Sample orientation checklist from University of Pittsburgh

The education and compliance office for human subject research at the University of Pittsburgh (PA) developed a six-page staff orientation checklist that is used when new staff members are hired.

Each item on the checklist table has a box for the date completed and the confirmed supervisor initials and date, as well as any additional comments.

Here are examples of some items included in the checklist:

- **RISE Interviews/Audits/O3IS Monitoring**
  - — RISE interview
  - — Observe RISE interview – read protocol and be familiar with study specific interview form and procedure tables
  - — Prepare study specific documents for a RISE interview, observe RISE interview, and write one section of the RISE report (to be determined by the lead)
  - — Lead a RISE interview - Prepare all study specific forms, conduct the interview and write the report
  - — Take responsibility for all correspondence and follow-up related to RISE interview
  - — If applicable, present RISE report at Executive Committee (EC) meeting
  - — Enter RISE data into the QA database
  - — Enter RISE summary into OSIRIS (electronic IRB application system)
  - — Organize and file hard copies of all documents
  - — Document participation in both biomedical and psychosocial protocols
- **Review of Regulations and Regulatory Agencies**
  - — Review Department of Health and Human Services regulations 45 CFR § 46, the "Common Rule" found at:

    http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
  - — SUBPART A – Basic HHS Policy for Protection of Human Research Subjects
  - — SUBPART B – Additional Protections for Pregnant Women, Human Fetuses and Neonates Involved in Research
  - — SUBPART C – Additional Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects
  - — SUBPART D – Additional Protections for Children Involved as Subjects in Research
  - — Review of Informed Consent Regulations
  - — Eight basic elements
  - — Six additional elements
  - — Detailed review of additional consent protections for pregnant women, human fetuses, neonates, children, prisoners and those adults unable to provide consent
  - — Review IRB Consent Checklist
  - — Review Consent Template in IRB Reference Manual
  - — Documentation of the Informed Consent Process
  - — Waivers of Informed Consent
  - — Waivers of Documentation of Informed Consent
  - — Observation of the Informed Consent Process
  - — Become familiar with the Office of Human Research Protections (OHRP) website at:

    http://www.hhs.gov/ohrp/
  - — Note the difference between guidance and regulations
  - — Review the Food and Drug Administration regulations:
  - — Review 21 CFR 50, 56, 312, 600 and 812. Found on the FDA website at:

    http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm
  - — Review FDA regulations pertaining to the informed consent process and waivers at 21 CFR § 50.25(a), 21 CFR § 50.25(b), 21 CFR § 50.27(a), 21 CFR § 50.27(b), 21 CFR § 56.111(a)(5)
  - — Waiver of consent for planned emergency use – 21 CFR § 50.24
  - — Review the International Conference on Harmonization (ICH) standards (international standards for research) found at: http://www.ich.org/cache/compo/276-254-1.html
  - — Focus on: E6 – http://www.fda.gov/downloads/RegulatoryInformation/Guidance/UCM129515.pdf