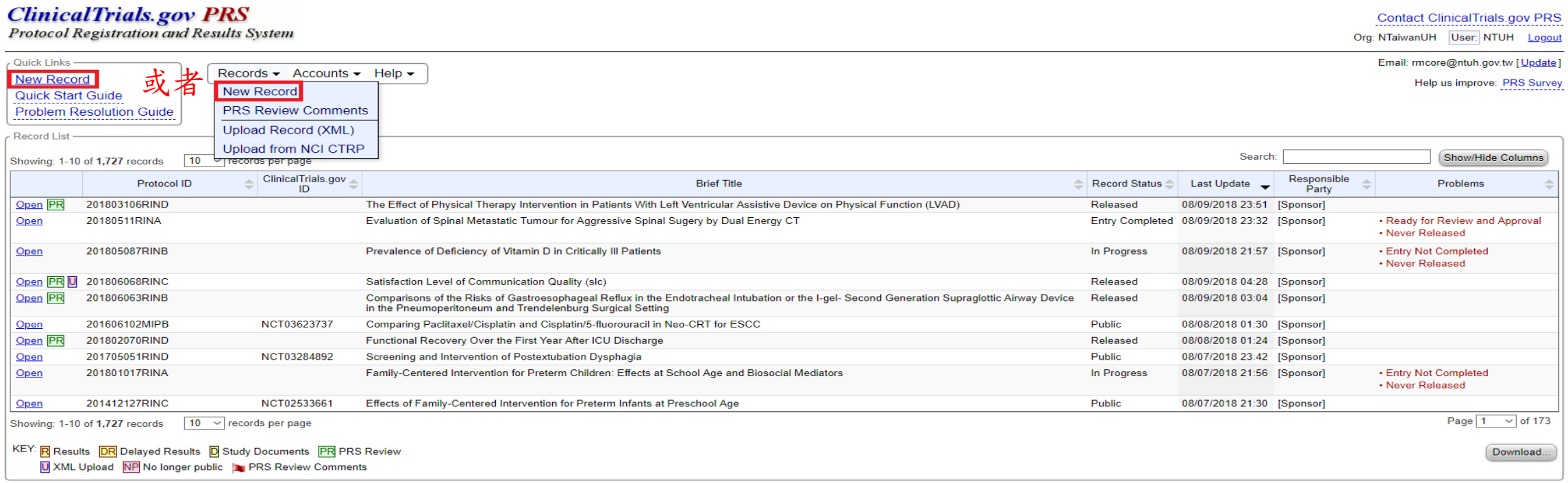
Required Item

*	Required by ClinicalTrials.gov
FDAA	Required to comply with US Public Law 110-85, Section 801
(FDAA)	May be required to comply with US Public Law 110-85, Section 801

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

[*] Conditionally required (see Definitions)

Register for your Clinical Trial



Create New Record

To avoid duplicate or invalid registration of your study, check the following before proceeding with registration:

1. **Studies may only be registered by the Responsible Party.** The Responsible Party for a clinical study is the Sponsor, Sponsor-Investigator, or Sponsor-designated Principal Investigator who meets specific requirements.
   - When a study is subject to U.S. Food and Drug Administration regulations and conducted under an investigational new drug application (IND) or investigational device exemption (IDE), the IND or IDE Holder is considered the Sponsor or Sponsor-Investigator.
   - When a study is not conducted under an IND or IDE, the entity or single person who initiates the study, by preparing and/or planning the study, and who has authority and control over the study, is considered the Sponsor or Sponsor-Investigator.
2. **Use the PRS account of the Sponsor or Sponsor-Investigator to register the study.** If the Sponsor has designated the Principal Investigator to be the Responsible Party for a study, that study must be registered using the PRS account of the Sponsor.
3. **Multi-site studies are NOT registered by individual sites.** If this is a multi-site study it must be registered only once, by the Responsible Party (IND/IDE holder or the person or organization who initiates the study and who has authority and control over the study) or its designated principal investigator (PI).
4. **Coordinate with all collaborators before registering.** If the study has multiple collaborators, contact the other organizations to confirm that the study has not already been registered and to notify them that your organization (or designated PI), as Responsible Party is registering the study.
5. **Refer to the ClinicalTrials.gov Review of Protocol Submissions document** for a description of items evaluated by ClinicalTrials.gov after protocol information is submitted.

