Informed Consent

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Objectives

- Define informed consent
- Discuss the development of the **informed consent document**
- Discuss the **informed consent process**

What is Informed Consent?

A process **by which a subject voluntarily confirms his or her willingness to participate in a trial, after having been informed of all aspects of the trial.**

The process may include subject recruitment materials, verbal instructions, questions/answer sessions and measures of subject understanding.

Historical Issues

1947
Nuremberg Code

THE
DECLARATION
OF HELSINKI

1964
Declaration of Helsinki

1996
ICH GCP Guidelines

Importance of Informed Consent

- To assure that participation is voluntary and that the rights, welfare and safety of subjects are protected.

- The consent form document serves as confirmation of the consent process.

研究者的責任
(Site Responsibilities)

- 協調受試同意書送審及通過之過程
- 取得受試者簽署之受試同意書
- 受試同意書版本若有更改，須取得受試者簽署更改後的受試同意書
- 保存受試者簽署之受試同意書

Development of Informed Consent Document

- The content of the informed consent is defined by
  - ICH-GCP required elements
  - Country specific legal/regulatory requirements
  - Sponsor specific requirements
  - Study specific requirements

ICH Required Elements of Informed Consent

- Trial involves research
- Purpose of trial
- Trial treatment, probability for random assignment
- Trial procedures, including invasive procedures
- Subject's responsibilities
- Aspects of trial which are experimental
- Foreseeable risks/ inconveniences

ICH Required Elements of Informed Consent

- Reasonably expected benefits
- Alternative treatments/procedures and potential risks and benefits
- Compensation/treatment for trial related injury
- Anticipated prorated payment, if any
- Voluntary participation - may refuse to participate or withdraw without loss of benefits
- Access to medical records by monitor, auditors, IRBs/IECs, regulatory authorities.

ICH Required Elements of Informed Consent

- Confidentiality of subject's records
- Subjects will be informed if new relevant information becomes available
- Contact information for information about trial, right of trial subjects, trial-related injury
- Circumstances under which participation may be terminated
- Expected duration of subject's participation
- Approximate number of number of subjects involved in trial

受試者同意書

JIRB NO.:□□-□□-□□

計畫名稱：

執行單位：
主持人：
電話：

自願受試者姓名：
性別：　　出生日期：　　病歷號碼：
通訊地址：
電話：

緊急聯絡人：(計畫主持人)　　監測者：(廠商連絡人)
電話：　　電話：
夜間連絡電話：　　夜間連絡電話：
傳真：　　傳真：

1. 採敘述式書寫，文字內容力求口語化（國三程度）。
2. 內容必須包括
   (1)試驗主題
   (2)試驗目的
   (3)試驗方法可能導致之副作用
   (4)可能導致之危險及其處理方法
   (5)預期試驗效果及利益
   (6)其他可能之治療方法及其說明
   (7)緊急狀況之處理
   (8)參加本研究計畫受試者費用負擔，損害賠償，個人權益，機密性。
3. 最少包含下列字句：本計畫執行機構將維護受試者在試驗過程中應得之權益，受試者於試驗過程中可隨時撤回同意，退出試驗。

計畫主持人

姓名：_____醫師　簽名：_____　簽名日期：_____

受試者

正楷姓名：_____　簽名：_____　簽名日期：_____

受試者法定代理人(受試者未滿二十歲) *若不需要請刪除

正楷姓名：_____　簽名：_____　簽名日期：_____

受試者保護人(受試者為精神疾病之患者) *若不需要請刪除

正楷姓名：_____　簽名：_____　簽名日期：_____

註1:緊急連絡人及監測者務必先行填寫，並依若干醫院填妥詳細。
註2:以下空白

Informed Consent

IRB & 衛生署審核通過

- 版本日期, 不可隨意更動.

主持人/授權人口頭說明
⇨受試者閱讀同意書

試驗目的及方法、副作用、效益 、其他治療方式 及其權利義務等.

