

PS1.300

Informed consent form of a clinical trial in primary care: avoidable mistakes

Rosa Vinas, MM Fores, I Zamora, B Riesgo, S Sarret, M Bandres

Institut Catala de la Salud ICS, ABS Santa Eulalia Sud, Hospitalet, Spain

Corresponding author: Mrs Rosa Vinas, Institut Català de La Salud ICS, ABS Santa Eulalia Sud, Barcelona, Spain. E-mail: rosavinas@camfic.org

Background: The Informed Consent Form (ICF) is one of the first documents of a clinical trial that inspectors of the European Medicines Agency (EMA) evaluate.

Aim: To teach how to explain and correctly fill in a ICF to avoid mistakes.

Methods and Results: The ICF is a written document that sponsor of the clinical trial writes to inform patients about all they need to know (the aim of the study, the voluntary participation and withdrawal, the number of patients who participate, the number of visits made to the center, the complementary tests, possible adverse effects, health insurance, drug characteristics,..).The research physician will inform the patients of all its content and gives it to read it carefully and then answer any questions that patients may have. Then both General practitioner and patient will sign it by mutual agreement, in his/her own handwriting twice. One copy is for the patient and the other is filled in the folder of the study. The ICF must also contain the telephone number of the medical team (with available 24 hours a day in case the patient has any problem). Inspectors check: missing data, mistakes in data (if patient names are filled in capital letters..),that the correct person has signed (some patients require the signature of a legal guardian)...

Conclusions: The ICF is very important in the study of a clinical trial document. The information that the patient receives must be clear and complete. The document is simple but can contain many spelling errors and missing data if it is not completed carefully and accurately to avoid mistakes. Been reviewed by a team member or monitor helps prevent the discovery of flaws in an inspection.