SMART IRB Reliance Agreement Version 3.0

Executive Summary of Key Changes in Version 3.0
(as compared to Version 2.0)

Changes to Eligibility to Participate in the Agreement

- **FWA No Longer the Only Form of Assurance Accepted.** Unless it is an Independent IRB Organization, an institution must still maintain an assurance of compliance with the Common Rule to participate in the agreement, but the assurance can be with any federal Common Rule agency (such as an assurance issued by the U.S. Department of Defense).

- **Institutional Oversight of Exempt Research No Longer Required.** Version 3.0 no longer requires institutions to maintain policies for oversight of research that is exempt from the Common Rule. Although important, how institutions oversee exempt research is beyond the scope of the agreement.

Changes to Scope and Application of the Agreement

- **Exemption Determinations and Associated Limited IRB Review More Expressly Covered.** Institutions may continue to use the agreement to obtain determinations from another institution or IRB that research is exempt from some or all Common Rule requirements. When they do, the agreement now explicitly provides that exemption determinations will be conducted in accordance with the Common Rule and that the Reviewing IRB will perform any Limited IRB Review that is required as part of the exemption determination.

- **Reviewing IRBs May Withdraw from Providing Review.** For significant cause, such as a Relying Institution's ongoing and uncorrected noncompliance with its obligations under the agreement, a Reviewing IRB may withdraw from providing review and oversight of research for the Relying Institution, with prior notice and explanation provided to the Relying Institution.

Changes to Collaborative Processes for Consideration of Reliance Requests, Selection of the Reviewing IRB/Reviewing IRB Institution, and Determination of Applicable Policies and Procedures

This project has been funded in whole or in part with Federal funds from the National Center for Advancing Translational Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. 75N950C00008.

- **Acknowledgment of Federal Regulatory or Funding Agency Processes and Policies.** For research subject to federal regulatory or funding agency processes or policies for initiation of reliance, for determination of the Reviewing IRB/Reviewing IRB Institution, or for conduct of the reliance relationship (such as research subject to the Common Rule's single IRB provisions or research funded by the U.S. Department of Veterans Affairs or U.S. Department of Defense), such processes and policies will override the correlating processes and terms set out in the agreement.

- **Documentation of Applicable Processes and Policies Required; Deemed Application of SMART IRB SOPs.** Institutions must document among themselves when a federal regulatory or funding agency process or policy for initiation of reliance, for determination of the Reviewing IRB/Reviewing IRB Institution, or for conduct of the reliance relationship applies. In the absence of applicable federal regulatory or funding agency processes or policies on these matters, the SMART IRB SOPs will be deemed to apply unless the institutions have specified in writing that they will follow alternate processes or policies; however, the agreement provisions override any such alternate processes or policies in the event of any conflict.

Changes to General Responsibilities of Participating Institutions

- **All Institutions Responsible for Ensuring Training and Requiring Compliance.** All Participating Institutions (not just Relying Institutions) must ensure that their personnel and their IRB members (if serving as a Reviewing IRB/Reviewing IRB Institution) have adequate education, training, qualifications, and resources to perform their obligations, and must require their personnel and (if applicable) their IRB members to comply with applicable laws, regulations, policies, and the agreement.

- **Obligation To Correct Noncompliance and Resolve Concerns in Good Faith.** Participating Institutions must correct noncompliance with applicable laws, regulations, policies, and the agreement. In regard to potential noncompliance with or breach of the agreement terms, affected Participating Institutions must work with one another in good faith to try to resolve concerns, and may attempt to resolve them through third-party consultations or other means, without waiving any rights under the agreement.

- **Notification of Federal For-Cause Investigations Required.** Participating Institutions must notify other Participating Institutions with whom they are then in a reliance relationship of any for-cause compliance investigations of the notifying institution or its personnel by the Office for Human

Research Protections (OHRP), Food and Drug Administration (FDA), National Institutes of Health (NIH), or other federal human subjects research regulatory or funding agencies, when the investigation is related to the research under review or could affect the conduct or the integrity of such research, the rights or welfare of participants, or the Reviewing IRB/Reviewing IRB Institution's authority or ability to perform its review and oversight obligations.

