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[REDACTED]

Walter Gualdon, Executive Director

CONFIDENTIAL MEDICAL PEER REVIEW

May 6, 2011

**VIA FACSIMILE AND CERTIFIED MAIL/RETURN RECEIPT REQUESTED**

Dem Y. Lalison, M.B.A., CPTC  
Executive Director  
Alabama Organ Center



Dear Mr. Lalison:

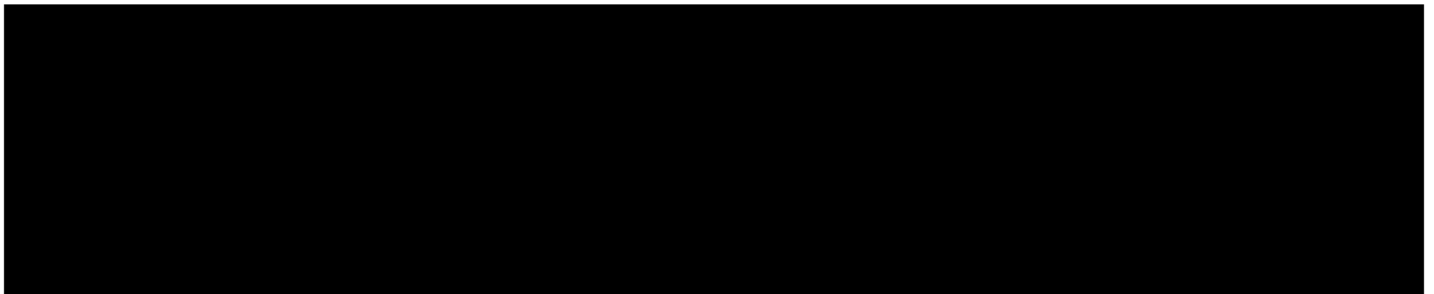
The United Network for Organ Sharing (UNOS) is the facilitator of the Organ Procurement and Transplantation Network (OPTN). The UNOS Department of Evaluation and Quality staff continuously reviews organ allocations for all OPTN members.

The UNOS Department of Evaluation and Quality received a complaint regarding the operating procedures of Alabama Organ Center. As a result of this complaint and as follow-up to Alabama Organ Center's routine site survey on January 13-14, 2010, DEQ conducted a special on-site survey on March 23-24, 2011. UNOS staff investigated the allegations in the complaint, which involved donors from 2007 through 2010. The site survey portion of the review focused on donors who occurred on or after February 5, 2010. Donors who occurred prior to February 5, 2010 were not included in the site survey report, but are addressed below.

After a detailed review of the information provided by the site survey, the following potential violations of OPTN Policy have been identified:

- Policy **2.2.4** (former OPTN Policy 2.2.3) Donor Evaluation: "Donor evaluation must be performed or coordinated by the Host OPO..."
- Policy **5.4.1** Internal Labeling Requirements: "The Host OPO is responsible for ensuring that a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ..."

Please see the chart below for more detailed information:



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Donor ID	Surveyors Findings	Policy
██████	No urine culture No direct Bilirubin	Policy 2.2.4.1
██████	No direct Bilirubin	Policy 2.2.4.3
██████	No EKG	Policy 2.2.4.4
██████	No EKG	Policy 2.2.4.4
██████	No urine culture	Policy 2.2.4.1
██████	No urinalysis done within 24 hours of cross clamp	Policy 2.2.4.1
██████	No blood cultures	Policy 2.2.4.1
██████	Labels for R/L kidney, PA, LI, HR had donor ID# WJK201	Policy 5.4.1

UNOS will submit this matter to the Membership and Professional Standards Committee (MPSC)/Policy Compliance Subcommittee (PCSC). If you would like to provide any additional information or documentation to the MPSC/PCSC as further detail or explanation, please forward this information no later than **May 13, 2011**. Please note submission of additional information is optional. If you do not respond by May 13, 2011, this matter will be forwarded to the MPSC/PCSC for review as summarized above.

The MPSC/ PCSC will review all the information and determine whether a policy violation occurred. Please be assured that UNOS will blind member specific information, including member name/location, employee names and patient/donor identifying information.

The bylaws and policies, which guide the sequence of allocation and listing practices, were developed after circulation and discussion among organ transplant professionals and patient representatives. OPTN/UNOS Bylaws and Policies have been adopted by the OPTN/UNOS Board of Directors in accordance with UNOS' contract with the Health Resources and Services Administration within the U.S. Department of Health and Human Services. UNOS is responsible under this federal contract for keeping these bylaws and policies current and for monitoring compliance by OPTN members.

The transplant community relies on its member's assistance to improve patient safety and the quality of care for transplant recipients. If you have any questions or need any additional information about the policy compliance process, please feel free to contact me at ██████████ or ██████████@unos.org.

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