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**From:** Institutional Review Board, BSD  
**Sent:** Wednesday, September 25, 2013 12:21 PM  
**To:** 'irbcontacts@lists.uchicago.edu'  
**Cc:** IRB-office-DL; OCR-office-DL  
**Subject:** updated Policies and Procedures Manual

Good morning,

The IRB has revised its Policies and Procedures Manual. The updated manual is dated September 10, 2013 and can be accessed on the IRB website at <http://bsd.uchicago.edu/policies-procedures/index.html> .

Of note for researchers, in response to multiple researchers' requests for this guidance, the P&P Manual now contains additional guidance on the consent process, consent documentation, and consent at age of majority. Specifically, the following language has been added to Section V.D., "Consent Form Records," concerning when and which signatures are required on the consent document:

“It is the expectation of the IRB that if consent documentation is required from a subject, the subject will sign a consent form prior to beginning any study procedures. The research team member who is obtaining consent should sign the form at the same time as the subject. The signed copy given to the subject would thus contain at least two signatures: the subject's own and a member of the research team's who is designated to obtain consent. If the consent form contains a signature line for the PI, the PI is not required to sign at the same time as the subject (if the PI is not the person obtaining consent), but the PI should sign prior to the subject receiving an experimental drug, receiving implantation of an experimental device, or undergoing any more than minimal risk research intervention in order to verify that this is an eligible subject. Signature line for signature of the PI may not be required for minimal risk studies. Minimal risk studies approved prior to September 24, 2013 may be revised at time of study renewal or with an amendment to remove signature line of PI from the approved consent form(s), at the discretion of the IRB.”

Consent forms for currently approved studies of minimal risk may be revised at time of continuing review to remove signature line of the PI, if desired by the research team, without submission of a formal amendment. If researchers wish to make this change prior to time of continuing review, an amendment is needed.

Other changes include:

- (1) Inclusion of policies from the internal IRB office SOPs in the Policies and Procedures manual so that they are available to researchers, including policies on
  - a) IRB Membership
  - b) Researcher Conflict of Interest
  - c) FDA requirements concerning IDEs and study expiration
  - d) Prisoner research requirements
- (2) Editorial revisions, including re-ordering and re-labeling of sections, removing outdated links, and revising references to paper submission forms to reflect online submission system

Effective immediately, please reference this version of the IRB Policies and Procedures Manual for guidance on current on ongoing research. Please contact the IRB office with any questions ([http://bsd.uchicago.edu/contact\\_us.html](http://bsd.uchicago.edu/contact_us.html) ).

Thank you.