Dear IRB contacts,

Please note that the BSD/UCMC IRBs have revised their Policies and Procedures Manual. The updated manual is dated October 30, 2018 and can be accessed on the IRB website at http://bsdirbbsd.uchicago.edu/policies-procedures/index.html. The updated manual is effective January 21, 2019 in conjunction with the effective date of the 2018 Common Rule regulations.

Changes include:

1. Revisions related to 2018 Common Rule, including
   (a) in Section III.A, revised definition of a human subject to specifically include biospecimens
   (b) in Section III.B, revised exemption categories
   (c) in Section VI, added text regarding consenting requirements
   (d) in Sections VI.A.3-5, new waiver of documentation of consent, alteration of consent, and waiver of consent criteria
   (e) in Section VI., separated Waiver of Authorization requirements from waiver of consent requirements
   (f) in Section VI.C.1-2, new consent form elements
   (g) in Section VI.D., new requirement for posting consent forms
   (h) in Section VIII.C., added section on Limited IRB Review
   (i) in Section X.A-B., added text to clarify when continuing review may no longer be required for certain types of research
   (j) in Section XI.A, updated text to reflect revised exemption categories
   (k) updated relevant regulatory citations throughout

2. Revised unanticipated problem (UP) reporting policy to reflect that internal events should be reported “in a timely manner” to match FDA guidance on UP reporting timelines

3. Revised policy on consenting individuals who cannot read or write to reflect two separate populations: low literacy subjects and physically disabled subjects

4. Minor editorial changes

Effective Monday, January 21, 2019, please reference this version of the IRB Policies and Procedures Manual for guidance on proposed or ongoing research. Please contact the IRB office with any questions.

Thank you.

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