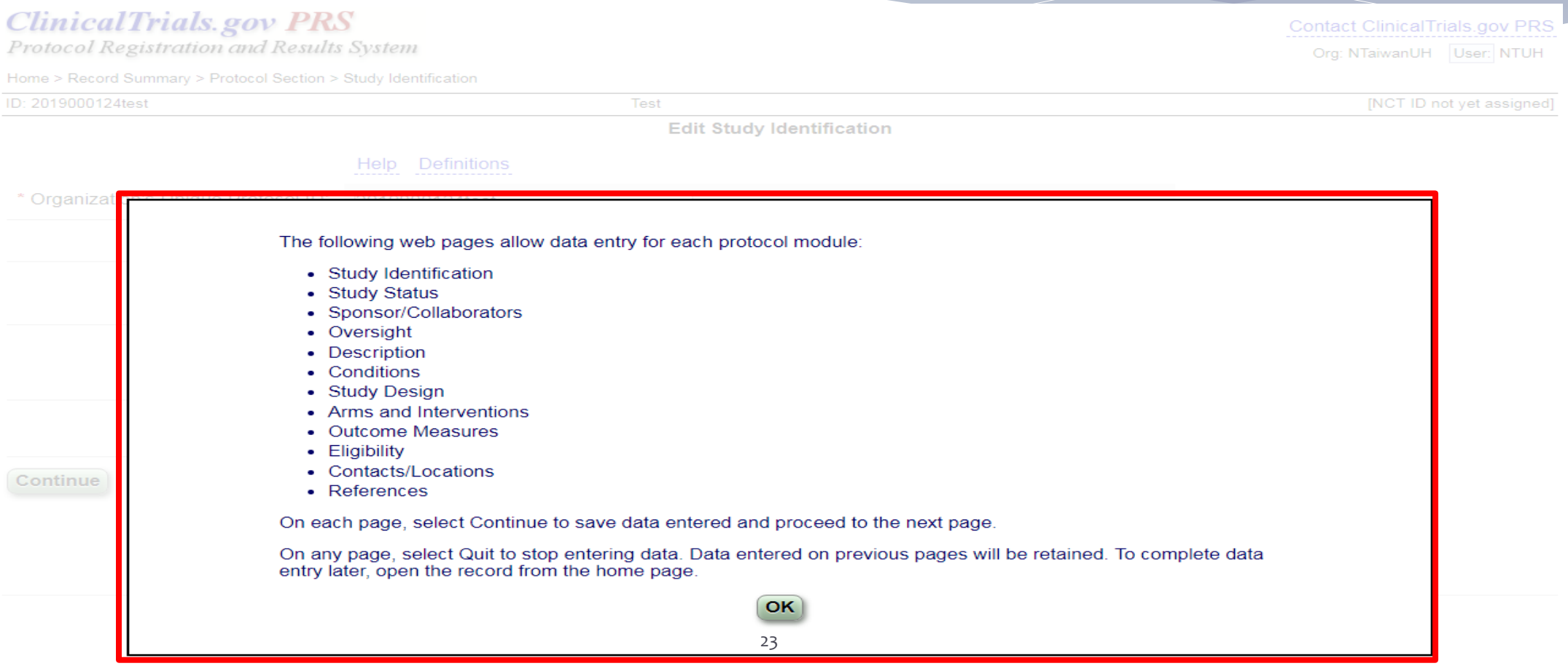
Help Definitions

* Organization's Unique Protocol ID:	Enter your IRB approve number
* Brief Title:	Protocol Title (Limit: 300 characters)
	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)

Required Information



ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Identification

ID: 465789 23 26+5 [NCT ID not yet assigned]

Edit Study Identification

Help Definitions

* Organization's Unique Protocol ID: Enter Your IRB Approve Number

* Brief Title: Protocol Title

NOTE: Titles should be in proper title case.
ERROR: A title this short cannot be sufficiently descriptive.

[*] Acronym: (if any)

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

* § Official Title:

ERROR: Official Title has not been entered.

[*] Secondary IDs: (if any) + Add Secondary ID

Continue Quit

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

Example:

- **Brief Title:** Women's Health Initiative
- **Acronym:** WHI
- **Displayed on ClinicalTrials.gov as:**

  Women's Health Initiative (WHI)

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

Edit Study Status

Help Definitions

* Record Verification Date:	Month: August Year: 2018
* Overall Recruitment Status:	--Select-- Before selecting Suspended, Terminated or Withdrawn see the Overall Recr
	Tip: Day is not required for Anticipated dates.
* § Study Start Date:	Month: --Select-- Day: Year: Type: --Select Date study is open for recruitment (Anticipated) or date first participant is enr
* Primary Completion Date:	Month: --Select-- Day: Year: Type: --Select Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: --Select-- Day: Year: Type: --Select 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)

Definition:

Date the protocol information was last verified. Verification date is shown along with organization name on ClinicalTrials.gov to indicate to the public whether the information is being kept current, particularly recruiting status and contact information.

Update verification date when reviewing the record for accuracy and completeness, even if no other changes are made.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Status

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Study Status

Help Definitions

* Record Verification Date:	Month: August Year: 2018
* Overall Recruitment Status:	Not yet recruiting Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.
	Tip: Day is not required for Anticipated dates.
* § Study Start Date:	Month: October Day: 01 Year: 2018 Type: Anticipated Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).
* Primary Completion Date:	Month: August Day: 01 Year: 2020 Type: Anticipated Final data collection date for primary outcome measure.
* § Study Completion Date:	Month: August Day: 01 Year: 2022 Type: Anticipated Final data collection date for study.

- Not yet recruiting
- Recruiting
- Enrolling by invitation
- Active, not recruiting
- Completed
- Suspended
- Terminated
- Withdrawn

Save Cancel

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Status

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

Edit Study Status

Help Definitions

* Record Verification Date: Month: August Year: 2018

* Overall Recruitment Status: Not yet recruiting
Before selecting Suspended, Terminated or Withdrawn see the Overall Recruitment Status definition.

Tip: Day is not required for Anticipated dates.

* § Study Start Date: Month: August Day: 01 Year: 2018 Type: Anticipated
Date study is open for recruitment (Anticipated) or date first participant is enrolled (Actual).

* Primary Completion Date: Month: August Day: 01 Year: 2020 Type: Anticipated
Final data collection date for primary outcome measure.

* § Study Completion Date: Month: August Day: 01 Year: 2022 Type: Anticipated
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)

Date that enrollment to the protocol begins

- Date the final Subject was examined or received an intervention for the purposes of final collection of data for the primary outcome.
- Choose from: Anticipated and Actual.

- Final date on which study data was (or is expected to be) collected.
- Choose from: Anticipated and Actual

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Sponsor/Collaborators

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

Edit Sponsor/Collaborators

Help Definitions

* Responsible Party: Sponsor

Select **Sponsor** unless the Principal Investigator has been designated as Responsible Party or the Principal Investigator is the Sponsor.

Select Sponsor

* Sponsor: National Taiwan University Hospital

Primary organization conducting study and associated data analysis (not necessarily a funding source).

Enter "National Taiwan University Hospital"

Collaborators:

× Delete

請輸入合作對象(其他醫院/廠商等)英文全名

+ Add Collaborator

Organization(s) providing support: funding, design, implementation, data analysis or reporting.
Required by International Committee of Medical Journal Editors (ICMJE) and World Health Organization (WHO)
Enter **only the organization name**.

