University of Kentucky's IRB consent/assent checklist assists with IC review

List helps staff keep track

The office of research integrity at the University of Kentucky in Lexington, KY, has developed a consent/assent checklist for a quality improvement review of informed consent documents.
Here are some sample items from the checklist:
Does the informed consent document contain:

- Protocol title
- Principal investigator
- Co-investigators/Study staff
- Department(s)
- Phone number(s)
- Statement that study involves research
- Explanation of the purposes of the research
- Expected duration of the subject's participation
- A description of the procedures to be followed
- Identification of any procedures which are experimental
- Description of any reasonably foreseeable risks or discomforts to the subject including social and psychological risks
- A statement indicating the likelihood of risks or discomforts occurring, if any, and the ramifications associated with the risks/discomforts
- Description of any benefits to the subject or to others which may reasonably be expected from the research
- Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and possibility of records being reviewed by sponsor, FDA, OHRP, university authorized personnel
- For research involving more than minimal risk, an explanation as to whether any compensation is available, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained.