Consensus Statement on the Live Organ Donor

The Authors for the Live Organ Donor Consensus Group

Solid Organ Transplantation from a live organ donor is an ethically acceptable and widely used practice. This approach to treatment affects not only the patient with end-stage organ failure, but also the healthy person who volunteers to donate and whose interests are equally important. Although the experience of live organ donation was initially limited to kidney transplantation, it now increasingly includes the transplantation of portions of the liver and lung. The transplantation of portions of the small intestine and the distal segment of the pancreas have also been performed from live donors. These recent approaches to human organ replacement have evolved because of the increasing shortage and long waiting times for cadaver organs. At many transplant centers today, approximately half of the kidney transplants performed are from live donors. These developments have necessitated a reexamination of the medical and ethical issues involving live organ donors.

On June 1 and 2, 2000, more than 100 representatives of the transplant community, including physicians, nurses, ethicists, psychologists, lawyers, scientists, social workers, transplant recipients, and living donors, met in Kansas City, Mo, under the sponsorship of the National Kidney Foundation and the American Societies of Transplantation, Transplant Surgeons, and Nephrology to evaluate current practices of living donor transplantation of the kidney, pancreas, liver, intestine, and lung. Representatives from the United Resource Networks, the United Network for Organ Sharing, and the National Institutes of Health also participated.

On the first day of the conference, the attendees participated in 7 assigned work groups. Three were organ specific (lung, liver, and kidney) and 4 were focused on social and ethical concerns (informed consent, donor source, psychosocial issues, and a live organ donor registry). In addition, on day 1 there were plenary sessions devoted to live donor pancreas and intestinal transplantation. On the second day of the conference, each work group presented a report of its deliberations to an open plenary session of all attendees.

With a goal of ensuring that the welfare of potential and actual donors remains preeminent in the process of live organ donation, a consensus statement was formulated by the conference attendees that applies to all living organ donors. The term consensus was not meant to imply universal agreement.

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The disclosure process should permit a "cooling off period" between consent and the scheduled donor operation to provide the potential donor ample time to reconsider the decision to donate. Someone other than a family member should be provided to be a translator for non-English-speaking potential donors. The use of an independent, unbiased translator/professional provides an environment for the potential donor to express hesitations, concerns, or health problems that the donor may not wish to discuss in the presence of a family member.

The disclosure process should enable the donor to have a clear understanding of the issues detailed in Table 1. The donor's expectations should be reviewed and confirmed by the donor. Perhaps the best measure of a successfully informed donor is determined by whether the donor is surprised by anything that happens after consent is given. The transplant team should note such events so that the disclosure process can be improved for future donors.

Voluntary Nature. Transplant centers must ensure that the decision to donate is voluntary. Altruism has been the underpinning of live organ donation since its inception. The absence of reproducible health benefits for donors (e.g., a previously unknown medical condition that is discovered in the evaluation process) and the current legal restrictions against financial compensation are compelling reasons for the transplant team to verify the donor's freedom from coercion.

Physicians involved with the care of potential recipients are, and ought to be, primarily concerned with the recipient's interests. Therefore, an independent advocate for the donor should be identified whose only focus is the best interests of the donor. Ideally, this would involve 2 separate medical teams—1 informing donors and 1 informing recipients. It is possible, however, that transplant centers might engage a health care professional such as a psychologist associated with the transplant service (but not a member of the recipient care team) to be the donor ad-

<table>
<thead>
<tr>
<th>Table 1. Elements of Disclosure for Potential Living Donors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description of the evaluation, the surgical procedure, and the recuperative period</td>
</tr>
<tr>
<td>Anticipated short- and long-term follow-up care</td>
</tr>
<tr>
<td>Alternative donation procedures, even if only available at other transplant centers</td>
</tr>
<tr>
<td>Potential surgical complications for the donor, citing the reports of donor deaths (even if never experienced at that transplant center)</td>
</tr>
<tr>
<td>Medical uncertainties, including the potential for long-term donor complications</td>
</tr>
<tr>
<td>Any expenses to be borne by the donor</td>
</tr>
<tr>
<td>Potential impact of donation on the ability of the donor to obtain health and life insurance</td>
</tr>
<tr>
<td>Potential impact of donation on the life-style of the donor, and the ability to obtain future employment</td>
</tr>
<tr>
<td>Information regarding specific risks and benefits to the potential recipient</td>
</tr>
<tr>
<td>Expected outcome of transplantation for the recipient</td>
</tr>
<tr>
<td>Any alternative treatments (other than organ replacement) available to the recipient</td>
</tr>
<tr>
<td>Transplant center-specific statistics of donor and recipient outcomes</td>
</tr>
</tbody>
</table>