Continue Back Quit

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Oversight

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Oversight

Help Definitions

* § U.S. FDA-regulated Drug:	No Studying one or more U.S. FDA-regulated drug or biologic products? For more information see the "Elaboration" in the Applicable Clinical Trial
* § U.S. FDA-regulated Device:	No 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)	No Studying drug/device product with U.S. FDA Investigational New Drug (IND
* Human Subjects Protection Review:	Board Status: Exempt
Data Monitoring Committee:	No
FDA Regulated Intervention:	No

Save Cancel

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

Indication that a clinical study is studying a drug product (including a biological product) subject to section 505 of the Federal Food, Drug, and Cosmetic Act or to section 351 of the Public Health Service Act. Select Yes/No.

Indication that a clinical study is studying a device product subject to section 510(k), 515, or 520(m) of the Federal Food, Drug, and Cosmetic Act. Select Yes/No.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Oversight

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

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: (Not public)	--Select-- Studying drug/device product with U.S. FDA Investigational New Drug (IND) Application or Investigational D
* Human Subjects Protection Review:	Board Status: --Select--
Data Monitoring Committee:	--Select--
FDA Regulated Intervention:	--Select--

Save Cancel

* Required

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

[*] Conditionally required (see Definitions)

IND/IDE Protocol? *(FDAAA)

Definition: Indicate if the protocol involves an Investigational New Drug Application (IND) or Investigational Device Exemption (IDE) under US Food and Drug Administration regulations

若您的計畫案預計向美國FDA申請新藥或新醫療技術登記，才需填YES。

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Oversight

ID: Enter Your IRB Approve Number | Protocol Title | 請按照下方文字輸入 | [NCT ID not yet assigned]

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 Dev

* Human Subjects Protection Review:

Board Status: Request not yet submitted

The following information is required if the study meets each of these criteria: not require
government, and is not conducted under an IND or IDE. [This information is not made pu

Board Name:
Board Affiliation:
Board Contact: Phone: Extension:
Email:
Address:

Data Monitoring Committee: --Select--

FDA Regulated Intervention: --Select--

Save Cancel

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

- **Board Name:**
  National Taiwan University Hospital Research Ethics Committee
- **Board Affiliation:**
  National Taiwan University Hospital
- **Phone:**
  +886-2312-3456 Extension: 88576
- **Email:**
  fctsai@ntu.edu.tw
- **Address:**
  No.1, Changde St., Zhongzheng Dist., Taipei City 100,Taiwan

Choose "YES" or "NO" from the drop down.
If the study has a Medical Monitor but no DMC, the answer is "NO".

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Oversight

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

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
For more information see the "Elaboration"

* U.S. FDA IND/IDE: --Select--
(Not public)
Studying drug/device product with U.S. FD

* Human Subjects Protection Review: Board Status: --Select--

Data Monitoring Committee: --Select--

FDA Regulated Intervention: --Select--

Save Cancel

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

FDA Regulated Intervention? (FDAAA)
Section 801 Clinical Trial? (FDAAA)
Definition: If this trial includes an FDA regulated intervention, indicate whether this is an "applicable clinical trial" as defined in US Public Law 110-85, Title VIII, Section 801. Briefly, application drug trials include controlled clinical investigations, other than Phase I investigations, of a drug or biologic subject to US FDA regulation. Application device clinical trials are controlled trials with health outcomes of devices subject to FDA regulation, other than small feasibility studies, and pediatric postmarket surveillance.
Select Tes/No.
若您的計畫案來源或經費與美國FDA有關，才需填YES。

ID: Enter Your IRB Approve Number | Protocol Title | [NCT ID not yet assigned]

Edit Study Description

Help Definitions

* Brief Summary:

Special Characters

Detailed Description:

Avoid duplicating information that will be entered

Save Cancel

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

Definition:
Short description of the protocol intended for the lay public. Include a brief statement of the study hypothesis. (Limit: 5,000 characters)

Definition:
Extended description of the protocol, including more technical information (as compared to the Brief Summary) if desired. Don not include the entire protocol; do not duplicate information recorded in other data elements, such as eligibility criteria or outcome measures. (Limit: 32,000 characters)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Conditions

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Conditions

Help Definitions

* Conditions or Focus of Study: × 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

ERROR: Condition is a required field.

Primary disease or condition being studied, or focus of the study

Keywords: + Add Keyword

Words or phrases the best describe the protocol. Avoid acronyms and abbreviations.

Save Cancel

* Required

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

[*] Conditionally required (see Definitions)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Design

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* Study Type: Interventional

* § Primary Purpose: --Select--

* Study Phase: --Select--
Use "N/A" for trials that do not involve drug or biologic pr

* § Interventional Study Model: --Select--

Model Description:

* § Number of Arms:

* § 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--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

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

Save Cancel

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Design

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* Study Type: Interventional

* § Primary Purpose: --Select--

* Study Phase: --Select--
Use "N/A" for trials that do not involve drug or biologic

Choices are N/A (for trials without Phases), 0, 1, ½, 2, 2/3, 3, and 4.

* § Interventional Study Model: --Select--

Model Description:

* § Number of Arms:

* § 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--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

Save Cancel

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Design

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* 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:

* § 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--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

Save Cancel

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

- **Single Group:**
  single arm study
- **Parallel:**
  participants are assigned to one of two or more groups in parallel for the duration of the study
- **Cross-over:**
  participants receive one of alternative interventions during the initial phase of the study and receive the other intervention during the second phase of the study
- **Factorial:**
  two or more interventions, each alone and in combination, are evaluated in parallel against a control group

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Design

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* 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:

➢ **Number of interventional groups. Enter 1 for single-arm study.**

* § 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--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

Save Cancel

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Design

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* 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:

* § Masking:
- ☐ Participant
- ☐ Care Provider
- ☐ Investigator
- ☐ Outcomes Assessor

➢ Single Blind
➢ Double Blind

- ☐ None (Open Label)

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

➢ Open

Masking Description:

* § Allocation: --Select--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

Save Cancel

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

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* 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:

* § 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--
Select N/A for single-arm studies.

