At-a-Glance

- **Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors**

- **Affected/Proposed Policies and Bylaws:** 12.2 (Informed Consent of Living Donors); 12.4 (Independent Donor Advocates); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants

- **Living Donor Committee**

  This proposal would establish policy requirements for the informed consent of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS); and the North American Transplant Coordinators Organization (NATCO) to the OTPN/UNOS Living Donor Committee.

- **Affected Groups**
  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Data Coordinators
  Transplant Coordinators
  Transplant Physicians/Surgeons
  PR/Public Education Staff
  Transplant Program Directors
  Transplant Social Workers
  Organ Recipients
  Organ Candidates
  Living Donors
  Living Donor Candidates
  Donor Family Members
  General Public

- **Number of Potential Living Donors Affected**
  In 2010, there were 6275 living kidney donors, and the proposed policy would affect all potential living donors, and all living kidney donors and their recipients.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The proposed changes are consistent with the strategic plan goals to:
  - Optimize a safe environment for living donor transplantation through improved living donor informed consent
  - Improve living donor consent through development and enactment of policies to protect patient safety and preserve the public trust
  - Identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

- **Specific Requests for Comment**
  The Committee is requesting specific feedback on elements of the proposal determined to be problematic as well as potential solutions for the Committee to consider.

Proposal to Establish Requirements for the Informed Consent of Living Kidney Donors

Affected/Proposed Policies and Bylaws: 12.2 (Informed Consent of Living Donors); 12.4 (Independent Donor Advocates); UNOS Bylaws, Appendix B, Attachment I, Section XIII (Transplant Programs) D (2) Kidney Transplant Programs that Perform Living Donor Kidney Transplants

Living Donor Committee

Summary and Goals of the Proposal:

This proposal would establish policy requirements for the informed consent of living kidney donors. This proposal is in response to a directive from the Health Resources and Services Administration (HRSA) and based on recommendations from a Joint Societies Steering Committee composed of representatives of the American Society of Transplantation (AST); the American Society of Transplant Surgeons (ASTS); and the North American Transplant Coordinators Organization (NATCO) to the OTPN/UNOS Living Donor Committee.

Background and Significance of the Proposal:

On June 16, 2006, the Health Resources and Services Administration (HRSA) published a notice in the Federal Register in which the Secretary of Health and Human Services directed the Organ Procurement and Transplant Network (OPTN) to develop policies regarding living organ donors and organ donor recipients, including policies for the equitable allocation of living donor organs (in accordance with section 121.8 of the Final Rule). The notice directed the OPTN to develop such policies in the same manner, and with the same public comment process, that it does for policies on deceased organ donors and deceased organ donor recipients. The notice stipulated that noncompliance with such policies will subject OPTN members to the same consequences as noncompliance with OPTN policies regarding deceased donor transplantation.

Based on this directive, the Committee began this new area of work by investigating current practices for the consent of living donors. In January 2007, the OPTN/UNOS President sent a letter to all living kidney and liver transplants programs requesting copies of their informed consent, medical evaluation, and living donor follow-up protocols. The letter explained that federal regulation now required the OPTN to develop policies regarding living donors and living donor organ recipients, and that the Committee planned to use these protocols to make recommendations to the OPTN/UNOS (United Network for Organ Sharing) Board of Directors regarding new living donor guidelines. The recommendations would be used to develop guidelines to ensure that individual institutions' living donor consent protocols consistently meet the needs and interests of potential living donors, and that they reflect the consensus of expertise among medical professionals involved in living donor transplantation.

The Committee completed an assessment of all submitted protocols. This evaluation revealed wide variation in the living donor consent process throughout the country. Some transplant centers did not have formalized guidelines for living donor consent. To provide OPTN Members with a shared knowledge base, the Living Donor Committee used the 80/20 rule in evaluating submitted protocols. If the majority (or 80%) of programs had a particular element as part of their standardized consent processes, the Committee included that element in the proposed guidelines. The Committee also reviewed and incorporated certain recommendations from a variety of sources, including the Advisory

Committee on Organ Transplantation (ACOT), Centers for Medicare and Medicaid Services (CMS), and the State of North Carolina living donor statutes in the development of these guidelines.

Guidelines for the Consent of Living Donors were released for public comment between July 13, 2007 and August 11, 2007. The Guidelines included recommendations for donor candidate selection, Independent Donor Advocacy, donor evaluation, management, and follow-up.

