30th PREMA ANNIVERSARY

Informed Consent

- **Process of Informed Consent and Requirements**
- **Essential Elements of Informed Consent**
- **Informed Consent Workshop**

“A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.”

ICH–GCP [1.28]

A subject must give his/her informed consent to be enrolled in a trial and before any study-specific procedures are conducted.

Awareness and understanding
Help the subject understand what will be required of him/her and what trial involvement will mean

Suitability
Ensure the subject fits all the entry criteria, is suitable for the trial, and is likely to comply with the protocol

- In the process, the subject should be informed about:

The trial	**The investigational product**
• purpose • involves research • procedures • study duration • responsibilities • compensation/payment	• risks and benefits • alternative treatment options

The Informed Consent process

Subjects' rights

- participation is voluntary
- can refuse/withdraw at any time
- will be informed of new findings that may affect participation
- will have sufficient time to consider/discuss participation before signing
- must give consent before any medical/ personal information can be used
- informed how medical/personal information will be used and who can access it

Who gives/obtains consent?

The following people may be involved in the informed consent process:

Subject	Site
➢subject ➢subject's representative and/or legal guardian ➢impartial witness ➢translator	➢investigator ➢appropriately delegated team member

Special Populations

There are special requirements governing informed consent in cases where the subject is:

- A minor
- Unable to provide informed consent
- Unable to read or write
- Unable to give informed consent owing to the nature of the trial/condition

The protocol, IRB/IEC, or regulatory authorities may identify other cases where there are special requirements for informed consent

Preparing for the informed consent precess

- **Obtain written approval from the IRB/IEC and /or regulatory authorities for:**
  - The ICF and, if required, the informed consent process
  - Other written material that will be provided to subjects
- **Before the informed consent interview make sure that you :**
  - Prepare thoroughly
  - Anticipate questions
- **And finally:**
  - Prepare a suitable room
  - Allow adequate time for the process and questions

The informed consent form

Provided by:

- Investigator in cooperation with sponsor

Local adaptations:

- To meet IRB/IEC requirements
- Translation – subjects must be able to understand
- Must conform to sponsor's SOPs and ICH-GCP

All changes will need to be reviewed and approved by the sponsor in a sponsored trial

The informed consent form

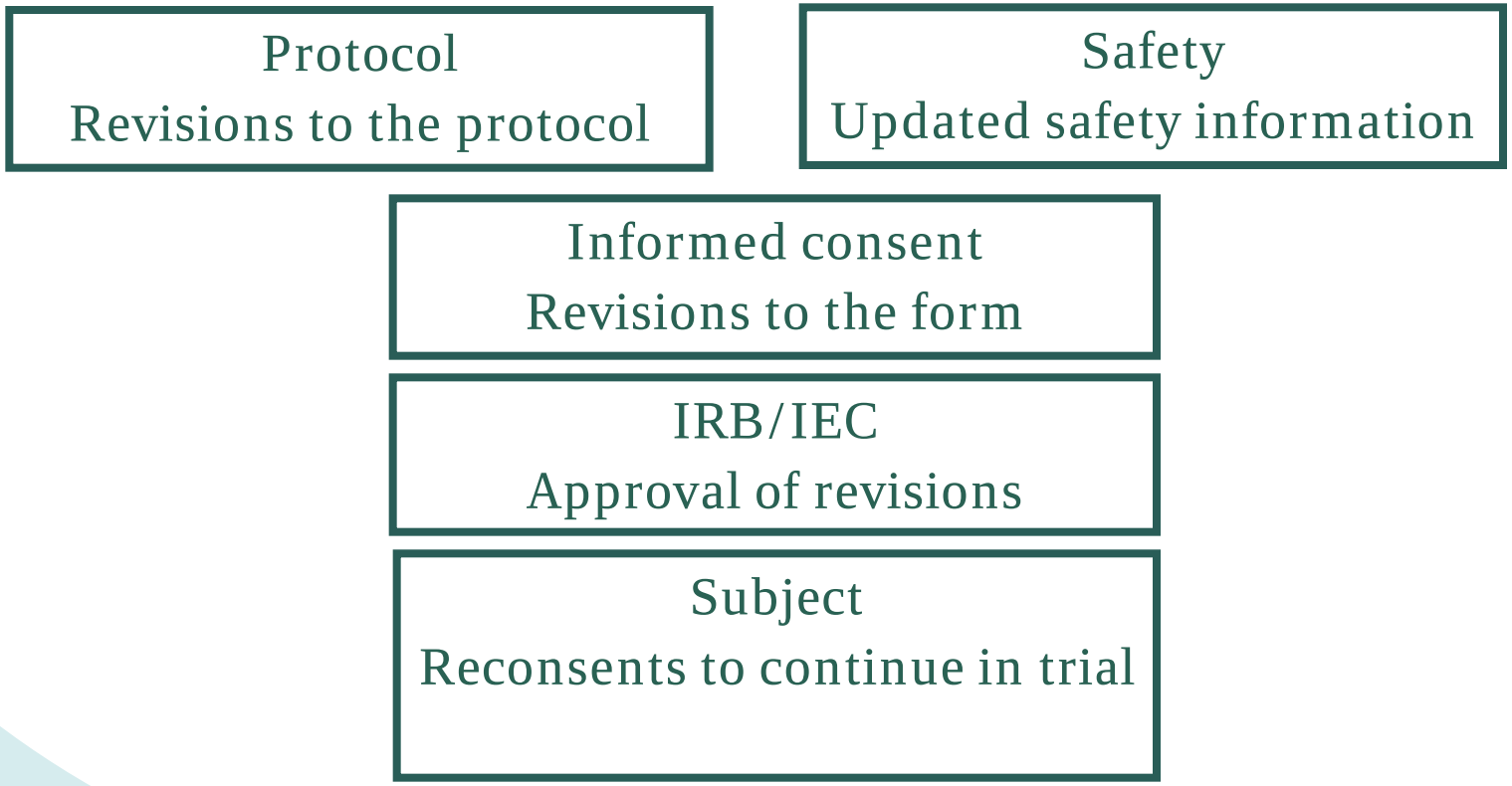
Sign and date	Copy	File
Subject (and/or representative and witness if applicable) and person who conducted the interview	Subject (and/or representative and witness if applicable) receives copy of form prior to study participation	Investigator is legally bound to keep the original, signed and dated, ICF