Choices are N/A (for single-arm study), Randomized Controlled Trial or Nonrandomized Trial.

* § Enrollment: Number of Subjects: Type: --Select--

Save Cancel

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Study Design

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventional Study Design

Help Definitions

* 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:

* § 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--
Select N/A for single-arm studies.

* § Enrollment: Number of Subjects: Type: --Select--

Save Cancel

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

Target or Actual Number of Subjects, you specify by selecting Anticipated or Actual in the accompanying Type menu. Upon study completion, you must update this to reflect actual and final total enrollment.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Arms and Interventions

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Arms and Interventions

Protocol Section Help Definitions

Edit

Arms

Information is required

Edit

Interventions

Information is required

Cross-Reference

[This section only applies when there are two or more Arms and one or more Interventions.]

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Arms and Interventions > Arms

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Arms

Help Definitions

+ Add Arm

Save Cancel

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

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Arms

Help Definitions

Arms:

* Arm Title:

Formerly Arm Label. Brief, descriptive label to be used as row or column heading in tables.

* Arm Type: --Select--

[*] Arm Description:

Describe the intervention(s) to be administered.
For drugs use generic name and include dosage form, dosage, frequency and duration.

× Delete Arm

+ Add Arm

Save Cancel

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

The short name used to identify the arm. (Limit: 62 characters)

5 item Pick list :
- Experimental
- Active Comparator
- Placebo Comparator
- Sham Comparator
- No intervention
- Other

May not be needed, if the Arm Label says all that's needed. If you use it. Limit is 999 characters.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Arms and Interventions

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Arms and Interventions

Protocol Section Help Definitions

Edit

Arms

Information is required

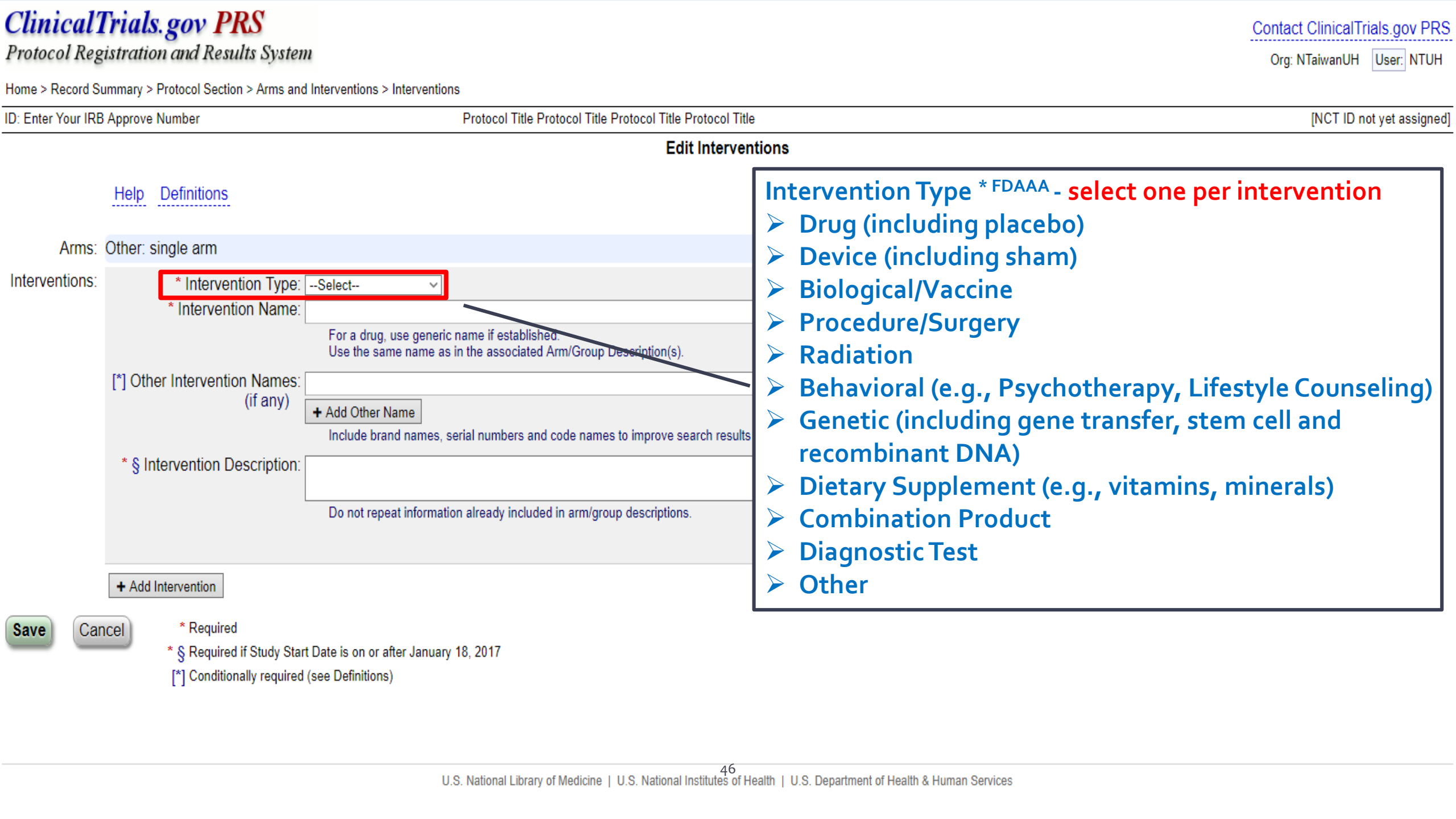
Edit

Interventions

Information is required

Cross-Reference

[This section only applies when there are two or more Arms and one or more Interventions.]