Public response to the proposal was mixed. Some respondents supported the proposed standardization of the consent of living kidney donors. Others opined that the proposed guidelines were too prescriptive, dictated medical practice, and would lead to increased litigation. There was also concern with the word "guidelines" as it may not have the same connotation as guidelines in other areas of medicine.

The Committee met by teleconference on August 14, 2007 to review public comment and to consider modifying the proposed guidelines. Based on public comment, the Committee agreed to make the guidelines less prescriptive and agreed to refer to the proposal as "recommendations" rather than "guidelines". The Committee revised the proposal and voted to send the revised proposal to the Board for consideration.

During the September 2007 Board meeting, the Board approved *Guidance for the Informed Consent of Living Donors.* This resource has been available through the OPTN website since September 2007 and may be viewed at http://optn.transplant.hrsa.gov/resources/professionalresources.asp?index=7.

In December 2009, HRSA informed the OPTN that although helpful, the voluntary recommendations for the consent of living donors developed to date were not sufficient and policies were still required.

In April 2010, representatives of the AST, ASTS, NATCO, OPTN/UNOS, and HRSA met to discuss and develop a new process for incorporating clinical input into developing OPTN policies that have the potential to direct or prescribe medical care. The need for such a process had been identified during the course of OPTN/UNOS's prior attempts to develop policies for the consent, medical evaluation, and follow-up of living donors.

During this meeting, it was noted that early involvement of the societies in the OPTN policy development process, for the purpose of identifying the appropriate medical requirements and the appropriate level of specificity of such requirements, could be an important advance that might allow such policies to be developed in a timelier way with better initial acceptance by the transplant community.

It was determined that a Joint Societies Policy Steering Committee (comprised of members from the AST, ASTS, NATCO, OPTN/UNOS, and HRSA) would be given an opportunity to make recommendations on any OPTN policy under development that has the potential to prescribe medical care, including policies for the consent, medical evaluation, and follow-up of living kidney donors.

The Joint Societies Policy Steering Committee formed a Joint Societies Work Group (JSWG) consisting of appointed members of the represented societies to develop recommendations to include the informed consent living kidney donors. The charge of the Joint Societies Work Group was to *"provide recommendations to the OTPN/UNOS regarding appropriate requirements for the medical evaluation*

(including the psychosocial evaluation) and informed consent of potential living kidney donors as well as post-donation follow-up and data submission."

In response to its charge, the JSWG created three resources representing the consensus of its members, including a position paper on the Informed Consent of Living Kidney Donors **(Exhibit A)**. These resource documents were approved by the Executive Committees of the parent societies and forwarded to UNOS and the Living Donor Committee for consideration in policy development.

A subcommittee of the Living Donor Committee reviewed the position paper on the Informed Consent of Living Kidney Donors. In general, the subcommittee agreed with the informed consent recommendations, but determined that some of the recommendations were too prescriptive, and should not be included in the proposal prepared for consideration by the full Committee. The Committee reviewed this proposal on July 20, 2011, and approved it for public comment.

Collaboration:

The proposal is based on recommendations from a Joint Societies Steering Committee composed of representatives of the AST, ASTS, and NATCO to the Living Donor Committee. The OPTN/UNOS Operation and Safety Committee was asked to review and provide feedback during development of the proposal.

Alternatives considered:

The Committee considered if some components of the recommendations from the JSWG for the consent of living kidney donors could also be applied to living liver donors so that group of donors could be addressed in the proposal. The Committee ultimately decided that policy for the consent of living liver donors would best be addressed at some future date in a separate proposal.

Strengths and weaknesses:

The proposal would lead to the standardization of the consent of living kidney donors. A weakness of the proposal is that it would not create standardization of the informed consent of all types of living donors.

Description of intended and unintended consequences:

The proposal creates the need to eliminate existing OPTN bylaws and UNOS bylaws, specifically, the requirement that kidney recovery hospitals must develop, and once developed, must comply with written protocols for informed consent and the Independent Donor Advocate. In its position paper on the Informed Consent of Living Kidney Donors the JSWG included existing OPTN bylaws and UNOS bylaw requirements for the Independent Donor Advocate. These requirements follow and it is proposed that they be moved to an existing but currently empty Independent Donor Advocate policy (12.4) section:

