

# 臨床試驗計畫案 登錄說明

臨床試驗管理中心  
**Clinical Trials Office**

# 源起

- 國際醫學雜誌編輯委員會投稿規定  
(The International Committee of Medical Journal Editors, ICMJE)
- 經人體倫理委員會核准之臨床試驗，需於第一位受試者參與前，將臨床試驗計畫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

# 源起

- 由研究者自行發起之研究計畫案，應由計畫主持人於取得IRB核準函後完成登錄
- 廠商贊助之研究計畫案，則由廠商主動完成登錄

登入位址

ClinicalTrials.gov  
Protocol Registration System (PRS)

<http://register.clinicaltrials.gov>

# 建立帳號

# 建立帳號

- 未尚有自己帳號之試驗案主持人(PI)
- 請先以馬偕醫院共用帳號登錄  
建立取得屬於自己的帳號
- 請依後續PTT步驟建立

# PRS account

馬偕醫院共用帳號

Administrator

Organization :

MackayMH

Username :

CTO-MMH

Password :

mmhcto2853

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

Login

Welcome to the [ClinicalTrials.gov](https://clinicaltrials.gov) Protocol Registration and Results System (PRS).

Organization:

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

Username:

Password:

[Forgot password](#)

Login

See [Submit Studies](#) on ClinicalTrials.gov for information on how to apply for a PRS.

See [PRS Guided Tutorials](#) for assistance with entering registration and results information.

[Send email to ClinicalTrials.gov PRS Administration.](#)



全院共用帳號  
請勿更改



馬偕紀念醫院  
MacKay Memorial Hospital

# 建立帳號

馬偕公共帳號進入  
Home Page

1. 點選

Accounts

2. 點選

New User Account

3. 進入

User Registration

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

Quick Links  
[New Record](#)  
[Admin Quick Reference](#)  
[Lookup Users](#)  
[Problem Resolution Guide](#)

Records Accounts Help

Change Password  
Update CTO-MMH User Account  
List MackayMH Administrator(s)  
Admin only:  
New User Account  
Modify User Account/Password  
Enable/Disable User Account

Record List  
Group: [ALL] All Records (83) Problem Resolution

Showing: 1-25 of 83 records 25 records per page

	Group	Protocol ID
<a href="#">Open</a>	CTO-MMH	17MMHIS193e
<a href="#">Open</a>	CTO-MMH	20STW2-01

**User Registration**

Group: CTO-MMH  
Access Level: Normal  
User Login Name: CHY  
Full User Name: Chin-Hua Yang  
Other User Information:  
User Email: jinhwa.b074@mmh.org.tw  
Enter email address carefully. Login information, including initial password, is sent to this address.  
☒ Send optional (PRS-generated) email messages  
Phone: 0975XXXXXX

Register Cancel



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## 建立帳號

1. Group:  
請選 **CHO-MMH**
2. Access Level:  
請選 **Normal**
3. Register後，系統隨即寄發帳號、密碼至 User Email
4. 收到mail，請以自己帳號、密碼重新登入

**User Registration**

Group: CTO-MMH ▼

Access Level: Normal ▼

User Login Name: CHY

Full User Name: Chin-Hua Yang

Other User Information:

User Email: jiiinhwa.b074@mmh.org.tw

Enter email address carefully. Login information, including initial password, is sent to this address.

☒ Send optional (PRS-generated) email messages

Phone: 0975XXXXXX

**Register** **Cancel**

# 登錄新案

# 點選 New record

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

Contact ClinicalTrials.gov PRS  
Org: MackayMH Admin: CTO-MMH Logout  
Email: mmhcto@gmail.com; a6284@mmh.org.tw [Update]  
Help us improve: PRS Survey

Quick Links  
[New Record](#)  
[Admin Quick Reference](#)  
[Lookup Users](#)  
[Problem Resolution Guide](#)