During the process

Fully informing the subject

- **Fully explain the trial and its procedures**
- **Communicate in non technical language**
- **Take any language barriers into consideration**
- **Ensure subjects are aware of their rights**
- **Allow enough time for any questions**

- Informed consent is a process
- Subjects must reconsent if protocol revisions might affect their willingness to continue



Reconsent may also be required if new information emerges about the treatment

Essential Elements of Informed Consent

- **Informed Consent (IC) Elements**
  - The ICH GCP Guideline 4.8.10
  - Local regulatory requirements
- **Should be included in**
  - Written informed consent form (ICF) or
  - Patient information sheet
  - Informed consent discussion

Essential Elements of Informed Consent

Informed Consent (IC) Elements

- **Information**
  - Trial information
  - Benefit/risk and alternative treatment
  - Contact person
- **Confidentiality**
  - authorization
- **Voluntarily**

Should not COERCIVE / FORCE
INDUCEMENT / PERSUADE

Essential Elements of Informed Consent

Explanations of:

(ICH-GCP 4.8.10 or page 20 of the translated version)

(a ก) Trial involves research

(b ข) Trial purpose

(c ค) Trial treatment(s) and probability for random assignment

(d ง) Trial procedures

(e จ) Subject's responsibilities

Essential Elements of Informed Consent

Explanations of:

(f ฉ) Trial experimental aspects

(g ช) Foreseeable risks/ inconveniences

(h ซ) Expected benefits

(I ฌ) Available alternative procedure(s) or course(s) of treatment and their potential benefits and risks

Essential Elements of Informed Consent

Explanations of:

(jญ) Available compensation and/ or treatment of trial-related injury

(kฎ) Prorated payment, if any, to subject for participation

(lฎ) Anticipated expenses, if any, to subject for participation

Essential Elements of Informed Consent

Explanations of:

(mฐ) Voluntary participation, may to participate and withdraw from trial, without penalty/ benefit loss

(n๓) Authorizing direct access to subject's medical records for verification, without violating confidentiality of subject to monitor/ auditor/ IRB or IEC/ regulatory authority

Essential Elements of Informed Consent

Explanations of:

(o ฒ) **Subject's record will be kept confidential and not made public subject's identity will remain confidential**

(p ณ) **New information, might influence subject's decision to continue participation, will be informed timely**

Essential Elements of Informed Consent

Explanations of:

(q ด) Contact person: for

- further trial information,
- subject's right
- trial-related injury

(r ต) Trial participating termination without subject's permission

(s ถ) Duration of subject's participation

(t ท) Number of subjects

Essential Elements of Informed Consent

WORKSHOP:

Informed Consent Element Review

- Read sample ICF
- Label the sample ICF with the letter (a) through (t) of the required elements of ICF for each statement.

10 minutes

Thank you


PReMA
Pharmaceutical Research &
Manufacturers Association