Investigator Responsibilities

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PReMA
Pharmaceutical Research & Manufacturers Association

Investigator

Ensure subject safety
Develop reliable data

How investigator should be?

- Have good resource
- Understand IRB requirement
- Understand inform consent process
- Execute effective patient management
- Adhere to Protocol

Have Good Resource

Have Good Resource

- **Investigators' qualification**
  - Education
  - Training
  - Experience

Have Good Resource

- **Investigator Qualifications**
  - Understand and Comply with GCP
  - Familiar with study product
  - Understand Study protocol

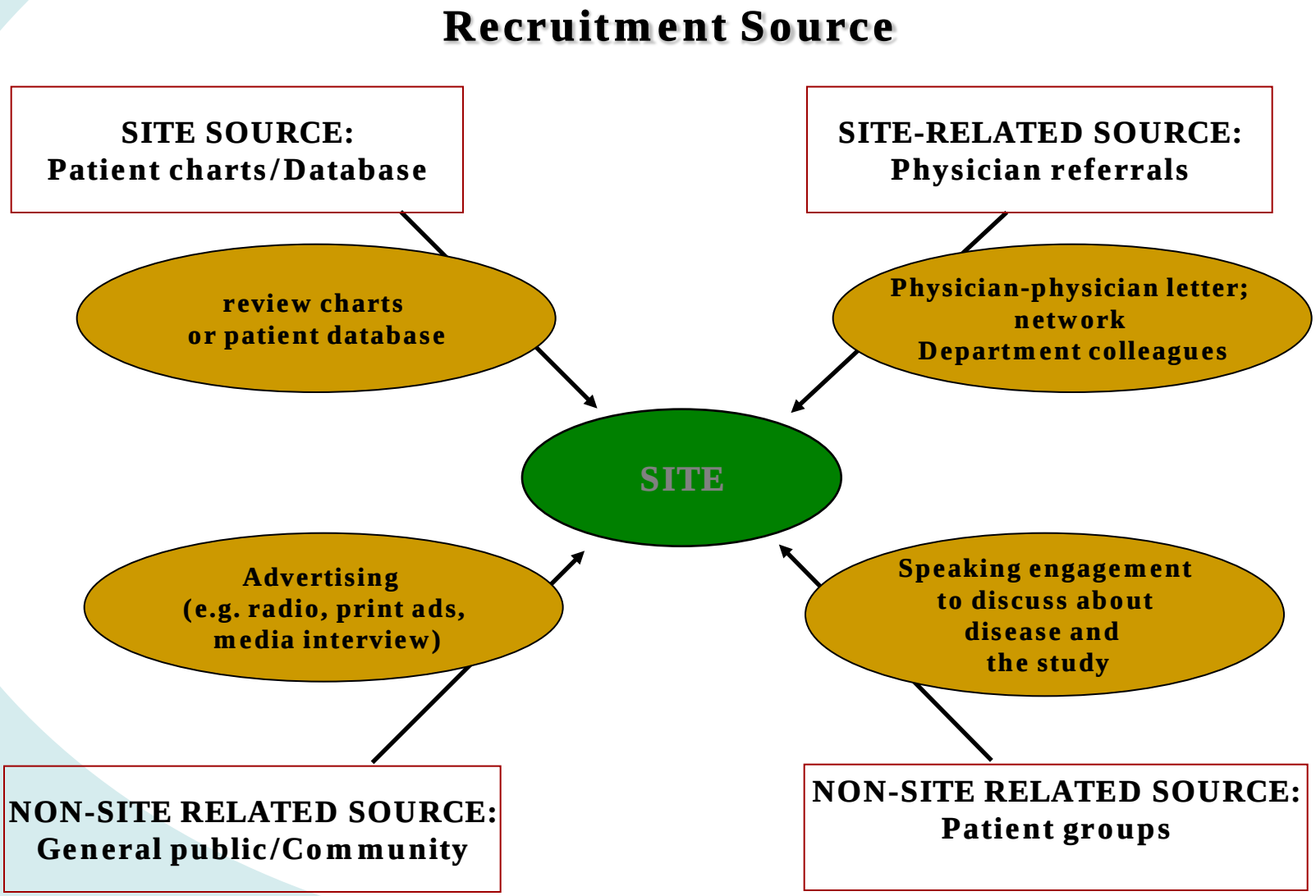
Have Good Resource

- **Recruitment Potential**
  - Subject pool
  - Subject resource

Recruitment Strategy

- **Study design and Timeline**
- **Subject Population (healthy subject or patient)**
  - Aware of study challenge and timeline
- **Recruitment Source**
- **Recruitment Method**
- **Recruitment Material**
- **Recruitment Plan**
- **Recruitment Tracking**

Recruitment Strategy



Have Good Resource

- **Qualified staff**
- **Qualified facilities**

Facility

Have Good Resource

- **Investigator has sufficient time to conduct and complete the study**
- **Site staffs are adequately informed on study related information.**

Have Good Resource

- **Study Product**
  - Store in accordance with protocol
  - Use in accordance with protocol

Have Good Resource

- **Study Product**
  - Accountability of study product
  - Properly maintain the record
    - Delivery and return
    - inventory
    - Use of study product
    - Reconciliation of study product

Understand IRB Requirement

Understand IRB/ERC Requirement

- **Provide study related doc to IRB/ERC for review and approve**

  Protocol, Inform consent, investigator's brochure or others

- **Sign protocol or alternative contract to confirm an agreement**

Understand IRB/ERC Requirement

- **Ensure the written approval on protocol, inform consent and other written doc provided to subject**
- **Provide any updated doc for review and approval**
  - Protocol, Inform consent, investigator's brochure or others