Records Accounts Help

Record List

Group: CTO-MMH All Records (74) Problem Records (47) Custom Filter

Showing: 1-25 of 74 records 25 records per page Search: Show/Hide Columns

	Group	Protocol ID	ClinicalTrials.gov ID	Brief Title	Record Status	Last Update	Record Owner	Responsible Party	Problems
<a href="#">Open</a>	CTO-MMH	MMHtest01			In Progress	01/20/2021 03:07	CTO-MMH	None	<ul style="list-style-type: none"><li>Entry Not Completed</li><li>Never Released</li></ul>

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. Conditions
7. Study Design
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

## 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:

\* Brief Title:

[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

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

依據Protocol Section  
依序填寫

\* Organization's Unique Protocol ID:

\* Brief Title:

[\*] Acronym:   
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
- ☐ **Expanded Access** availability of an experimental product



填完Study Identification後即可在Home page查詢到已填入之計畫案

[Continue](#)

[Cancel](#)

\* Required

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

[\*] Conditionally required (see Definitions)

## Record List

Group:

All Records (73)

Problem Records (46)

[Custom Filter](#)

Showing: 1-10 of 73 records

10

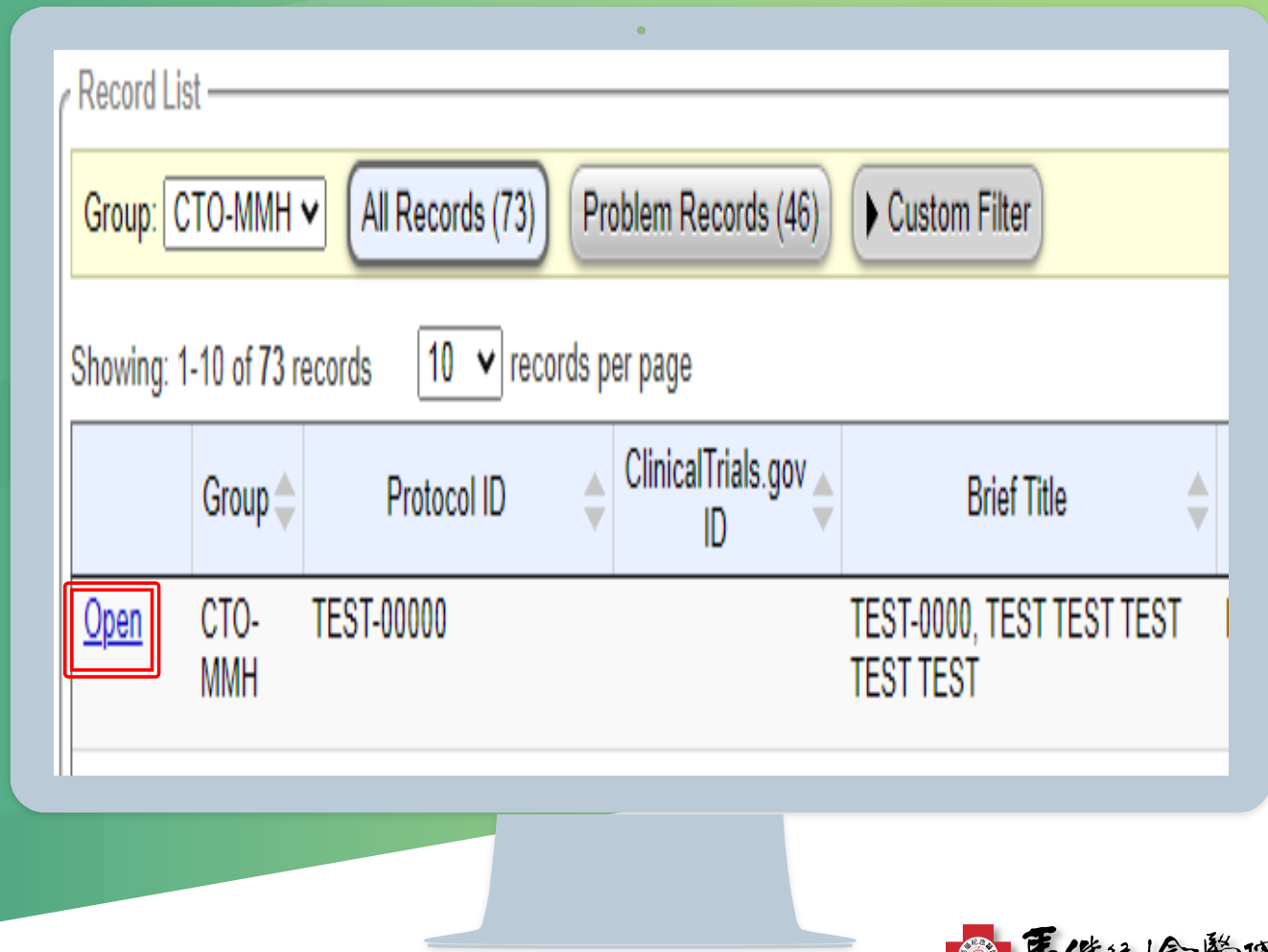
records per page

	Group	Protocol ID	ClinicalTrials.gov ID	Brief Title
<a href="#">Open</a>	CTO-MMH	TEST-00000		TEST-0000, TEST TEST TEST TEST TEST



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在Home page每一計畫案左側按下  
Open 可以繼續編輯未完成之  
Protocol Section



續按下 **Open** 可以  
繼續編輯未完成之  
Protocol Section

[Spelling](#) [Preview](#) Draft Receipt ([PDF](#) [RTF](#)) [Download XML](#) [Delete...](#) Admin Only: [Copy Protocol](#) [Change Owner](#)

[Open](#)

### Protocol Section

Identifiers: [NCT ID not yet assigned] Unique Protocol ID: TEST-00000

Brief Title: TEST-0000, TEST TEST TEST TEST

Module Status:

Study Identification: ✓ 4 Notes

Study Status: Information is required

Sponsor/Collaborators: ✓

Oversight: Information is required

Study Description: Information is required

Conditions: Information is required

Study Design: Information is required

Arms and Interventions: Information is required