Informed Consent

The conference participants highlighted the following elements of informed consent as essential for competent individuals to decide to donate: understanding, disclosure, voluntary nature (freedom to choose to proceed with donation or decline), and documentation of consent.

Understanding. Donors must be able to assimilate accurate information regarding the risks and benefits to themselves. They must understand the benefits to the recipient, but also the alternative treatments available to the recipient. This information must be presented in a way that both the donor and recipient can readily understand. Therefore, how such information is presented and processed by potential donors may vary according to their educational background. All donors should demonstrate capacity to understand the essential elements of providing consent to live donation, with information presented at a level of medical sophistication suitable for that individual.

Disclosure. In live organ donation, risk and benefit are defined in a manner different from other areas of medicine. Potential donors are healthy individuals who rarely receive medical gain (i.e., only in the event an underlying condition is revealed by the evaluation and consequentially treated) and so would not otherwise be considered "patients." Nevertheless, donors become special "patients" beginning with the testing to determine whether they can donate. It is incumbent on the transplant center to provide full and accurate disclosure to potential donors of all pertinent information regarding risk and benefit to the donor and recipient. The relationship between the donor and recipient should not alter the level of acceptable risk. A familial relationship does not impose on the donor (or the recipient) the necessity to take on additional medical risk to accomplish donation. Table 1 lists the items that should be included in the disclosure made to the donor.

The consensus statement will review each of the components of this premise as developed at the national conference and address newer issues related to donor sources, organ exchanges, and the need for ongoing data collection.
Donor advocates should be empowered with full veto authority if they believe donation to be ill advised.

At some transplant centers, the policy is to not share donor information with the recipient, respecting the autonomy and confidentiality of both the donor and recipient. Thus, recipient inquiries regarding donor suitability are referred to the donor for a response. There may be instances, however, in which the potential donor seeks the support of the transplant team to decline donation. For example, if the potential donor anticipates being ostracized from the family by saying "no" to the recipient, the transplant team could assist the potential donor in developing an appropriate medical disclaimer, enabling the potential donor to decline gracefully. This option helps facilitate a fundamental component of informed consent, freedom of choice to be a donor or not. Revealing a borderline medical contraindication such as mild hypertension or an abnormal laboratory value such as blood glucose might provide an excuse for a person not to donate. This should only be done with the potential donor's permission. Alternatively, the medical team could provide the recipient with a general statement of lack of suitability for donation or state that a potential donor has been ruled out without recording a specific diagnosis.

The medical team should not falsify donor medical information to the recipient in an attempt to provide the donor with a reason to decline. Falsified medical conditions may subsequently impose undesired ramifications in the potential donor's life. It is conceivable that a fabricated health problem recorded in the medical chart of either the donor or recipient might be used later to hinder potential donors in attaining a benefit such as unrestricted life insurance or from acting as organ donors for other recipients, such as their own children. Therefore, the reason for a person to decline to donate might be furnished to the recipient if appropriate, but only after agreement of the medical team, the donor advocate, and the potential donor.

Documentation. Core documents in living donor transplantation should include not only the usual informed consent releases but also documentation of the disclosure process, the donor's capacity to balance risk and benefit, freedom from coercion and that the donation is not conditioned on direct monetary compensation. The documentation also should demonstrate that the recipient is aware of and accepts the risks (and benefits) that have been determined for the potential donor. The donor should have a medical record separate from the recipient's medical chart to maintain and protect donor confidentiality.

Medical Suitability
A potential living organ donor should be healthy; however, the determination of medical suitability will differ according to the organ to be donated. Pregnancy is a contraindication to live donor organ donation until after delivery.

