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CONFIDENTIAL MEDICAL PEER REVIEW

October 11, 2016

**VIA SECURE EMAIL**

[Redacted]

Chief Executive Officer  
Indiana Donor Network

[Redacted]

[Redacted]

Medical Director  
Indiana Donor Network

[Redacted]

Dear [Redacted]:

The OPTN/UNOS Membership and Professional Standards Committee (MPSC) met on October 10, 2016, to review the results of a routine site survey of Indiana Donor Network (INOP), including additional information on INOP's declaration of death and documentation.

**Background**

As you know, UNOS conducted a routine site survey of INOP on August 30-31. During the record review, site surveyors identified potential missing elements of brain death documentation in donor charts. The lead surveyor asked for an immediate containment plan to prevent brain death documentation irregularities. INOP provided the plan before the end of the survey. The surveyors sent the initial report with a request for additional documentation, which your OPO provided. The MPSC leadership, including the Chair, Vice Chair, and Chair of the Performance Analysis and Improvement Subcommittee, reviewed the survey and documentation.

According to Appendix L.10 of the Bylaws, the MPSC Chair will determine the appropriate review pathway for potential policy violations. On October 7, 2016, the MPSC Chair reviewed INOP's potential policy violations and the concerns with the OPTN President, MPSC Vice Chair, and representatives from the Health Resources and Services Administration (HRSA) to determine if the matter should be reviewed under the Imminent Threat or Expedited Review process. At the conclusion of the discussion, the Chair determined that the matter should proceed through the Expedited Review process, described in the Bylaws, Appendix L.13

As part of the Expedited Review, the MPSC convened as an Expedited Threat Review Committee via teleconference on October 10, 2016. The MPSC reviewed all information INOP submitted as of September 27, 2016. Based on its review the MPSC approved the following:

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RESOLVED, that the Membership and Professional Standards Committee is considering recommending an action up to and including a referral to the Secretary of Health and Human Services and that the Board of Directors declare Indiana Donor Network a Member Not in Good Standing for violation of Policy 2.2 (OPO Responsibilities).

The Committee voted 25 For, 0 Against, and 0 Abstentions.

### MPSC Concerns

The MPSC is concerned that issues with brain death documentation represent a potentially severe risk to patient safety, the integrity of the transplant system, and the public trust. The MPSC noted that the OPO seems to have detailed policies and training on brain death, but the records and documentation do not support that staff are following those policies. The Committee feels that this violation could also reflect other serious issues with the OPO. For example, the MPSC is concerned that the OPO's quality system did not identify issues with brain death declaration documentation, and wants to speak with the OPO as soon as possible.

### Options and Timelines

Referral to the Secretary, Member Not in Good Standing, the Expedited Threat Review pathway, and the member's procedural rights when the MPSC is considering an adverse action are specifically defined in Appendix L of the Bylaws, which can be accessed on the OPTN website at <http://optn.transplant.hrsa.gov>. Please note that according to the Bylaws, The MPSC Chair may change the review pathway of a potential violation at any time as information is gathered and the assessment of the urgency and severity of the risk to patient health or public safety changes.

INOP has the following options:

1. Request an interview. If your institution wishes to exercise its right to an interview, written notification must be submitted to [REDACTED], Senior Compliance Operations Analyst, Member Quality Department as soon as possible but no later than **5:00 pm EDT on October 25, 2016**, via secure email to [REDACTED] or at the address in the letterhead using a method that can be tracked and provides proof of receipt. The interview does not constitute a hearing and is preliminary in nature. Should your institution exercise its right to an interview, the interview will be held at the MPSC's next meeting on **Thursday, October 27, 2016, at 11:00 am CDT**. If INOP chooses not to appear before the MPSC, the Chair may decide to escalate the issue to the Imminent Threat Review Pathway.

