



DATE: December 30, 2010

TO: ACTG Clinical Trials Unit (CTU) Principal Investigators
ACTG Clinical Research Site (CRS) Leaders
ACTG Specialty Laboratory Directors

FROM: Dr. Daniel R. Kuritzkes, ACTG Principal Investigator and Chair, ACTG Executive Committee (AEC)
Dr. Susan L. Koletar, Chair, ACTG Performance Evaluation Committee (PEC)
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cc: ACTG CRS Study Coordinators and Specialty Laboratory Managers

Subject: Cryopreservation Certification Requirements

In September 2010 the Immunology Quality Assessment (IQA) Cryopreservation Proficiency Program initiated formal assessment of CRS performance in the viability and viable recovery of cryopreserved peripheral blood mononuclear cells (PBMCs). This memorandum is to inform you that ACTG sites and specialty laboratories performing cryopreservation of PBMCs for ACTG protocols are to be ACTG "Certified" or "Provisionally Certified" to continue enrolling subjects. The PEC will monitor compliance with the cryopreservation certification requirements beginning with the December 2010 assessment. A table showing the conversion of IQA viability and viable recovery status to ACTG certification is attached.

The ACTG requires a provisionally certified CRS to become certified by the next quarterly IQA proficiency assessment. **A CRS that is provisionally certified in two consecutive assessments or not certified in one assessment will be notified that the site's enrollment screens for protocols requiring cryopreserved PBMCs will be closed until the site becomes certified.**

For detailed information on the IQA Cryopreservation Proficiency Assessment Program, please refer to the IQA website: https://iqa.center.duke.edu/modules/iqa_plabs/index.php?id=6.

Should you have any questions regarding the ACTG certification requirements, please do not hesitate to contact us.

Table: IQA Viability and Viable Recovery Status Conversion to ACTG Certification

| IQA Viability Status | IQA Viable Recovery Status | ACTG Certification Status |
|-----------------------------|-----------------------------------|----------------------------------|
| A | A | Certified |
| A | PA | Provisionally Certified |
| A | OP | Not Certified |
| PA | A | Provisionally Certified |
| PA | PA | Provisionally Certified |
| PA | OP | Not Certified |
| OP | A | Not Certified |
| OP | PA | Not Certified |
| OP | OP | Not Certified |

A = Approved
PA = Provisionally Approved
OP = On Probation