Intervention Type * FDAAA - select one per intervention

- Drug (including placebo)
- Device (including sham)
- Biological/Vaccine
- Procedure/Surgery
- Radiation
- Behavioral (e.g., Psychotherapy, Lifestyle Counseling)
- Genetic (including gene transfer, stem cell and recombinant DNA)
- Dietary Supplement (e.g., vitamins, minerals)
- Combination Product
- Diagnostic Test
- Other

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Arms and Interventions > Interventions

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Interventions

Help Definitions

Arms: Other: single arm

Interventions:

* Intervention Type: --Select--

* Intervention Name:

For a drug, use generic name if established.
Use the same name as in the associated Arm/Group Description(s).

[*] Other Intervention Names: (if any)

× Delete

+ Add Other Name

Include brand names, serial numbers and code names to improve search results on the ClinicalTrials.gov web site.

* § Intervention Description:

Do not repeat information already included in arm/group descriptions.

+ Add Intervention

Save Cancel

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

For drugs use generic name; for other types of interventions provide a brief descriptive name. (Limit: 160 characters)

(Limit: 1000 characters)
Example:
50 mg/m2, IV (in the vein) on day 5 of each 28 day cycle. Number of Cycles: until progression or unacceptable toxicity develops.

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Outcome Measures

Help Definitions

* Primary Outcome Measure:

Outcome 1

Title:

Description:

Time Frame:

× Delete Outcome

+ Add Primary Outcome

[*] Secondary Outcome Measures: (if any)

+ Add Secondary Outcome

Other Pre-specified Outcomes:

+ Add Other Outcome

Save Cancel

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

A concise name for the specific measure that will be used to determine the effect of the intervention(s) or, for observational studies , Limit: 254 characters

Time point(s) at which outcome measure is assessed. (Limit: 254 characters)

Examples of Outcome Measure Titles and Time Frames

Safety/Adverse Event Outcome Measure

Title: Number of Participants with Serious and Non-Serious Adverse Events
Time Frame: Up to 3 weeks

[Source: TTT Workshop – Dose Escalation Study Design (modified)]

Time-to-Event Outcome Measure

Title: Time to Disease Progression
Time Frame: up to 31 months

[Source: Helpful Hints – Parallel Design Example (modified)]

Efficacy Outcome Measure

Title: Percentage of Participants with ≥ 50% Decrease in Pain Visual Analogue Scale (VAS)
Time Frame: 8 hours

Pharmacokinetic Outcome Measure

Title: Area Under the Concentration-Time Curve (AUC 0-72h)
Time Frame: prior to the initial dose on day 1 and 0.25, 0.5, 0.75, 1, 2, 3, 4, 5, 6, 7, 8, 16, 24, 36, 48 and 72 hours post-dose

[Source: TTT Workshop – Dose Escalation Study Design]

Change Outcome Measure

Title: Change from baseline in pain on the 11-point Short Pain Scale (SPS-11) at week 24
Time Frame: Baseline, Week 24

[Source: TTT Workshop - Example Parallel Study Design]

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Eligibility

Help Definitions

* Sex:	--Select-- Biological sex of eligible participants.
[*] Gender Based:	--Select-- If applicable, indicate if participant eligibility is based on self-representation of gender identity.
* Age Limits:	Minimum: --Select-- Maximum: --Select--
* § Accepts Healthy Volunteers:	--Select--
* Eligibility Criteria:	Inclusion Criteria: - Exclusion Criteria: - Special Characters

Save Cancel

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

Choices are Male, Female, Both

Yes: Eligibility is based on gender
No: Eligibility is not based on gender
If "Yes", provide descriptive information about Gender criteria.
Limit: 1000 characters.

Blank with selection of N/A (No Limit) is allowed for minimum, maximum or both.

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit Eligibility

Help Definitions

* Sex: --Select--
Biological sex of eligible participants.

[*] Gender Based: --Select--
If applicable, indicate if participant eligibility is based on self-representation of gender identity.

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

* § Accepts Healthy Volunteers: --Select--

* Eligibility Criteria:

Inclusion Criteria:
-

Exclusion Criteria:
-

Special Characters

Yes or No

List criteria with Hyphen, then space, then text in words, phrases or sentences. Limit 15,000 characters.

Save Cancel

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

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > Contacts/Locations

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Contacts/Locations

Protocol Section Help Definitions

Edit

Overall Contacts

Central Contact Person:

Central Contact Backup:

Overall Study Officials:

Copy locations... from a master list, extracted from this organization's records.

+ Add Location

U.S. National Library of Medicine | U.S. National Institutes of Health | U.S. Department of Health & Human Services

➢ 煩請填寫正確聯絡資訊 以利聯繫

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > IPD Sharing Statement

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit IPD Sharing Statement

Help Definitions

Plan to Share IPD: --Select--

Indicate if there is a plan to make individual participant data (IPD) available to other researchers.

Save Cancel

* Required

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

[*] Conditionally required (see Definitions)

Indicate whether there is a plan to make individual participant data (IPD) collected in this study, including data dictionaries, available to other researchers (typically after the end of the study)

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH

Home > Record Summary > Protocol Section > References

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Edit References

Help Definitions

Citations:

+ Add Citation

Links:

+ Add Link

Available IPD/Information: References to deidentified individual participant data (IPD) sets and supporting information.

+ Add Data/Information

Save Cancel

* Required

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

[*] Conditionally required (see Definitions)

Citations to publications related to the protocol: background and/or results. Provide either the PubMed Unique Identifier (PMID) of an article or enter the full bibliographic citation.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH | User: NTUH | Logout

Home > Record Summary

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Record Summary

Home | Help

Record Status

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

Next Step: Confirm data entry complete **Entry Complete**

Record Owner:	NTUH	Access List:	[] Edit
Last Update:	09/06/2018 23:31 by NTUH	Upload:	Allowed Edit
Initial Release:	[Not yet released]	PRS Review:	[Not yet released]
		Public Site:	[Not yet registered]
		FDAAA:	Non-ACT (No FDA-regulated drug/device)

確認沒有任何錯誤訊息(WARNING/ERROR messages)產生，最後記得點選"Entry Complete"，方算完成臨床試驗登錄。

Spelling | Preview | Draft Receipt (PDF RTF) | Download XML | Delete...

