

Date: February 14, 2012

To: ACTG Principal Investigators, Laboratory Directors and Laboratory Managers

From: Dr. Robert Coombs, ACTG Network Laboratory Principal Investigator

Re: Laboratory Certifications Not Required for Research Laboratories Conducting Testing for the ACTG

Cc: Daniella Livnat (DAIDS), ACTG Laboratory Coordination

ACTG clinical trial sites have been receiving requests from their DAIDS site monitors to produce documentation of certifications for central laboratories or research laboratories. This memo is to document that these types of laboratories are performing research/experimental assays for the ACTG and therefore, are not required to have certifications for clinical testing.

In addition the ACTG Repository (BRI) is not a testing laboratory and does not require any certification.

Please place this Network Memo in your regulatory files so that your DAIDS monitor can refer to it during site monitoring visits.

For those laboratories that do have clinical testing certifications (e.g. CLIA/CAP), HANC has created a central library where laboratories can post their certificates. For additional information or to access posted certificates use the following link: http://www.hanc.info/labs/Pages/laboratoryCertificates.aspx.

If you have any questions regarding this memo please contact the ACTG Laboratory Group at <u>ACTGLaboratoryCoordination@s-3.com</u>.

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