Outcome Measures: Information is required

Eligibility: Information is required

Contacts/Locations: Information is required

IPD Sharing Statement:

References:



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輸入完成後詳細檢視登錄資料

出現紅色字體為登錄不完全

選擇Edit繼續編輯

[Record Summary](#) [Preview](#) [Edit All](#) [Help](#) [Definitions](#)

[Edit](#)

### Study Identification

Unique Protocol ID: 555545454

Brief Title: Tetterfd (ABI)

Official Title:

Secondary IDs:

ERROR: A title this short cannot be sufficiently descriptive.

ERROR: Official Title has not been entered.

[Edit](#)

### Study Status

Record Verification:

Overall Status:

Study Start:

Primary Completion:

Study Completion:

Information is required

登錄不完全





# Protocol Section

1. **Study Identification**
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. Conditions
7. Study Design
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

Home > Record Summary > Protocol Section > Study Identification

ID: TEST-00000

TEST-0000, TEST TEST TEST TEST TEST

## Edit Study Identification

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

\* Organization's Unique Protocol ID:

TEST-00000

\* Brief Title:

TEST-0000, TEST TEST TEST TEST TEST

NOTE: Titles should be in proper title case.

NOTE: A title this short may not be sufficiently descriptive.

[\*] Acronym:  
(if any)

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

\* § Official Title:

TEST-0000, TEST TEST TEST TEST TEST

NOTE: Titles should be in proper title case.

NOTE: A title this short may not be sufficiently descriptive.

[\*] Secondary IDs:  
(if any)

+ Add Secondary ID

Save

Cancel

\* Required

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

[\*] Conditionally required (see Definitions)

# Protocol Section

1. Study Identification
2. **Study Status**
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. Conditions
7. Study Design
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

Home > Record Summary > Protocol Section > Study Status

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

**Edit Study Status**

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

\* Record Verification Date: Month:  Year:

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

Tip: Day is not required for Anticipated dates.