簽署同意書及載明日期

- 受試者/主持人須同一天簽名
- 正本由主持人保存, 複(印)本交由受試者保存.

篩選

Informed Consent Document

- **Site Responsibilities**
  - Review informed consent document for completeness
  - Determine if contact information is preprinted
  - Identify the master informed consent document and designate a storage location for the consent form master

Informed Consent Document

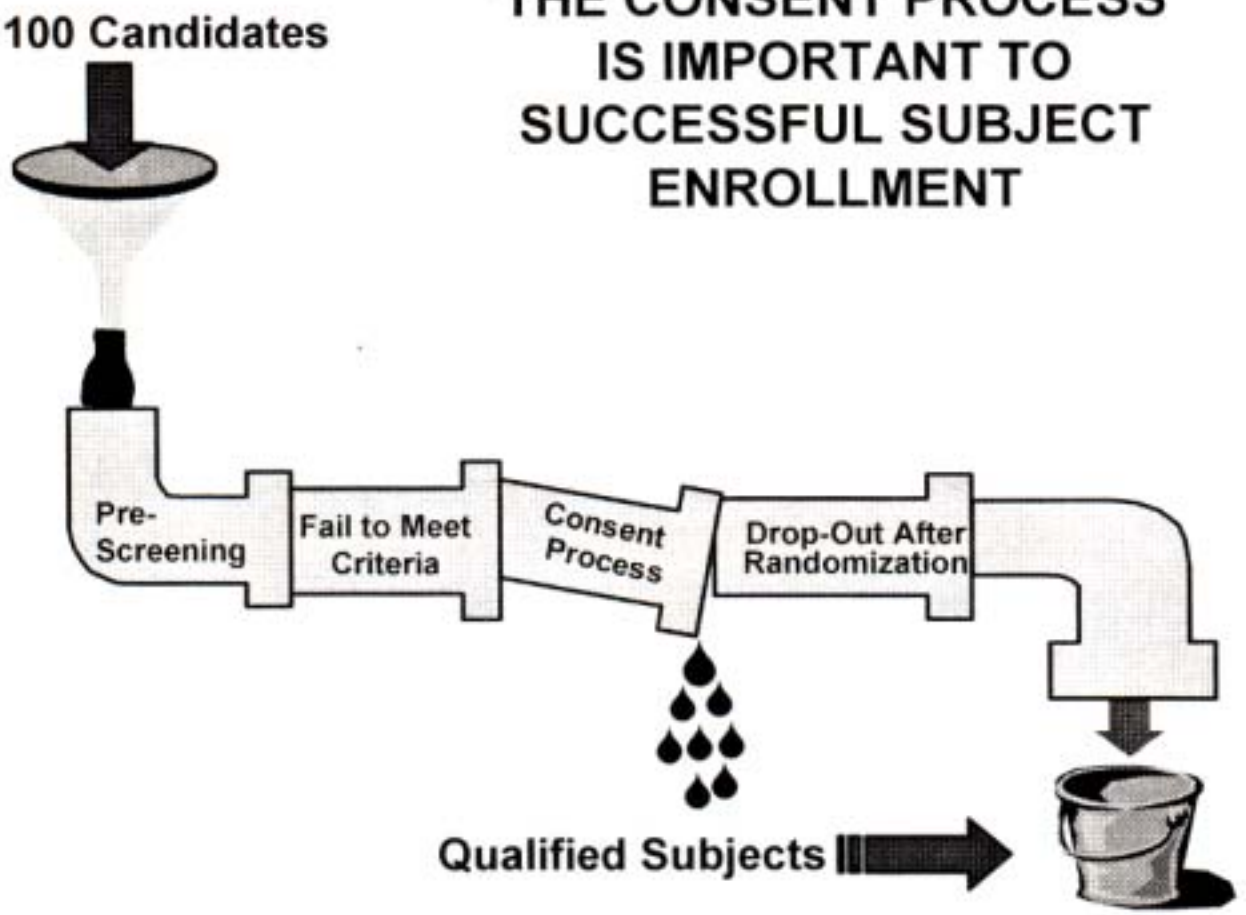
- **Site Responsibilities**
  - **Prepare copies**
  - **Check completeness of copied versions**
  - **Ensure availability of copying machine if copy of informed consent document will be given to subject.**