Understand IRB/ERC Requirement

- **Progress Report**
  - Submit study update to IRB/ERC accordingly
  - Promptly report to IRB/ERC if any significant change to study or increase risk to subject

Understand IRB/ERC Requirement

- **Safety Report**
  - Immediately report any serious adverse event to sponsor
  - Follow IRB/ERC regulation on any of AE report
  - Use code number to identify subject
  - In case of dead, additional information such as autopsy is needed

Understand IRB/ERC Requirement

- **Final Report**
  - Notify IRB/ERC upon completion
  - Providing IRB/IEC with a summary of the trial's outcome

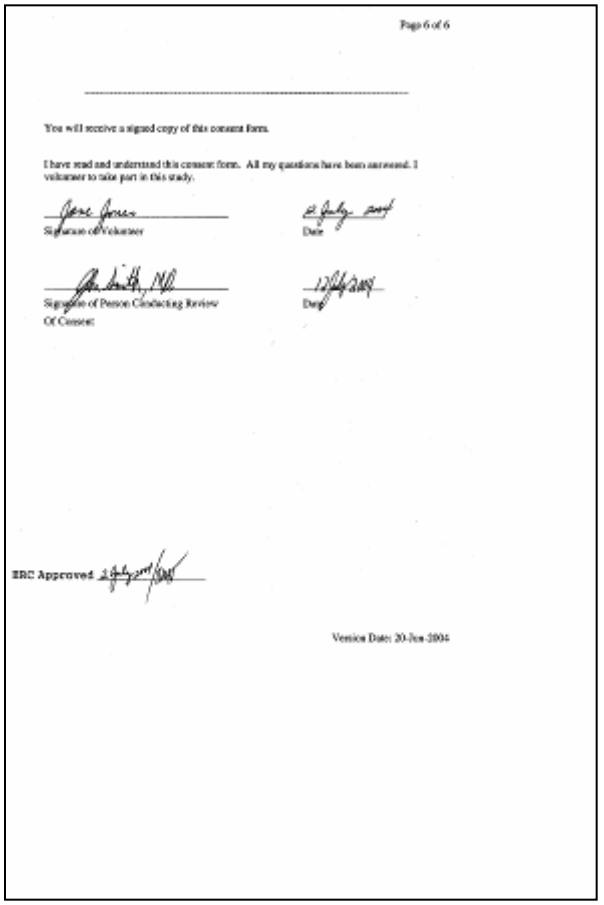
Understand Inform Consent Process

Understand Inform Consent Process

- Obtain IC before a subject enters the study
- Use the most understandable language to communicate
- Avoid coerce or unduly influence a subject
- No language waive or appear to waive any legal right or liability for negligence
- Provide time and opportunity to read and decide
- Answer all questions

Understand Inform Consent Process

- **Inform consent**
  - Personally signed and dated by subject or legal representative



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You will receive a signed copy of this consent form.

I have read and understood this consent form. All my questions have been answered. I volunteer to take part in this study.

Signature of Volunteer

Date

Signature of Person Conducting Review Of Consent

Date

IRC Approved

Version Date: 20-Jun-2004

Understand Inform Consent Process

- **An impartial witness is presented through out the process of inform consent if a subject is unable to read**
- **An impartial witness must personally sign and date**
- **New information in inform consent should be informed to a subject in the timely manner after IRB/ERC review and approve**

Execute Effective Subject Management

Execute Effective Subject Management

- **Medical Care of Subject**
  - Responsible for study related medical decisions
  - Adequate medical care is provided in the event of AE during the study
  - Inform a subject's primary doctor of subject participation

Execute Effective Subject Management

- **Premature Termination/Suspension**
  - Promptly inform subject
  - Assure appropriate therapy and follow up for the subject
  - Comply with any IRB/ERC or regulatory requirement

Execute Effective Subject Management

If investigator terminates or suspends the study without prior agreement with the sponsors, must inform

- Sponsor
- IRB/IEC
- Provide written explanation to sponsor and IRB/IEC for the termination

Execute Effective Subject Management

If IRB/IEC terminates or suspends its approval

- Inform the institution
- Notify sponsor with explanation

If sponsor terminates or suspends a study

- Inform IRB/IEC and Investigator
- provide explanation of the termination or suspension

Adhere to Protocol

Adhere to Protocol

- **Protocol Compliance**
- **No deviation unless**
  - Agreed by sponsor
  - Approved by IRB/ERC
- **Document any deviation**

Adhere to Protocol

Exception!!!

To eliminate immediate hazard from subject

Adhere to Protocol

- **Randomization procedures and unblinding**
  - Following protocol randomization procedure
  - Unblinding according to protocol
  - Document and notify on any premature unblinding

Adhere to Protocol

- **Record and Report**
  - Ensure accuracy, completeness, legibility and timeliness of data entered to the case report form
  - Ensure the consistency of the data
  - Ensure that any change to the data is initialed, dated and explained

Record and Report (cont.)

Example:

Source Document

Visit date:
06/05/08

Temp: 37.3 ◦F.

Suchai Kit, M.D.

CRF

AN: 6005

Visit: # 2

Date of Visit:

06/05/08

Temp 37.3

PV
7May08

~~38.3~~ ◦F

Record and Report (cont.)

- **Retain any document drop under essential document**
- **Prevent accidental or premature destruction of document**
- **Make available for monitoring , auditing or inspecting**

Essential Document (ICH GCP 8)

Summary

Sources

ICH E6
http://www.fda.gov/cder/guidance/959fnl.pdf

ICH GCP (Thai version)
Available at Thai FDA

WHO
http://www.who.int/medicines/areas/quality_safety/safety_efficiency/gcp1.pdf

Thank you


PReMA
Pharmaceutical Research &
Manufacturers Association