The American Society of Transplantation guidelines for living kidney donor evaluation are our recommended resource for clinicians in determining medical suitability. An updated version of the guidelines published in 1995 will be completed this year and available in early 2001.

The guidelines of the American Society of Transplant Surgeons state that potential living liver donors should be healthy adults (aged 18 years and older) who have been carefully evaluated and approved by a multidisciplinary team including hepatologists and surgeons. The mass of the donor liver available for the recipient is an important criterion. Living donor liver transplantation in children involves the removal of an adult donor's left lateral segment (segments II and III). Adult-to-adult living donor liver transplantation involves the use of either a full-left (segments II, III, and IV) or full-right hepatic lobe (segments V, VI, VII, and VIII). Selection of the potential donor is based on an algorithm of suitability that includes radiological imaging of the liver (to assess the following intrahepatic anatomy: hepatic artery, portal vein, hepatic veins, and bile ducts), liver volumetric data, and the presence or absence of steatosis. Percutaneous liver biopsy may be helpful in selected cases (eg, when steatosis is suggested by imaging studies) but is not deemed essential.

Recipient issues such as medical urgency and the presence or absence of portal hypertension influence the appropriateness of live donor liver transplantation. The suitability of the live donor liver recipient is determined by standard criteria that are used for the selection of liver allotransplant recipients from cadaveric donors. Live donor liver transplantation should only be performed by established cadaveric (United Network for Organ Sharing-approved) centers with appropriate surgical expertise and with sufficient institutional resources, support, and ongoing oversight. A position paper outlining practice guidelines from the liver working group (M. Abecassis, MD, and C. Miller, MD) and the American Society of Transplant Surgeons (M. Adams, MD) has been published as a joint document.

Living lung donation involves the transplantation of the right- and left-lower lobes from a pair of adult donors to adult or pediatric recipients. Each donor donates only one lower lobe. The decision concerning which lobe of the lung can be donated is based on an optimal size match between the potential donor and recipient. For adult recipients, the donors should be at least as tall as the recipient. For small children, care must be exercised to ensure that the lower lobe will not be oversized. Donors should be at least age 18 years and preference is given to donors younger than 55 years. The potential donor preferably should not be more than 25% above ideal body weight due to both health concerns for the donor and technical considerations for the donor surgery.

Selection of potential donors is also based on the results of chest radiography, pulmonary function testing, ventilation-perfusion scanning, and computed tomography. While donors with no smoking history clearly are prefer-
able, smokers can be considered if they are tobacco free for 6 months prior to donation and have normal results for pulmonary function testing and radiographic studies. Individuals with well-controlled, mild hypertension may be considered for living lung donation if there is no end-organ damage, no echo-cardiographic evidence of left ventricular hypertrophy, and the potential donor has negative cardiac stress test results. Cardiac stress testing is also recommended in potential donors older than 40 years with any known risk factors for coronary artery disease. Donors with diabetes may be considered if they are non-insulin dependent and have good glycemic control with no end-organ disease.

**Psychosocial Suitability**

A psychosocial evaluation is necessary for each potential donor. The goals of such an evaluation are 3-fold: to evaluate psychological, emotional, and social stability to rule out unsuitable donors and enhance the donation process by identifying individual or donor-related factors that warrant appropriate intervention; to establish whether the potential donor is competent to give informed consent; and to assess the degree to which the decision to donate is being made freely, without undue pressure or coercion.

**Psychosocial Stability.** Evaluation of psychosocial stability is important for 2 reasons. First, some persons may be so unstable that they are not good candidates for donation. Active psychosis or severe substance abuse, for example, might preclude the provision of effective medical care in the operative and postoperative periods. Financial hardship or severe marital problems are examples of social instability that might make live organ donation impractical or opportune. Assessment of psychosocial stability is also important because it offers an opportunity to enhance rather than simply prohibit the donation process. For example, depression can be treated and counseling provided for individuals with substance abuse or marital problems.

Factors that need to be taken into consideration in the psychosocial evaluation of the potential donor include, but are not limited to, ambivalence, guilt, depression, substance abuse, and vulnerability to coercion; the extent to which the decision to donate is consistent with the potential donor's values, including religious beliefs and sense of charity and community; the nature of the relationship between the donor and the recipient; the potential benefits to the donor; the potential medical risks and urgency of the donation; and the potential economic risks associated with donation.