12.4.1 The IDA must assist the potential donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process so donor inattention and misunderstanding can be detected. The donor must demonstrate an understanding of the risks and benefits of donation to the IDA. IDA responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor
- Advocate for the rights of the potential donor
- Assist the potential donor in obtaining and understanding information regarding the:
  1) Consent process;
  2) Evaluation process;
  3) Surgical procedure;
  4) Medical and psychosocial risks;
  5) Benefit and need for follow-up

The current bylaws also contain a definition for the Independent Donor Advocate that was not included in the position paper on the Informed Consent of Living Kidney Donors developed by the Joint Society Work Group. It is proposed that the definition for the Independent Donor Advocate be moved to policy (12.4) section as well, the definition follows:

12.4. Independent Donor Advocate

The living donor recovery hospital must provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

Supporting Evidence and/or Modeling:

***Table* 1. Living Kidney Donors in the US**
January 1, 2005 – December 31, 2010

	Transplanted Living Donor Kidneys
Year of Donation	
2005	6,570
2006	6,434
2007	6,043
2008	5,968
2009	6,387
2010	6,275

Based on OPTN data as of July 8, 2011
Data subject to change base on future data submission or correction

Several consensus statements have been published affirming basic principles governing the informed consent of prospective living kidney donors (Adams et al., 2002; Ethics Committee of the Transplantation Society, 2004; Abecassis et al., 2000). These principles include ensuring that

prospective donors are capable of making the decision to donate, willing to donate, free of coercion or undue pressure to donate, medically and psychosocial suitable to donate, and fully informed of the risks and benefits of donation. These principles provide the framework for the current proposal.

Expected Impact on Living Donors or Living Donation

Standardized consent could improve the confidence of living donors in the safety of donation. Overall, a standardized consent process should improve the transparency of the living donation process and increase the consistency of the donation process across transplant centers. Greater consistency in ensuring that prospective donors are informed about and understand the potential risks and benefits of donation may contribute to better post-donation outcomes for donors.

Expected Impact on Specific Patient Populations

There should be no direct impact on the candidate pool. However, the proposal has the potential to affect all persons who are evaluated to be a living kidney donor and all living kidney donors.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

HHS Program Goals	*Strategic Plan Goals*
Patient Safety	The OPTN will promote safe, high-quality care for living donor transplant candidates, living donor transplant recipients, and living donors
Best Use	To achieve the best use of donated organs, the OPTN will refine policies by incorporating objective, measurable criteria related to concepts of donor risk/quality and recipient benefit
Operational Effectiveness	The OPTN will identify process and system improvements that best support critical network functions, and work to disseminate them to all members who could benefit

Plan for Evaluating the Proposal:

The Committee will request biannual blinded reports on the number of transplant centers found out of compliance through UNOS Living Donor Program Audits.

Additional Data Collection:

The proposal does not require changes to the OPTN data collection system.

Expected Implementation Plan:

If this policy proposal is approved by the Board of Directors, living donor recovery centers would be required to follow new policies for the informed consent of living kidney donors. The UNOS Living Donor Programs Auditors will evaluate center compliance. The proposal will not require programming in UNet^{SM}.

Communication and Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy notice	Relevant staff at transplant centers and OPOs	Policy notice delivered through e-newsletter and stored in member archive.	30 days after the board of directors votes to approve the policy change.
Article in UNOS Update	Update readers	Print copy delivered by US mail	The earliest possible issue following board approval of the policy change
System Notice	Relevant staff at transplant centers and OPOs	Email	30 days prior to implementation and again at implementation
Mention in e-newsletter in the Policy-related category	Relevant staff at transplant centers and OPOs	E-mail and access to member archive website	Publish in e-newsletter the month the policy change is implemented and in the e-newsletter issue the following month
Blurb on transplant administrators list serv	Transplant Administrators	Electronic list serv	Post implementation of policy change

Monitoring and Evaluation:

Transplant centers must develop, implement and comply with a process for the consent of living kidney donors. They must also document that the process was performed in adherence to OPTN policy requirements and make this documentation available upon request.

The Department of Evaluation and Quality will request a corrective action if the transplant center's documentation does not comply with the requirements of this policy and forward the survey results to the OPTN/UNOS Membership and Professional Standards Committee.

Policy or Bylaw Proposal:

The proposed changes to policy 12.2 would be entirely new policy requirements that typically would be presented with underlining. Since the proposed changes would be difficult to read with underlining, the proposed changes are being presented differently. For your convenience, the proposed new policies are

presented here without underlining. Strikeouts are used to indicate what language would be removed from the bylaws.