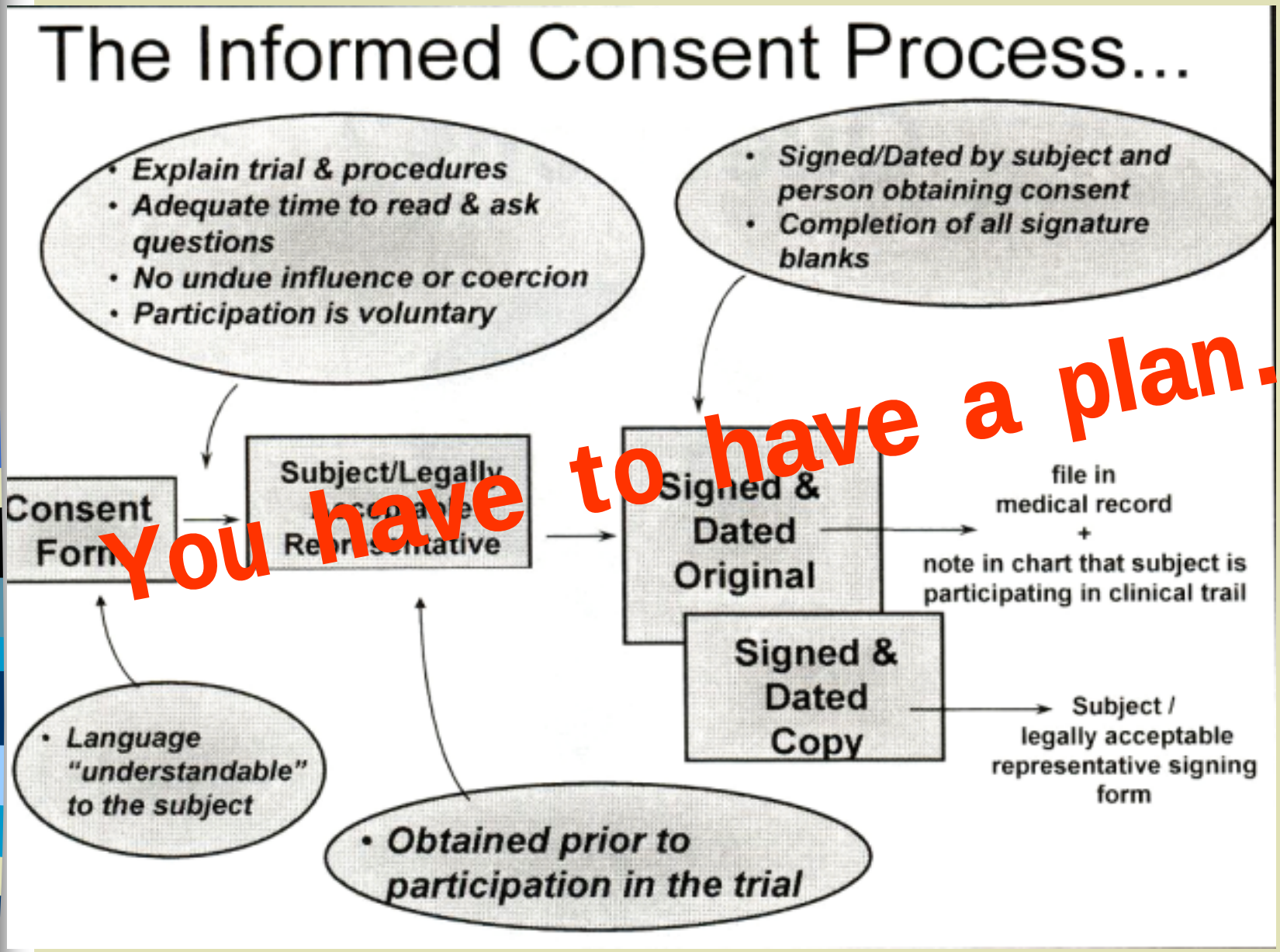
The Informed Consent Process

Informed consent is more than just a signature on the informed consent document.

