Appendix 8. Template Checklists for Reviewing IRBs and Relying Institutions to Identify When to Address Local Considerations after Initial Approval of a Study

These template checklists serve as guides for Reviewing IRBs and Relying Institutions to identify when amendments, events, or other updates might trigger a local consideration that could affect IRB review for a specific site. When events or amendments identified in the checklists occur:

a) Reviewing IRBs may need to review local considerations they collected (e.g., via the Institutional Profile, Study-Specific Document, and Implementation Checklist) to ensure they are taking into account relevant information in their review of that site; and

b) Relying Institutions need to determine whether they must communicate new or updated local considerations information to the Reviewing IRB.

Reviewing IRB

	Amendment Content
☐	Addition of a new subject population, especially children, pregnant women, prisoners, individuals with impaired decision-making capacity, LGBTQIA, other potentially vulnerable subject populations
☐	Addition of non-English speakers
☐	Significant change in recruitment method
☐	Addition of genetic testing
☐	Addition of testing for an infectious disease
☐	Addition of pregnancy testing or collection of information about pregnancy status
☐	Providing research results to participants
☐	Addition of or change in contraception used in the study
☐	Change in study drug or device storage or distribution
☐	Addition of a new drug or device that could affect billing
☐	Change in informed consent language that is commonly affected by institutional policy, such as compensation for injury language and study costs
☐	Addition of a new consent process

Relying Institutions

	Event
☐	Change in state or local law or institutional policy that could affect a ceded research study
☐	Change in study personnel, including the site Relying Institution PI (PI)
☐	New or additional ancillary review required that could affect IRB review
☐	New or changes in conflict of interest
☐	New or changes in funding
☐	If the Relying Institution is serving as the HIPAA Privacy Board, changes that could affect HIPAA authorization language that are not consistent with any IRB-approved informed consent language
☐	Changes in research activities taking place at the Relying Institution