12.2 Informed Consent of Living Kidney Donors

Introduction:

Education is important to enable the potential donor to understand all aspects of the donation process, especially the risks and benefits.

Informed Consent will ensure that a potential donor understands:

1) That he or she will undertake risk but will receive no medical benefit from the donor nephrectomy.

2) That there are both general risks of the operation as well as center specific risks.

Living Donor Consent

The consent process for any potential living donor must include, but is not limited to, the following:

a. Assurance that the potential donor is willing to donate, free from inducement and coercion, and understands that he or she may decline to donate at any time. Potential donors must be offered an opportunity to discontinue the donor consent or evaluation process and to do so in a way that is protected and confidential, with enough time from the potential donor's perspective for the potential donor to reflect on his or her decision before and after evaluation. The independent donor advocate (IDA) must be available to assist the potential donor during this process. (see Policy 12.4)

b. Instruction about all phases of the living donation process. Teaching or instructional material can include any media (e.g., written, video, audio) or one-on-one or small group interaction. Teaching or instruction must be provided in a language in which the donor is acceptably fluent to understand all relevant issues and engage in a meaningful dialogue with the transplant program staff. The goal is to provide instruction in a method or at a level that will allow the potential donor to comprehend all phases of living donation and its associated risks and benefits.

c. Assurance that the recovery hospital will take all reasonable precautions to provide confidentiality for the donor and recipient.

d. Disclosure that it is a federal crime, subject to $50,000 fine or five years in prison, for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations). In certain cases, donors may be reimbursed for limited

travel expenses and may receive basic cost of living assistance.

e. Disclosure that the recovery hospitals must provide an Independent Donor Advocate (IDA).

f. The stipulation that the recovery hospital must provide potential donors with both national and program-specific transplant recipient outcomes from the most recent SRTR center-specific reports. This information must include the hospital's 1-year patient and graft survival, national 1-year patient and graft survival, and notification about all CMS outcome requirements not being met by the transplant hospital.

g. Education about expected post-donation kidney function and how chronic kidney disease (CKD) and end-stage renal disease (ESRD) might potentially impact the donor in the future to include:

1) Donors lose 25-40% of kidney function at donation

2) Baseline risk of ESRD is the same as for members of the general population with the same risk profile.

3) If they develop CKD, their progression to ESRD may be more rapid than people with two kidneys. They may also be at a higher risk for CKD if they sustain damage to the remaining kidney.

4) Current practice is to prioritize prior living donors who become transplant candidates.

h. Disclosure of alternate procedures or courses of treatment for the recipient including deceased donor transplantation.

- The donor must be made aware that a deceased donor kidney might become available for the recipient before the donor evaluation is completed or the living donor transplant occurs.

- Potential donors must be provided a realistic estimate of the likelihood of successful transplantation for the transplant candidate, given the specific set of risk factors that the transplant candidate may have for any increased morbidity or mortality. The donor must be informed if the transplant candidate has risk factors for increased morbidity or mortality that the transplant candidate does not wish disclosed.

i. The disclosure that the donor will receive a thorough medical and psychosocial evaluation.

j. The disclosure that the potential donor's medical evaluation could reveal conditions that the transplant center must report to governmental authorities,

such as HIV or other infectious diseases with mandatory public health reporting requirements.

k. Disclosure that recovery hospitals are required to report living donor follow-up information for two years, and the agreement of the potential donor to commit to post-operative follow-up testing coordinated by the living donor recovery hospital for a minimum of two years.

In order to be adequately informed, potential donors need to understand there are inherent risks associated with evaluation for living donation. These risks include, but are not limited to allergic reactions to contrast, discovery of reportable infections, discovery of serious medical conditions, discovery of adverse genetic findings unknown to the donor, and discovery of certain abnormalities that will require more testing at the donor's expense or create the need for unexpected decisions on the part of the transplant team. The potential donor must consent for evaluation, which includes, but is not limited to the following:

- The potential donor must understand that the medical evaluation will be conducted by a surgeon and/or other type of physician experienced in living donation to assess risks to the potential donor after donation. This will include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease. In addition, the psychosocial evaluation will be conducted by a psychiatrist, psychologist, clinical social worker, clinical nurse specialist, or advanced practice nurse in transplantation to determine decision-making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion.

