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eCONSENT APPROVAL NOTICE
MOD01273330

DATE: 4 Apr 2022
TO: Irene Bosch
PROTOCOL: Center of Complex Interventions - IDx20-001, Community frequent antigen testing to monitor COVID-19 in senior public housing setup (Pro00059157)
APPROVAL DATE: 31 Mar 2022

Use of eConsent is Approved.

Based on the confirmations provided to the IRB, it is expected that:

1. The eConsent(s) will include the complete and exact contents of the most current, IRB approved study consent(s).
2. The eConsent process includes obtaining signature(s) in compliance with applicable law and a method to confirm the identity of the signer(s).
3. The stored eConsent(s) identify the signers and date (time, if applicable) of signing; signed eConsent(s) are stored with appropriate access, and all versions are retrievable.
4. The signers must review all consent contents prior to signing the eConsent (i.e., there is no function available to skip directly to the signature field(s)).
5. All subject-facing materials used during the eConsent process (e.g., web-linked materials, graphics, videos, glossary, etc.) will be submitted for IRB approval.
6. If CIRBI eConsent Attestation responses change, an eConsent Modification will be submitted to the IRB for review. Note: An eConsent Modification is not required when revisions are only to the IRB approved study consent document(s).

Individual sites using a different eConsent system/process (e.g., different app, vendor) or different eConsent subject-facing materials from the sponsor (e.g., Video Storyboard, Glossary of Terms, links, etc), require a site-level eConsent review (reviewed as part of the initial site/SSU submission or in a site eConsent Modification).

If you wish to appeal the IRB's determinations and/or imposed modifications, please submit supporting documentation to address the IRB's concerns by creating an Appeal Modification in CIRBI.

Please review the IRB Handbook located in the "Reference Materials" section of the Advarra CIRBI™ Platform (www.cirbi.net). A copy of the most recent IRB roster is also available.

Thank you for continuing to use Advarra IRB to provide oversight for your research project.