- **Self-Funded Liability Coverage Meets Insurance Requirement; No Insurance Requirement for Government/Public Institutions.** Any Participating Institution, including a private institution, may rely on self-funded liability coverage (instead of or in addition to traditional insurance policies) to satisfy the agreement's insurance requirement. All government/public institutions (whether federal, state, or local) are exempted from the agreement's insurance requirement.

Changes to Indemnification Provisions

- **New SMART IRB Indemnification Addendum Provided as Option for Participating Institutions Seeking Indemnification.** Entering indemnification agreements continues to be optional; however, the agreement contains a new SMART IRB Indemnification Addendum for Participating Institutions that wish to join it.

Changes to HIPAA Provisions

- **Relying Institutions Determine How HIPAA Authorization Forms and Waivers of HIPAA Authorization are Addressed.** Relying Institutions that are HIPAA Covered Entities determine whether they will provide their own HIPAA authorization forms and perform their own HIPAA waiver determinations for research or whether they will request the Reviewing IRB Institution/Reviewing IRB to provide such forms and perform such determinations. Reviewing IRB Institutions/Reviewing IRBs that are federal departments or agencies, that are not HIPAA Covered Entities, or that otherwise do not provide such forms or perform such determinations (whatever the reason) are not obligated to agree to a request. Even when the Reviewing IRB Institution/Reviewing IRB agrees to provide such forms or perform such determinations, Local Considerations (if any) identified by the Relying Institution drive whether the HIPAA authorization form is merged into the research informed consent form and whether a waiver of HIPAA authorization is ultimately approvable. The party providing an authorization ensures that the form contains HIPAA's required elements and statements for an authorization and that the form permits the use and disclosure of Protected Health Information as necessary for the research.

Changes to Reviewing IRB Responsibilities

- **Common Rule as Standard for Research Not Subject to Federal Human Subjects Regulations.** When reviewing research that is not federally funded, FDA regulated, or otherwise subject to human subjects protection regulations, the Reviewing IRB will apply Common Rule standards to the review (e.g., Common Rule criteria for approval of the research), unless a different standard is agreed upon by the Reviewing IRB and Relying Institution.

- **Reviewing IRBs Must Consider Certain Requests on Informed Consent Forms.** The Reviewing IRB will consider a Relying Institution's requests for institution-specific modifications to informed consent forms that are necessary to address legal or regulatory issues or federal agency-specific requirements.

Changes to Relying Institution Responsibilities

- **Relying Institutions Responsible for Reports to Funding Agencies, Sponsors, and Other Authorities.** Reviewing IRBs will generally continue to make any required reports of unanticipated problems, serious or continuing non-compliance, and suspensions or terminations of IRB approval to federal human subjects research regulatory agencies (e.g., OHRP, FDA). However, any and all other reports or notifications of such events that may be required to a funding agency, sponsor, or other authority, will be the Relying Institution's sole responsibility.

- **Relying Institutions Responsible for Identifying All Requirements Other Than Requirements of Federal Human Subjects Protection or Clinical Investigation Regulations.** Reviewing IRBs must identify and interpret the requirements of the Common Rule, the FDA's clinical investigation regulations, and other federal human subjects protection regulations as applicable to the research they review. Relying Institutions must identify, interpret, and communicate to Reviewing IRBs the requirements of any other federal, state, or local laws or regulations and any federal agency-specific requirements applicable to the research (as part of Local Considerations).

Changes to Other Provisions

- **Grace Period for Termination of Participation for Loss of Assurance or IRB Registration.** A Participating Institution whose Assurance is suspended, restricted, terminated, or expires, or if serving as a Reviewing IRB/Reviewing IRB Institution, whose IRB registration is lost or lapses, has 30

business days (or up to 60 business days if agreed by other affected institutions) to fully reinstate its Assurance/IRB registration before its participation in the agreement is terminated.

- **Provision for Electronic Joinder Agreements.** Joinder Agreements for Version 3.0 of the agreement will be electronic and will be executed using electronic or digital signatures.

- **Addition of Governing Law and Venue Provision.** Except with respect to federal agencies and except with respect to other public institutions where limited by law, governing law and venue in a proceeding initiated by a Participating Institution against another Participating Institution will be of/in the state of the defending Participating Institution.