- The potential donor must be informed that the recovery hospital has the duty to justify reasonable medical and psychosocial risk, and that a donor may be refused because of persisting uncertainty in these areas as well as for findings indicating that the donor has specific risk factors. Donors need to understand that the decisions of the transplant program are final. Donors need to understand they could be evaluated by another transplant program that may have different selection criteria.

l. A specification of the surgical and longer-term medical, psychosocial, and financial risks associated with being a living kidney donor. These risks may be transient or permanent and include, but are not limited to the following:

    i) Surgical Risks:

        - Scars, pain, fatigue, and other consequences typical of any surgical procedure; and

        - Decreased kidney function. Every kidney donor will experience a decrease in the kidney function compared to pre-donation. The amount will depend upon the potential donor's age and history. The anticipated change in

individual kidney function must be discussed with each donor.

ii) Potential Longer-Term Medical Risks:

- Abdominal or bowel symptoms such as bloating and nausea;
- Impact of obesity, hypertension, or other donor-specific medical condition on morbidity and mortality of the potential donor;
- Findings in the donor medical examination, and all donor risks, must be interpreted in light of the known epidemiology of both CKD, which largely arises in mid-life, (40-50 years old) and ESRD, which usually occurs after age 60. The limits of a normal examination in a young donor to predict lifetime risk must be acknowledged; and
- Kidney failure and the need for dialysis or kidney transplant for the donor.

iii) Potential Psychosocial Risks:

- Problems with body image;
- Post-surgery depression or anxiety;
- Feelings of emotional distress or bereavement if the transplant recipient experiences any recurrent disease or in the event of the transplant recipient's death; and
- Impact of donation on the donor's lifestyle.

iv) Potential Financial Impacts:

- Personal expenses of travel, housing, child care costs, and lost wages related to donation might not be reimbursed; however, the potential donor must be informed that resources might be available to defray some donation-related costs;
- Need for life-long medical follow-up at the donor's expense; and,
- Impact of having the transplant in a hospital not approved by CMS to perform transplants may affect the recipient's ability to have the anti- rejection medications covered under Medicare Part B.

v) Potential Longer-Term Financial Risks:

- Loss of employment or income;
- Impact on the ability to obtain future employment including, but not limited to military service, law enforcement, aviation, and fire department employment;
- Impact on the ability to obtain or afford health, disability, and life insurance; and,
- Future health problems experienced by living donors following donation may not be covered by the recipient's insurance.

m. Disclosure initially, and as a part of the final step in donor acceptance or refusal, that selection policies and protocols may vary significantly among transplant hospitals, specifically in accepting or declining donors who may be at increased medical risk.

12.4. Independent Donor Advocate

The living donor recovery hospital must provide an independent donor advocate (IDA) who is not involved with the potential recipient evaluation and is independent of the decision to transplant the potential recipient.

12.4.1 The IDA must assist the potential donor with the evaluation process and focus on their needs and questions. The IDA must be knowledgeable about risks and benefits associated with all phases of the donation process so donor inattention and misunderstanding can be detected. The donor must demonstrate an understanding of the risks and benefits of donation to the IDA. IDA responsibilities include, but are not limited to the following:

- Promote the best interests of the potential living donor
- Advocate for the rights of the potential donor
- Assist the potential donor in obtaining and understanding information regarding the:

  1) Consent process;

  2) Evaluation process;

  3) Surgical procedure;

4) Medical and psychosocial risks;

5) Benefit and need for follow-up.

ATTACHMENT I
TO APPENDIX B OF UNOS BYLAWS
Designated Transplant Program Criteria

(2) Kidney Transplant Programs that Perform Living Donor Kidney Recovery: Kidney transplant programs that perform living donor kidney recovery ("kidney recovery hospital") must demonstrate the following:

a. Personnel and Resources Kidney recovery hospitals must demonstrate the following regarding personnel and resources:

(i) That the kidney recovery hospital meets the qualifications of a kidney transplant program as set forth above; and

(ii) In order to perform open donor nephrectomies, a qualifying kidney donor surgeon must be on site and must meet either of the criteria set forth below:

(1) Completed an accredited ASTS fellowship with a certificate in kidney; or

(2) Performed no fewer than 10 open donor nephrectomies (to include deceased donor nephrectomy, removal of polycystic or diseased kidneys, etc.) as primary surgeon or first assistant within the prior 5-year period.

(iii) If the center wishes to perform laparoscopic donor nephrectomies, a qualifying kidney donor surgeon must be on site and must have:

(1) Acted as primary surgeon or first assistant in performing no fewer than 15 laparoscopic nephrectomies within the prior 5-year period.