Open **Protocol Section**

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Enter Your IRB Approve Number

Brief Title: Protocol Title Protocol Title Protocol Title Protocol Title (PT)

Module Status:

- Study Identification: ✓ 1 Note
- Study Status: ✓
- Sponsor/Collaborators: ✓
- Oversight: ✓
- Study Description: ✓
- Conditions: ✓ 2 Notes
- Study Design: ✓
- Arms and Interventions: ✓ 3 Notes

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH | User: NTUH | Logout

Home > Record Summary

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Record Summary

Home | Help

Record Status

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

Next Step: Confirm data entry complete

Record Owner: NTUH
Last Update: 09/06/2018 23:31
Initial Release: [Not yet released]

Spelling | Preview | Draft Receipt (PDF

Open **Protocol Section**

Identifiers: [NCT ID not yet as
Brief Title: Protocol Title Proto
Module Status:
Study Identifi
Study S
Sponsor/Collabo
Oversight: ✓
Study Description: ✓
Conditions: ✓ 2 Notes
Study Design: ✓
Arms and Interventions: ✓ 3 Notes

Record Status	Description
In Progress	User is creating (or modifying) the record.
Completed	User has finished - record is ready for review.
Approved	Administrator (or Responsible Party) has reviewed record and has made any necessary changes.
Released	Administrator (or Responsible Party) has submitted the record to ClinicalTrials.gov.

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH Logout

Home > Record Summary

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Record Summary

Data entry has already been completed for this record.

Home Help

Record Status

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

Reset to In-Progress...

Next Step: NTaiwanUH Administrator needs to Approve and Release record

Record Owner:	NTUH	Access List:	[] Edit
Last Update:	09/06/2018 23:31 by NTUH	Upload:	Allowed Edit
Initial Release:	[Not yet released]	PRS Review:	[Not yet released]
		Public Site:	[Not yet registered]
		FDAAA:	Non-ACT (No FDA-regulated drug/device)

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

Open **Protocol Section**

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Enter Your IRB Approve Number

Brief Title: Protocol Title Protocol Title Protocol Title Protocol Title (PT)

Module Status:

- Study Identification: ✔ 1 Note
- Study Status: ✔
- Sponsor/Collaborators: ✔
- Oversight: ✔
- Study Description: ✔
- Conditions: ✔ 2 Notes
- Study Design: ✔
- Arms and Interventions: ✔ 3 Notes

ClinicalTrials.gov PRS
Protocol Registration and Results System

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH Logout

Home > Record Summary

ID: Enter Your IRB Approve Number | Protocol Title Protocol Title Protocol Title Protocol Title | [NCT ID not yet assigned]

Record Summary

Data entry has already been completed for this record.

Home Help

Record Status

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

Reset to In-Progress...

Next Step: NTaiwanUH Administrator needs to Approve and Release record

Record Owner:	NTUH	Access List:	[] Edit
Last Update:	09/06/2018 23:31 by NTUH	Upload:	Allowed Edit
Initial Release:	[Not yet released]	PRS Review:	[Not yet released]
		Public Site:	[Not yet registered]
		FDAAA:	Non-ACT (No FDA-regulated drug/device)

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

Open **Protocol Section**

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: Enter Your IRB Approve Number

Brief Title: Protocol Title Protocol Title Protocol Title Protocol Title (PT)

Module Status:

- Study Identification: ✓ 1 Note
- Study Status: ✓
- Sponsor/Collaborators: ✓
- Oversight: ✓
- Study Description: ✓
- Conditions: ✓ 2 Notes
- Study Design: ✓
- Arms and Interventions: ✓ 3 Notes

ClinicalTrials.gov Protocol Registration Data Element Definitions for Interventional and Observational Studies
→ https://prsinfo.clinicaltrials.gov/definitions.html

