AURORA RSPP GUIDANCE DOCUMENT: USE OF ELECTRONIC INFORMED CONSENT IN CLINICAL INVESTIGATIONS

Aurora Health Care’s Research Subject Protection Program (RSPP)

This guidance serves to summarize the joint OHRP and FDA Guidance on the use of electronic informed consent (E-IC) in clinical investigations – release date December 15, 2016.

Definitions:

Electronic informed consent refers to the use of electronic systems and processes that may employ multiple electronic media, including text, graphics, audio, video, podcasts, passive and interactive Web sites, biological recognition devices, and card readers, to convey information related to the study and to obtain and document informed consent.

Biometrics means a method of verifying an individual's identity based on measurement of the individual's physical feature(s) or repeatable action(s) where those features and/or actions are both unique to that individual and measurable.

Scope: This guidance clarifies the regulations surrounding the use of E-IC in research studies. Most of the issues raised in the OHRP/FDA guidance are issues that the IRB already considers when reviewing research where informed consent is obtained. The biggest difference when using E-IC (vs. paper) involves the regulations found at 21 CFR 11. The regulations at 21 CFR 11 discuss electronic records and electronic signatures, and how verification of the validity of the electronic record/signature is obtained/maintained. Compliance with Part 11 regulations fall to the investigator/institution, and not the IRB. This guidance also clarifies the information to be reviewed/obtained/maintained by the IRB.

Highlights of the OHRP/FDA guidance...

- E-IC must contain all elements of informed consent required by HHS and/or FDA regulations (45 CFR 46.116 and 21 CFR 50.25).
- E-IC may be used to either supplement or replace paper-based informed consent processes in order to best address the subject’s needs throughout the course of the study. Some subjects may prefer one method over another. Subjects should have the option to use paper-based or electronic informed consent methods completely or partially throughout the informed consent process/study participation.
- The investigator is responsible for ensuring that legally effective informed consent is obtained before that subject takes part in the study. Whether part or all of the E-IC process takes place on-site or remotely, the responsibility for obtaining informed consent remains with the investigator and the study personnel to which responsibility has been appropriately delegated. The investigator cannot delegate authority to obtain informed consent to the electronic system.
- Whether E-IC is obtained from the subject on-site or remotely, the process must provide sufficient opportunity for the subject to consider whether to participate. The investigator should have methods in place to ensure that the E-IC process allows subjects the opportunity to consider whether or not to participate and to ask questions about the study before signing consent, as well as at any time during the subject’s involvement in the research.
- If the E-IC is updated or amended, the subject or the subject’s LAR must sign the amended E-IC before the subject continues in the study.
- OHRP and FDA regulations permit the flexibility of using electronic and paper informed consent methods independently or in combination throughout the course of the study. Thus, amendments to the E-IC do not need to be electronic in nature.
• Electronic signatures
  o OHRP: permits electronic signatures if such signatures are legally valid within the jurisdiction where the research is to be conducted
  o FDA: In order to be considered equivalent to full handwritten signatures, electronic signatures must comply with the applicable requirements under 21 CFR 11.
    ▪ The electronic system must capture and record the date that the subject/LAR provides consent/assent for participation (21 CFR 50.27(a)).
    ▪ Part 11 includes a requirement for verification of the individual’s identity.
      • Electronic signatures based on the use of biometrics for verification of identity must be designed to ensure that they cannot be used by anyone other than their genuine owners (21 CFR 11.200(b)).
      • Specific requirements are provided when biometrics are not used to verify the identity of the individual (e.g. a login/password combination).
  o Both FDA and DHHS regulations require that the person signing an informed consent document receive a copy of that document (unless documentation of consent is waived). FDA regulations do not require that the copy be signed although it is recommended that the copy include the date the consent was signed. [Note ICH/GCP E6 guidelines require that a signed and dated copy be provided to the person signing the informed consent document.]
    o When using E-IC, the requirements are no different – a copy of the E-IC must be provided to the subject/LAR.
      ▪ The copy can be paper or electronic. An electronic copy may be provided on an electronic storage device or via email.
      ▪ If the copy includes one or more hyperlinks to information on the Internet, the hyperlinks should be maintained and information should be accessible until study completion.
      ▪ If the E-IC uses hyperlinks or other Web sites or podcasts to convey information specifically related to the research, the information in these hyperlinks/podcasts should be provided in any printed paper copy provided to the subject/LAR.
  • HIPAA authorizations for research may be obtained electronically provided the individual receives a copy of the signed authorization.
  • The IRB must receive, review and retain all forms (electronic and paper) and informational materials, including any videos and Web-based presentations, which the subject will receive/view during the E-IC process.
    o The contents of any hyperlinks, websites, podcasts used to convey study-related information to the subject must be reviewed by the IRB in order to determine if the study-related information that has been supplied is accurate and appropriate. Because Web sites are often modified over time, IRBs must maintain the version of the Web site information that contains the study-related information that the IRB reviews and approves, either electronically or as a hard copy (45 CFR 46.115 and 21 CFR 56.115).