It is a **Process** to give subjects opportunity to agree to participate

THE CONSENT PROCESS IS IMPORTANT TO SUCCESSFUL SUBJECT ENROLLMENT




The Informed Consent Process...
• Explain trial & procedures
• Adequate time to read & ask questions
• No undue influence or coercion
• Participation is voluntary
• Signed/Dated by subject and person obtaining consent
• Completion of all signature blanks
You have to have a plan.
Consent Form
Subject/Legally Acceptable Representative
Signed & Dated Original
file in medical record + note in chart that subject is participating in clinical trail
Signed & Dated Copy
Subject / legally acceptable representative signing form
• Language "understandable" to the subject
• Obtained prior to participation in the trial

The Consent Process Plan

- Identify the obstacles to subject participation and ways to overcome the obstacles
  - Transportation
  - Family
  - Work
  - Number of visits
  - Number of blood draws

The Consent Process Plan

- Identify words subject may not understand in consent form
- Compile list of question the subjects may ask about the study and appropriate responses

The Consent Process Plan

- Decide who will conduct consent discussion
  - Investigator may obtain consent
  - Investigator may delegate responsibility to a *knowledgeable* person.
  - Investigator is ultimately responsible for assuring informed consent has been appropriately obtained

The Consent Process Plan

- Decide where consent discussion will be held
  - Conduct in a quiet area
  - Subject should have adequate uninterrupted time
  - Easy access to a study doctor
  - Provide space for family members or friends to be present during the consent discussion

The Consent Process Plan

- Provide adequate time to explain the study and study procedures to the subject
- Provide adequate time for subject to read and consider
- Provide time for questions to be answered

WHO CAN SIGN THE CONSENT?

十、 同意與簽章

研究人員已詳細解釋有關本研究計畫之目的、性質與研究方法，及可能產生之危險與利益。

研究計畫主持人_____(簽章) 日期:_____

解釋人(研究醫師或指定代理人)_____(簽章) 日期:_____

本人已詳細瞭解上述研究方法及參與本計畫之優點與潛在危險性。有關本試驗計畫之疑問，業經計畫主持人或指定代理人詳細予以解釋。本人同意接受為本研究計劃之自願受試者。

受試者簽章_____ 日期:_____

法定代理人(受試者於法律上屬無行為能力人及獲禁治產權宣告者)

簽章:_____ 日期:_____

口頭同意之見證

茲證明研究人員已完整地向受試者解釋本研究內容與相關細節。

見證人簽名_____ 日期:_____

When Should Informed Consent Be Obtained?

- Obtain consent after approval by Sponsor and IRB/IEC/Agency
- Obtain consent prior to altering care of the subject for purpose of participating in research study
- Obtain consent prior to initiation of any clinical procedures that are performed solely for purpose of determining eligibility for research

Documentation of Informed Consent Process

- Check that contact information is complete on original and copy given to subject
- Provide subject with a copy of the signed and dated informed consent document or second signed and dated original
- File the original signed and dated informed consent document in the subject file
- Document study participation in medical records of subject

Updates to the Informed Consent Document

- The consent document may be revised when:
  - Protocol amendment(s) are necessary
  - New relevant safety information becomes available
  - New information becomes available that might influence the subject's decision to participate/continue in the clinical study

Provide

Information to the subject

Correct timing

Answer all questions

Sign and date by subject

Sign & date by person administering consent

Organize filing