In addition, the psychosocial evaluation can address a variety of other issues, including the ability of the potential donor and family to cope effectively with stresses associated with transplantation (before and after donation), the temporary change (limitations) in the donor's role within a family, the necessity of making alternative arrangements for child care when the donor is the primary care provider, outside assistance required when the transplant is between spouses, the interaction with the donor's employer, financial hardships imposed on the donor and family as a result of the donation (including lost wages, out-of-pocket travel, inability to obtain sick leave, and lack of job security), and the ability of the donor to subsequently obtain life insurance without additional cost. For example, with regard to obtaining insurance, a survey of health insurance companies conducted by Spital and Kokmen found that the majority of health care organizations did not consider healthy kidney donors to be at increased risk for medical problems and would not raise their premiums. To guarantee that a factual basis supports this contention of future insurability, more relevant prospective data are needed that would include live organ donation of the lung, liver, intestine, and pancreas. Since the Spital and Kokmen report, some of the conference participants have been told by potential donors that their life insurance options would be limited if they became an organ donor. In such cases, it may be necessary for transplant centers to inform the insurance carrier of existing data documenting that the patient is not at increased risk of death because of donation. Some organizations are attempting to offer insurance options specific to live organ donors (ie, life, health, and disability insurance).

In summary, psychosocial evaluation offers an opportunity not merely to veto donation, but to intervene proactively to enhance both the donor's decision to donate and the actual donation experience of all involved parties.

**Competence.** Psychosocial evaluation also offers an opportunity to evaluate the competence of the donor to give informed consent for donation. Discovery of psychosocial problems, including psychiatric illness, should not automatically exclude persons who wish to donate. Rather, such findings signal the need for more intense evaluation, discussion, and possible intervention to optimize donation.

**Coercion.** Psychosocial evaluation also offers an opportunity to evaluate and discuss the possibility of coercion of the potential donor. Although it is possible that some financial incentive for donation may be intentionally hidden from the psychosocial evaluator, the stated altruistic motive of the donor should be ascertained and documented. Because direct monetary compensation for live organ donation is currently illegal, if the medical team becomes aware that such a transaction has occurred or is contemplated, it provides grounds for terminating the evaluation.

A possible subservient relationship between potential donor and recipient (eg, employer and employee) may place the potential donor in a vulnerable position because, as an employee, he or she may fear loss of employment if declining to donate. This kind of imbalance should be carefully discussed with the potential donor and taken into consideration by the team in making their final decision about approval. As discussed earlier, the evaluation may serve as an opportunity to help the potential donor grace-
fully withdraw from an uncomfortable situation.

The psychosocial evaluation should be performed by a trained mental health professional (i.e., clinical social worker, psychologist, psychiatrist, or psychiatric nurse) experienced in transplantation. However, the potential conflict of interest between a commitment to the recipient and the interest of the donor should be recognized when considering who performs the evaluation. The psychosocial evaluator should be a professional not involved in the care of the recipient.

For a potential donor undergoing mental health treatment, the mental health professional caring for this patient should contribute to the evaluative process. However, the final responsibility for determining psychosocial acceptability rests with the institution performing the transplant.

Further study and examination are necessary so that incomplete data may be strengthened and recommendations revised accordingly. Particular study should examine the psychosocial evaluation process across transplant programs, psychosocial characteristics that may influence or predict donor outcomes, motivational factors influencing the decision to donate, and potential financial disincentives.

Such comprehensive examination would also allow for a comparison of responses between various donor sources (i.e., relationship between donor and recipient), as well as the organ type donated.

**LIVE ORGAN DONOR SOURCE**

Whereas live organ donation was once restricted to those with a genetic link to the recipient, improvements in recipient immunosuppression have expanded the potential live donor pool to unrelated individuals who have an emotional relationship to the recipient and to donors who were strangers to their recipients before transplantation. However, a stranger source of a live donation is currently being entertained exclusively for renal transplantation. Furthermore, paired live donor exchange programs are also being considered only as an option for renal transplant recipients whose willing donors are unable to provide a kidney because of a biological obstacle such as blood type incompatibility.