ClinicalTrials.gov PRS
Protocol Registration and Results System

If you need to edit your protocol

Contact ClinicalTrials.gov PRS
Org: NTaiwanUH User: NTUH Logout

Quick Links
New Record
Quick Start Guide
Problem Resolution Guide

Records ▾ Accounts ▾ Help ▾

Email: rmcore@ntuh.gov.tw [Update]
Help us improve: PRS Survey

Enter your Protocol ID or Brief Title

Record List

Showing: 1-10 of **1,734** records 10 records per page

Search: Show/Hide Columns

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Responsible Party	Problems
Open	Enter Your IRB Approve Number		Protocol Title Protocol Title Protocol Title Protocol Title (PT)	Entry Completed	09/06/2018 23:31	[Sponsor]	• Ready for Review and Approval • Never Released
Open	201709016RIPC		Taiwan Cohort - Chronic ThromboEmbolic Pulmonary Hypertension Registry	Entry Completed	09/06/2018 23:29	[Sponsor]	• Ready for Review and Approval • Never Released
Open	201006057M	NCT01252017	Nilotinib for Cytomegalovirus Prophylaxis and Treatment After Allogeneic Hematopoietic Stem Cell Transplantation	Entry Completed	09/06/2018 22:27	[Sponsor]	• Ready for Review and Approval • Update Not Released
Open D	201801059DINC	NCT03662594	Growth of High-Quality Oxides on The Inner Surface of ECMO Circuit by ALD to Reduce Thrombus Formation	Public	09/05/2018 20:34	[Sponsor]	
Open	201805087RINB	NCT03639584	Prevalence of Deficiency of Vitamin D in Critically Ill Patients	Public	09/05/2018 08:14	[Sponsor]	
Open	201807118RINB	NCT03661944	Can Functional Performance Assessments in Overhead Athletes With Shoulder Injury Assess the Ability of Return to Play (RTP)?	Public	09/05/2018 04:44	[Sponsor]	
Open	201601091RIND	NCT02779088	The Physical Fitness Cohort Study in the Community-dwelling Elderly in the WanHwa Area.	In Progress	09/05/2018 02:13	[Sponsor]	• PRS Review Comments • Entry Not Completed • Not Recently Updated • Update Not Released
Open	201805043RINC		Shoulder Brace on Muscle Activation and Scapular Kinematics in Patients With Shoulder Impingement Syndrome and Rounded Shoulder Posture	In Progress	09/04/2018 04:58	[Sponsor]	• PRS Review Comments • Entry Not Completed
Open	201207070RIC	NCT02814396	The Application of Multichannel ECG Analytic System in Cardiovascular Diseases	In Progress	09/03/2018 04:18	[Sponsor]	• Entry Not Completed • Not Recently Updated • Update Not Released
Open	201801017RINA		Family-Centered Intervention for Preterm Children: Effects at School Age and Biosocial Mediators	In Progress	09/02/2018 21:52	[Sponsor]	• PRS Review Comments • Entry Not Completed • Update Not Released

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KEY: R Results DR Delayed Results D Study Documents PR PRS Review
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ClinicalTrials.gov PRS
Protocol Registration and Results System

If you need to edit your protocol

Contact ClinicalTrials.gov PRS

Org: NTaiwanUH User: NTUH Logout

Email: rmcore@ntuh.gov.tw [Update]

Help us improve: PRS Survey

Quick Links
- New Record
- Quick Start Guide
- Problem Resolution Guide

Records ▾ Accounts ▾ Help ▾

Record List

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Search: Show/Hide Columns

	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Responsible Party	Problems
Open	Enter Your IRB Approve Number		Protocol Title Protocol Title Protocol Title Protocol Title (PT)	Entry Completed	09/06/2018 23:31	[Sponsor]	• Ready for Review and Approval • Never Released
Open	201709016RIPC		Taiwan Cohort - Chronic ThromboEmbolic Pulmonary Hypertension Registry	Entry Completed	09/06/2018 23:29	[Sponsor]	• Ready for Review and Approval • Never Released
Open	201006057M	NCT01252017	Nilotinib for Cytomegalovirus Prophylaxis and Treatment After Allogeneic Hematopoietic Stem Cell Transplantation	Entry Completed	09/06/2018 22:27	[Sponsor]	• Ready for Review and Approval • Update Not Released
Open D	201801059DINC	NCT03662594	Growth of High-Quality Oxides on The Inner Surface of ECMO Circuit by ALD to Reduce Thrombus Formation	Public	09/05/2018 20:34	[Sponsor]	
Open	201805087RINB	NCT03639584	Prevalence of Deficiency of Vitamin D in Critically Ill Patients	Public	09/05/2018 08:14	[Sponsor]	
Open	201807118RINB	NCT03661944	Can Functional Performance Assessments in Overhead Athletes With Shoulder Injury Assess the Ability of Return to Play (RTP)?	Public	09/05/2018 04:44	[Sponsor]	
Open	201601091RIND	NCT02779088	The Physical Fitness Cohort Study in the Community-dwelling Elderly in the WanHwa Area.	In Progress	09/05/2018 02:13	[Sponsor]	• PRS Review Comments • Entry Not Completed • Not Recently Updated • Update Not Released
Open	201805043RINC		Shoulder Brace on Muscle Activation and Scapular Kinematics in Patients With Shoulder Impingement Syndrome and Rounded Shoulder Posture	In Progress	09/04/2018 04:58	[Sponsor]	• PRS Review Comments • Entry Not Completed
Open	201207070RIC	NCT02814396	The Application of Multichannel ECG Analytic System in Cardiovascular Diseases	In Progress	09/03/2018 04:18	[Sponsor]	• Entry Not Completed • Not Recently Updated • Update Not Released
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KEY: R Results DR Delayed Results D Study Documents PR PRS Review
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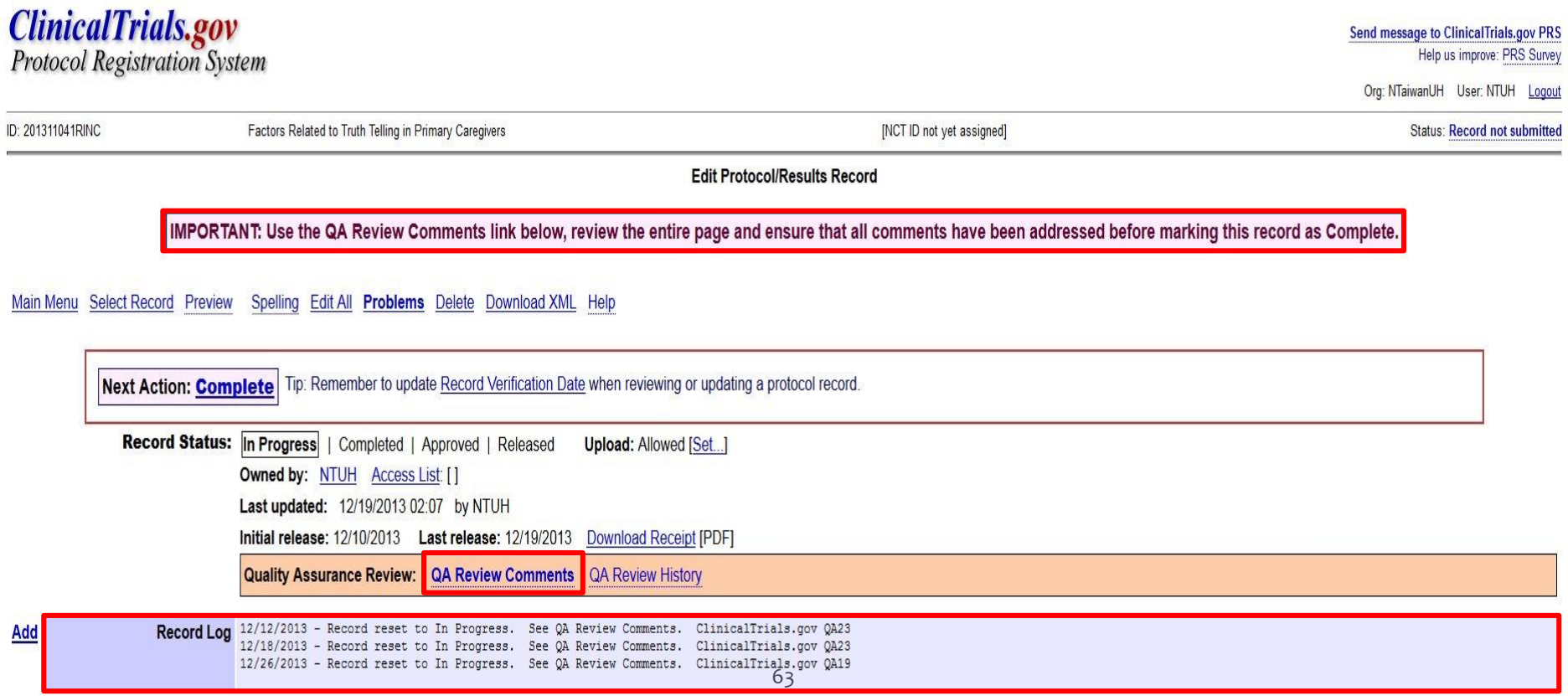
Frequently Asked Question