If the laparoscopic and open nephrectomy expertise resides within different individuals then the program must demonstrate how both individuals will be available to the surgical team. It is recognized that in the case of pediatric living donor transplantation, the living organ donation may occur at a center that is distinct from the approved transplant center.

All surgical procedures identified for the purpose of surgeon qualification must be documented. Documentation should include the date of the surgery, medical records identification and/or UNOS identification number, and the role of the surgeon in the operative procedure.

(iv) The kidney recovery hospital must have the resources available to assess the medical condition of and specific risks to the potential living donor;

~~(v) The psychosocial assessment should include an assessment of the potential donor's capacity to make an informed decision and confirmation of the voluntary nature of proceeding with the evaluation and donation; and~~

~~(vi) That the kidney recovery hospital has an independent donor advocate (IDA) who is not involved with the potential recipient evaluation, is independent of the decision to transplant the potential recipient and, consistent with the IDA protocol referred to below, is a knowledgeable advocate for the potential living donor. The goals of the IDA are:~~

~~(1) to promote the best interests of the potential living donor;~~

~~(2) to advocate the rights of the potential living donor; and~~

~~(3) to assist the potential living donor in obtaining and understanding information regarding the:~~

~~(a) consent process;~~
~~(b) evaluation process;~~
~~(c) surgical procedure; and~~
~~(d) benefit and need for follow-up.~~

~~b. Protocols: Kidney recovery hospitals must demonstrate that they have the following protocols:~~

(i) Living Donation Process: Kidney recovery hospitals must develop, and once developed must comply with written protocols to address all phases of the living donation process. Specific protocols shall include the ~~evaluation,~~ pre-operative, operative, post-operative care, and submission of required follow-up forms at 6 months, one-year, and two-years post donation.

Kidney recovery hospitals must document that all phases of the living donation process were performed in adherence to the center's protocol. This documentation must be maintained and made available upon request.

~~(ii) Independent Donor Advocate: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the duties and responsibilities of Independent Donor Advocate (IDA) that include, but are not limited to, the following elements:~~

~~(1) a description of the duties and primary responsibilities of the IDA to include procedures that ensure the IDA:~~

~~(a) promotes the best interests of the potential living donor;~~

~~(b) advocates the rights of the potential living donor; and~~

~~(c) assists the potential donor in obtaining and understanding information regarding the:~~
~~(i) consent process;~~
~~(ii) evaluation process;~~
~~(iii) surgical procedure; and~~
~~(iv) benefit and need for follow-up.~~

(iii) Medical Evaluation: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the medical evaluation of the potential living donors that must include, but are not limited to, the following elements:

(1) a thorough medical evaluation by a physician and/or surgeon experienced in living donation to assess and minimize risks to the potential donor post-donation, which shall include a screen for any evidence of occult renal and infectious disease and medical co-morbidities, which may cause renal disease;

(2) a psychosocial evaluation of the potential living donor by a psychiatrist, psychologist, or social worker with experience in transplantation (criteria defined in Appendix B, Attachment I) to determine decision making capacity, screen for any pre-existing psychiatric illness, and evaluate any potential coercion;

(3) screening for evidence of transmissible diseases such as cancers and infections; and

(4) anatomic assessment of the suitability of the organ for transplant purposes.

(iv) ~~Informed Consent: Kidney recovery hospitals must develop, and once developed, must comply with written protocols for the Informed Consent for the Donor Evaluation Process and for the Donor Nephrectomy, which include, at a minimum, the following elements:~~

~~(1) discussion of the potential risks of the procedure including the medical, psychological, and financial risks associated with being a living donor;~~

~~(2) assurance that all communication between the potential donor and the transplant center will remain confidential;~~

~~(3) discussion of the potential donor's right to opt out at any time during the donation process;~~

~~(4) discussion that the medical evaluation or donation may impact the potential donor's ability to obtain health, life, and disability insurance;~~

~~(5) disclosure by the kidney recovery hospital that it is required, at a minimum, to submit Living Donor Follow-up forms addressing the health information of each living donor at 6 months, one-year, and two-years post donation. The protocol must include a plan to collect the information about each donor; and~~

~~(6) the telephone number that is available for living donors to report concerns or grievances through the OPTN.~~

~~(7) documentation of disclosure by the kidney recovery hospital to potential donors that the sale or purchase of human organs is a federal crime and that it is unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation. This documentation must be maintained in the potential donor's official medical record~~.