Case record faum.

- Case record form is a trial data document used for collecting and recording the patient info in a standarized and uniform manner.

- It plays a pivotal role in maintaining accuracy & consistency in data collection.

Properties

(1) A good CRF facilitate designing and creating a clean database with minimum queries & better approach.

This structural approach ensures uniform in information gathering and a reduced risk of errors.

(2) Source of document.

- It serves as a primary source of document of evidence of participation of each subject in the clinical trial.

- It should provide information in a comprehensive manner as per the provided protocol.

(3) Quality control -

- Case record form acts as a tool for quality control as it facilitates consistency and standarized data collection across multiple sites.

(4) CRF development -

- case record forms consistantly develop their own designs & protocol to eliminate flaws.

- The development as:
  (i) CRF design
  (ii) Medical advisor
  (iii) Clinical monitor
  (iv) Data manager
  (v) Statistician

(5) Data analysis facilitation -

- Researchers can easily extract relevant information for statistical analysis contributing to robustness of the study findings.

(6) Regulatory compliance -

- Compliance with regulatory standards is a critical aspect of clinical research.

- The CRF ensures that the study aligns with ethical guidelines and regulatory requirements, covering aspects such as ICF and privacy.

(7) There are 3 main parts of a case record form:

(i) Header module
(ii) Safety module
(iii) Efficacy module

There are different design layouts of a CRF.

(i) Non-time dependant data -

- It is the data collected at a snapshot of time.

Ex: Demographics.
Medical history.

(ii) Time-dependant data:

- It is the data collected repeatedly over time
  Ex: Vital signs.

(iii) Cumulative data:

- It is the data collected over time but is not linked to a specific visit.
  Ex: Adverse rxn.
  concomitant medications

SAMPLE

Name: Date: Age:	Gender: M / F
Did any adverse event occur after the last visit?	Yes ☐ NO ☐
If "yes", please provide info about adverse events below.	
Did any unscheduled visit happened after the last visit?	Yes ☐ NO ☐

Informed consent form.

- Essential part of the design of every research project involving human subjects.

- Researchers & human subjects in their research have both, an ethical & legal obligation to secure the IC of the potential research subjects prior to initiation of trial.

Instructions and info in ICF:

(1) Purpose of the study -

- Describe purpose of study in lay terms
- Include a statement as why this is considered a research study
- Provide definitions for specific research design features.

(2) Procedures -

- Incl. a thorough description of specific procedures involved in the study.

- Incl. detail Incl/Excl. criteria, length of involvement.

- Describe the types of ques. the subject will be asked.

(2) Risks:

- This element will ask if the study has more than minimal risks.

- If present, you will be described with a detailed info of the potential risks involved.

(4) Benefits -

- Describe all expected benefits and who will benefit.

NOTE:

- 'Compensation for participation is not a benefit.'

- Provision for free drugs are procedures is not a benefit.

(5) Compensation and costs -

- Describe in detail about the type amount and terms of payment if the subject participates.

(6) Withdrawal or Termination from study -

- subjects should be informed of the circumstances under which their participation may be terminated w/o subject's consent.

(7) Confidentiality -

- Incl. info about the protection of the subject's rights, safety and well-being.

(8) New findings -

- Any significant new info will be provided to the subject by the investigator.

(9) Compensation for injury -

- standard non-attenuate text describes the provision of subject injury incurred as a result of this study.

(10) Contact info:

- Incl. contact info to answer study questions and a standard text

that instructs subjects to contact the research protection office if they have any comment or questions regarding the conduct of the study.

(iii) Voluntary participations -

- The decision to participate or not participate, is solely upto the subject.

Informed consent process

- The process in which, the subject confirms his or her participation in the study, after having been informed about all the aspects of the study that are relevant to the subject's decision of participation is called as Informed consent process.

- It is attained by the means of a written, signed and dated Informed consent form.

Process of consent:

(1) Choose the right environment & location to attain consent.

(2) Involve multiple healthcare professionals as necessary.

(3) Include family members in the process as warranted.

(4) Ensure that the subject has gained sufficient understanding.

(5) Continue the process of attaining consent throughout the study.

Informed consent process.

Discussion — Review — concerns — Time — Sign.

Review of info by nurse

Allow adequate time

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Discussion b/w physician and subject

Addressing the concerns of the subject

Obtain signature

Steps of attaining consent:

(1) Obtain approval of the informed consent from IRB.

(2) Present the prospective subject with the consent document.

(3) Explain the imp points of the research or participation to the subject.

(4) Prompt the subject to ask any questions and answer all or any questions

(5) Give a copy of consent doc to the subject.

(6) Allow the subject, time to discuss participation with family, friends, family physician etc.

(7) If the subject is willing, have him or her sign the document.