Publication Date

* Protocol Records are made available to the public through the ClinicalTrials.gov web site within 2 to 5 business days of release following system validation and quality assurance review. The ClinicalTrials.gov identifier (NCT number) will be assigned at that time, and will then be visible in the PRS.

* Records that contain Results may take up to 30 days.

QA Comments


ClinicalTrials.gov
Protocol Registration System
Send message to ClinicalTrials.gov PRS
Help us improve: PRS Survey
Org: NTaiwanUH User: NTUH Logout
ID: 201311041RINC
Factors Related to Truth Telling in Primary Caregivers
[NCT ID not yet assigned]
Status: Record not submitted
Edit Protocol/Results Record
IMPORTANT: Use the QA Review Comments link below, review the entire page and ensure that all comments have been addressed before marking this record as Complete.
Main Menu Select Record Preview Spelling Edit All Problems Delete Download XML Help
Next Action: Complete
Tip: Remember to update Record Verification Date when reviewing or updating a protocol record.
Record Status: In Progress | Completed | Approved | Released
Upload: Allowed [Set...]
Owned by: NTUH Access List: [ ]
Last updated: 12/19/2013 02:07 by NTUH
Initial release: 12/10/2013
Last release: 12/19/2013
Download Receipt [PDF]
Quality Assurance Review: QA Review Comments QA Review History
Add
Record Log
12/12/2013 - Record reset to In Progress. See QA Review Comments. ClinicalTrials.gov QA23
12/18/2013 - Record reset to In Progress. See QA Review Comments. ClinicalTrials.gov QA23
12/26/2013 - Record reset to In Progress. See QA Review Comments. ClinicalTrials.gov QA19

ClinicalTrials.gov
Protocol Registration System

QA Review Comments - Dec-26-2013 06:44

QA Review History

Help - Protocol Data Entry: Key resources for understanding how to register a study
Protocol Review Criteria (PDF): Information on ClinicalTrials.gov review of protocol submissions

Comment Resolution Status: Not updated This record has not been updated since these comments were recorded.

Tip: Scroll down as needed to see *ALL* comments.

Expand All
Show Only Sections With Comments

Factors Related to Truth Telling in Primary Caregivers

This study is not yet open for participant recruitment.
Verified by National Taiwan University Hospital, December 2013

Sponsor:	National Taiwan University Hospital
Collaborators:	
Information provided by (Responsible Party):	National Taiwan University Hospital
ClinicalTrials.gov Identifier:	

Study Release Date: Dec-19-2013 02:51:02.4

Protocol

Purpose	Expand Section
Eligibility	Expand Section
Contacts and Locations	Expand Section
More Information	Expand Section

請針對問題內容逐一修改，回覆完畢後請按”Complete”

Comments [1] :

Please use the Description fields, within the Outcome Measures, to further specify the metrics (i.e. indicators, analysis, scale, questionnaire, etc.) that will be used to characterize 'truth telling,' and 'care burden.'

The Primary Outcome Measure Time Frame includes more than one time point. Each Outcome Measure should typically only specify a single time point of assessment. A common exception to this is a measure assessing change between two time points (e.g., "Change from Baseline Systolic Blood Pressure at 6 months"). If the Outcome Measure(s) are assessing a change, please revise the Outcome Measure Title(s) to specify that "change" is being assessed. If not assessing change, please revise and enter additional Outcome Measures so that there is only one Time Frame per Outcome Measure. Re-release the record after any edits are made.

It is recommended that the condition field list the primary condition or disease being studied (e.g., "Breast Cancer", "Sexual Dysfunction"). Please limit the use of verbs and sentence structure.

Please format keywords, one per line.

No Released Results for study.

Reminder

- 計畫主持人沒有正確填寫臨床試驗計畫資料，電腦系統將拒絕此計畫登錄作業。
- 若您的計畫案為介入性臨床試驗，請務必記得要在收第一位受試者前完成登錄。
- 進行中的臨床試驗計畫，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)。

Contact

* 臨床試驗中心 統計諮詢小組
* 電話：(02)3366-8656
* E-mail：rmcore@ntuh.gov.tw
* 辦公室位置：

  台北市中正區徐州路17號8樓813室 統計諮詢辦公室