**Live-Donor Kidney Donation by Paired Exchange**

The exchange of living donor kidneys between pairs of individuals with incompatible ABO blood types (and lymphocyte crossmatch) was considered by conference participants to be ethically acceptable. Such exchanges were not considered to be a form of commerce as suggested by some who are opposed to this approach. The clinical situation arises, for example, when a donor with blood type A, B, or AB is incompatibly paired with a recipient who has a B, A, or O blood type. In reality, the opportunity for paired exchange would mainly occur between A and B blood type donor-recipient pairs. If the recipient is an O blood type, a blood type O-incompatible donor is unlikely to be available for a paired exchange (unless T-cell crossmatch incompatible), because the O blood type is universal and thus, by definition, a donor with blood type O could not be part of an incompatible pair.

The location of the donor procedures and the potential meeting of the donor-recipient pairs remain at the discretion of both the donor-recipient pairs and the transplant centers. Potential recipients should be given full disclosure of the donors' medical characteristics as they pertain to quality of the donor organs. To accomplish a paired living donor exchange, conference participants suggested that the donor operative procedures be performed simultaneously, even if at different medical facilities, to avoid the hazard of 1 donor declining after the other donor procedure has been performed. Although it is medically possible to transport a living donor organ some distance from the donor to the recipient hospital, 1 benefit of live organ donation is avoiding preservation ischemia and thus, ideally, the donor procedure should be performed in an operating room adjacent to the recipient.

**List-Paired Exchange of Kidneys**

An alternative proposal presented to the conference described a list-paired exchange in which the incompatible living donor would provide an allograft to a patient on the cadaver waiting list in exchange for the cadaver donor pool providing a priority allograft (i.e., ABO compatible) to the donor's incompatible recipient. This approach yields an additional donor source for patients awaiting cadaver organs and because every paired exchange transplant removes a patient from the waiting list, it precludes the incompatible recipient from having to go on the waiting list. Thus, it also increases access to organs for the remaining transplant candidates.

Nevertheless, for those waiting for an O blood type cadaver organ, this approach was considered by conference participants to be disadvantageous for 2 reasons: it assigns a first-refusal priority to the original incompatible recipient for the next available O blood type pool allograft, and it reduces the number of O blood type kidneys available to those who have no opportunity for live donation. Therefore, the donor source work group urged appropriate disclosure of such a pilot plan to individuals on the local cadaver organ waiting list (perhaps including a survey of their approval) before implementing list-paired exchanges widely.

As an alternative, a separate list could be created that identifies living donor-recipient incompatible pairs to accomplish the exchange. This approach avoids the problem of granting increased priority to recipients in incompatible pairs. However, as noted above, it mainly would be restricted to A and B blood type recipients, and it would not resolve the shortage of O blood type allografts available from the cadaver pool.

Finally, an option that could expand the use of incompatible donors for recipients with O blood type would be to offer nondirected living donors (indi-
viduals donating to unknown recipients) of the O blood type the opportunity to donate to the O blood type— incompatible recipient who provides the list with a living donor with A, B, or AB blood type. Such a pool could be set up regionally so that donors with O blood type would give to recipients on a regional list rather than a single center’s list of established ABO blood type— incompatible pairs. The allocation of the O blood type—donor kidney would be based on the next available and medically suitable patient with O blood type on the list within the region, as determined by 0-mm HLA (if identified) or time waiting. This would create a system of equitable allocation while also precluding the need for donors with O blood type to travel to distant centers. Any algorithm seeking to employ list—paired exchanges should be first applied within a limited area as a pilot study, under United Network for Organ Sharing surveillance, with prospective monitoring of both beneficial and adverse consequences.

Nondirected or Stranger Donation
A nondirected potential living donor (also referred to as a “Good Samaritan” donor) is an individual who wishes to donate an organ to a candidate unknown to the potential donor. In contrast, directed donation, the traditional process, involves an individual who donates an organ to an identified recipient.

The criteria for ethical acceptability for nondirected live donor organ donation were considered by conference participants to be the same as those applied to directed donation, with careful attention to the psychosocial evaluation. The medical risks of living kidney donation are less than those observed for a living liver or lung organ donor. Thus, the medical and psychosocial suitability of a person to be a nondirected or Good Samaritan donor must be assessed on a case—by—case basis.

