The Living Kidney Donor: New OPTN Policy Requirements for Informed Consent

May 29, 2013
2:00 – 3:00 p.m. ET

Objectives

- Describe new living kidney donor policy requirements for the informed consent process
- Recognize the importance of the new living kidney donor documentation requirements
- Identify professional resources to assist with compliance
- Give examples of how the new policy requirements can benefit potential living kidney donors
Policy 12.2
Informed Consent

Lee Bolton, MSN, ACNP
Policy Analyst

Informed Consent Policy

June 2006
• HRSA directed OPTN to develop policies

August 2007
• Guidelines released for public comment

September 2007
• Guidance document approved
• Living donor program bylaws approved
Bylaw Elements 2008 - 2013

- Potential risks
- Confidentiality
- Right to opt out
- Access to insurance
- Follow-up submission
- Grievance reporting
- Compensation is a federal crime

OPTN

Informed Consent Policy

December 2009
- HRSA requested policies be developed

September 2011
- Policy proposal for informed consent distributed for public comment

June 2012
- Informed consent bylaws moved into OPTN Policies 12.10 and 12.11

November 2012
- OPTN/UNOS Board approved new policy for informed consent of living kidney donors

February 2013
- New informed consent program requirements went into effect

OPTN
Purpose of Informed Consent

- To determine that the potential living kidney donor understands:
  - Risks
  - Receive no medical benefit
  - There are both general and center-specific risks
Requirements of Informed Consent

- Willing to donate
- Free from inducement and coercion
- Informed that the potential donor may decline to donate at any time
Complying with Policy 12.2

- UNOS DEQ staff will review donor records to verify that the hospital:
  - Obtains written assurance
  - Includes documentation in medical record

Documentation

- Instruction about ALL phases of the living donation process per Policy 12.2b
  - Informed consent
  - Medical and psychosocial evaluation
  - Pre- and post operative care
  - Follow-up
Documentation

Disclosures

- Confidentiality
- Valuable consideration
- IDA
- Alternate procedures
- Evaluation

OPTN

Documentation

Disclosures

- Data
- Reporting follow-up information
- Discovery of infectious disease or malignancy

OPTN
Documentation

- Medical risks
- Surgical risks
- Potential psychological risks
- Financial impacts

Document, document, document!

- Conversations
- Interactions
- Educational sessions
Documentation for the Evaluation

- Medical and psychosocial evaluation **Policy 12.3**
- Refusal
- Associated risks

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Monitoring Elements

- Policies
- Procedures
- Documentation

OPTN
Be prepared for…

- Staff interviews
- Medical record reviews
- Request policies
- Corrective Action Plan (CAP)

OPTN

Resources

Evaluation Plan

Changes are denoted by blue highlight, and can be found in the Change Log.

Table of Contents

Monitoring Compliance

Policy 2: Minimum Procurement Standards For An Organ Procurement Organization (OPO)
Policy 2.1: Host OPO ................................................................. 10
Policy 2.2.1: Evaluation of Potential Donors ................................ 11
Policy 2.2.2: Evaluation of Potential Donors ................................ 12

OPTN
Living Donation Experience

Doug Penrod, RN
Living Donor
Transplant Outreach Liaison
Donation Experience

March 2007
- Decision to donate

March 2007
- Develop Guidance Document for Living Donors

February 2008
- Recipient identified

February 2008
- Guidance Document containing voluntary recommendations developed
- Bylaws requiring programs to develop and follow protocols in place
March 2008

- Transplant scheduled

March 2008

- Guidance Document containing voluntary recommendations developed
- Bylaws requiring programs to develop and follow protocols in place

Donation Experience

OPTN

Donation Experience - Bylaws

- Personal vs. professional
- Changes made as a result of personal experience
Living Donation Experience

Kathy Schwab, RN, CCTC
Living Donor
Compliance Coordinator

Donation Experience

December 2012

- Directed donation to sister
Donation Experience

- Donation and transplant occurred at the same center
- Comfort level was high
- Informed consent had become standardized

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Donation Experience

Meetings

- Nephrologist
  - Informed consent was signed and witnessed
  - Information was reviewed

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Donation Experience

Meetings

- Nurse Coordinator
  - Group education
  - 1 on 1 education

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Policy 12.0

- Standardize protocols
- Better understanding
- Support effective practices
- Sharing of information with donor
Informed Consent Strategies

- IDA as a Social Worker
- Ongoing process
- Teach-back

Informed Consent Strategies

- Additional information to make a fully informed decision
- Standard of practice
Question and Answer Session

Lee Bolton, MSN, ACNP
Diana Marsh, RN, BSN
Doug Penrod, RN
Kathy Schwab, RN, CCTC