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

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

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

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

# Protocol Section

1. Study Identification
2. Study Status
3. **Sponsor/Collaborators**
4. Oversight
5. Study Description
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9. Outcome Measures
10. Eligibility
11. Contacts/Locations
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13. References

Home > Record Summary > Protocol Section > Sponsor/Collaborators

ID: TEST-00000

TEST-0000, TEST TEST TEST TEST TEST

## 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.

\* Sponsor:

Mackay Memorial Hospital

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

Collaborators:

✕ Delete

+ 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**.

Save

Cancel

\* Required

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

[\*] Conditionally required (see Definitions)



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# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. **Oversight**
5. Study Description
6. Conditions
7. Study Design
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

Home > Record Summary > Protocol Section > Oversight

ID: TEST-00000

TEST-0000, TEST TEST TEST TEST TEST

## 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 Device Exemption (IDE)?

\* 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)



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MacKay Memorial Hospital

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. **Study Description**
6. Conditions
7. Study Design
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

Home > Record Summary > Protocol Section > Study Description

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

### Edit Study Description

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

\* Brief Summary:

[Special Characters](#)

Detailed Description:

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

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

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. **Conditions**
7. Study Design
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

Home > Record Summary > Protocol Section > Conditions

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

**Edit Conditions**

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

\* Conditions or Focus of Study:

[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.

Keywords:

\* Required

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

[\*] Conditionally required (see Definitions)

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. Conditions
7. **Study Design**
8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. References

Home > Record Summary > Protocol Section > Study Design

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

**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 Participants:  Type: --Select--

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

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. Conditions
7. Study Design
8. **Arms, Interventions**
9. Outcome Measures
10. Eligibility
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13. References

[Home](#) > [Record Summary](#) > [Protocol Section](#) > Arms and Interventions

ID: TEST-00000

TEST-0000, TEST TEST TEST TEST TEST

## 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.]



# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
6. Conditions
7. Study Design
8. Arms, Interventions
9. **Outcome Measures**
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Home > Record Summary > Protocol Section > Outcome Measures

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

### Edit Outcome Measures

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

\* Primary Outcome Measure:

*Outcome 1*

Title:

Description:

Time Frame:

[\*] Secondary Outcome Measures:  
(if any)

Other Pre-specified Outcomes:

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

# Protocol Section

1. Study Identification
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4. Oversight
5. Study Description
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9. Outcome Measures
10. **Eligibility**
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12. IPD Sharing Statement
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Home > Record Summary > Protocol Section > Eligibility

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

**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)

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
5. Study Description
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8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. **Contacts/Locations**
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13. References

Home > Record Summary > Protocol Section > Contacts/Locations > Overall Contacts

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

### Edit Overall Contacts

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

\* Central Contact Person:

First Name:  MI:  Last Name:  Degree:

Phone:  Ext:  Email:

Either Central Contact or Facility Contacts are required.  
The individual's official title may be substituted for Last Name (leave First Name, MI and Degree blank).

Central Contact Backup:

First Name:  MI:  Last Name:  Degree:

Phone:  Ext:  Email:

Overall Study Officials:

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

# Protocol Section

1. Study Identification
2. Study Status
3. Sponsor/Collaborators
4. Oversight
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8. Arms, Interventions
9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. **IPD Sharing Statement**
13. References

Home > Record Summary > Protocol Section > IPD Sharing Statement

ID: TEST-00000

TEST-0000, TEST TEST TEST TEST TEST

**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)



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# Protocol Section

1. Study Identification
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9. Outcome Measures
10. Eligibility
11. Contacts/Locations
12. IPD Sharing Statement
13. **References**

Home > Record Summary > Protocol Section > References

ID: TEST-00000 TEST-0000, TEST TEST TEST TEST TEST

**Edit References**

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

Citations:

Links:

Available IPD/Information:

References to deidentified individual participant data (IPD) sets and supporting information.

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

# 聯繫資訊

## 臨床試驗管理中心 *Clinical Trials Office*

TEL : 25433535

EXT : 2851~2853

Thanks!