The Committee has requested that the OPO provide the following information as soon as possible, in addition to the previously requested six month review of donors:

- An organizational chart for the OPO
- Information on the October 5 Clinical Advisory meeting, including any review or resulting corrective actions
- A description or flow of how the donor process works for INOP, including what staff are present for a vented referral, what staff are present for a brain death declaration, what those staff members' backgrounds are, and when the Administrator on Call

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(AOC) may get involved. For staff backgrounds, please include total experience as well as time in an OPO.

- Family Services Coordinator job description
- CV of the Medical Director
- Information on when the OPO has to order an apnea test or other confirmatory test, who interprets the results of the test.
- A root cause analysis of how the quality department did not identify any of these issues as deviation from OPO policy
- Any existing Board-approved Quality Plan
- A description of the background required to be an AOC
- A report on the outcome of the Professional Services Department review of hospital brain death policies, and any resulting actions.

Additionally, the MPSC has suggested that INOP plan for the following staff to appear in-person before the committee:

- INOP's Chief Executive Officer
- Chair of the Board of Directors
- Chief Medical Officer
- Director of Quality
- Director of Family Services
- Chair of the Clinical Advisory Committee (if not the CMO)
- An AOC (if none of the previously mentioned positions fills this role)
- An organizational trainer

After an interview, the MPSC may issue a lesser action or continue to recommend potential referral to the Secretary of HHS and Member Not in Good Standing. If the MPSC continues to recommend these actions, your institution will be entitled to a hearing with the MPSC.

2. Request a hearing. Your institution has the right to waive its right to an interview and proceed directly to a hearing with the MPSC. If your institution wishes to exercise its right to a hearing, you must submit written notification to [REDACTED] by **5:00 pm EDT on October 25, 2016**, using a method described in item one above.

The Bylaws describe the hearing process. During a hearing you would be entitled to present any information relevant to the general nature of the organization's ability to comply with Bylaws and Policies. All materials about the institution that were considered by the MPSC, consisting of supplemental information furnished by the institution and copies of correspondence, will be made available to you upon request. If your institution submits a hearing request within the prescribed time period, UNOS staff will notify you of the hearing date, time, and place. The hearing should convene no fewer than 7 days and no more than 60 days after receipt of the request. Your institution's representatives must be present to participate in the hearing, which may also include legal counsel.

After a hearing, the MPSC may issue a lesser action or continue to recommend referral to the Secretary of HHS and Member Not in Good Standing. If the MPSC continues to

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recommend these actions, your institution will have the right to appear before the Board of Directors.

3. Decline the interview and hearing, and accept the adverse action of Member Not in Good Standing and referral to the Secretary. Your institution must acknowledge that it accepts this action by submitting written notification to [REDACTED] by **5:00 pm EDT on October 25, 2016**, using a method described in item one above. The MPSC may then recommend that the Board move forward with the adverse action of Member Not in Good Standing. Your institution would have the right to appear before the Board of Directors. The MPSC may also recommend that the Board of Directors refer the matter to the Secretary of HHS for further action.

If your institution waives both its right to an interview and a hearing and accepts its right to appear before the Board of Directors, your appearance will take place at the Board of Directors meeting on December 5-6, 2016, in St. Louis, Missouri.

***Should your institution not request an interview, request a hearing, or accept the adverse action in the manner described above, the institution is deemed to have waived its right to an interview and a hearing and the MPSC may continue to recommend that the Board of Directors refer INOP to the Secretary of HHS and declare INOP a Member Not in Good Standing.***

Please be aware that this correspondence and all related documents and information are protected by applicable peer review statutes. Members must keep all information provided in the medical peer review processes and settings confidential. Therefore, all inquiries, deliberations, recommendations, and actions of the MPSC, Board of Directors, other committees, and Regional Review Committees must be kept confidential by members during the review process and after the matter is closed. The Board of Directors may make public certain final adverse actions as outlined in the Bylaws.

If you have any questions or concerns, or need any additional information regarding this resolution, please contact [REDACTED]

Sincerely,

[REDACTED]

[REDACTED]  
Chair, OPTN/UNOS Membership and Professional Standards Committee

cc: [REDACTED] President, OPTN/UNOS Board of Directors  
Brian M. Shepard, Executive Director and CEO, UNOS