The recipient should be selected by application of standard waiting list allocation criteria. The transplant team should also ensure that the recipient feels comfortable accepting the nondirected organ under the specified circumstances. The identities of the donor and recipient should be protected in much the same fashion as is currently done with cadaver transplantation: anonymity should be the rule unless the donor and recipient mutually agree to make contact by letter, telephone, or face—to—face meeting. Some transplant centers restrict such meetings until after the transplant is performed to avoid potential discrimination in the recipient selection process. Whether or not a volunteer donor should be allowed to select the recipient or a class or subgroup to which potential recipients are limited remained controversial among the conference participants. Those who endorsed a policy of “no strings” donation to the pool of waiting recipients did so for the following reason. If a volunteer donor makes their donation contingent on selecting the recipient, it could present an ethical obstacle for the transplant team. The transplant team is otherwise obligated to distribute organs by an objective plan that fosters equity, irrespective of a social class or group to which potential recipients would be unequally limited.

Donating a Second Organ
The conference participants considered it ethically acceptable for a person to donate more than 1 organ simultaneously or serially (eg, the left lobe of a liver and a kidney) if the medical and psychosocial requirements for each organ donation were fulfilled. Obviously the risks to the donor could be increased by a simultaneous donation, so sound judgment is necessary to maintain the medical dictum of first do no harm.

A potential donor may wish to donate a solitary kidney (having donated a kidney previously), while realizing that such a donation would render that individual anephric. The donation from a person who has only 1 kidney was considered unacceptable by most conference participants because physicians should not perform a procedure that knowingly sacrifices one person’s health (resulting in the necessity of long—term dialysis) for another’s.

Minors as Live Organ Donors
Although minors (individuals younger than 18 years) have successfully donated kidneys to family members in rare instances, using a minor as a live donor remains controversial and requires careful donor consideration. There are several concerns about allowing minors to act as live kidney donors. Organ donation by minors strains the concept of voluntarism and the ability to provide valid consent, presents a clear conflict of interest for parents when siblings are involved, and it highlights the inadequacy of our knowledge regarding the minor’s lifetime with a solitary kidney. In reality, the minor provides assent for donation, and the legal guardian provides the consent. Thus, the conference participants were generally opposed to live organ donation from a minor.

However, exceptional circumstances that would permit the ethical use of a minor as a live donor were established by the conference attendees (Table 2).

**FINANCIAL CONSIDERATIONS IN LIVE ORGAN DONATION**

Living organ donors should not personally bear any costs associated with donation. In addition, guidelines should be established that are similar to those for short—term disability to defray lost wages. Nevertheless, direct financial
compensation for an organ from a living donor remains controversial and illegal in the United States. The current position of The Transplantation Society, the international organization, should be noted: "Organs and tissues should be freely given without commercial consideration or commercial profit."

The reason that direct monetary compensation might be considered for live organ donation is to provide a stimulus for increasing the number of organs available for transplantation. Although it may be plausible to accomplish this objective by compensation, there was no information available describing such efforts, nor were data available to dispute or conclude that financial compensation will significantly expand the living donor pool.

Those participants who were opposed to payment for organs based their objection mainly on the fear of exploitation of the poor, the risk of donors withholding medical information that could result in the transmission of infectious disease, and the aversion to human organs being considered commodities. Those who advocated payment for organs cited the autonomous rights of individuals as the foremost consideration, and they supported the development of regulatory agencies that would oversee organ sales.

**LIVE ORGAN DONOR REGISTRY**

The conference endorsed the development of a living donor registry that would collect demographic, clinical, and outcome information on all living organ donors. The rationale for the development of such a registry includes concern for donor well-being, limitations of current knowledge regarding the long-term consequences of donation, the potential to evaluate the impact of changes in criteria for donor eligibility on the outcome of donors, and the need within the transplant community to develop mechanisms to provide for quality assurance assessments.

There was broad support among conference participants for the initiation of a steering committee to oversee the development of this registry. Specifics of the registry proposal would be referred to this committee. To optimize data collection, it was recommended that participation in a registry be mandatory so that data collection can be tailored to the needs of the contributing disciplines, and that participants be compensated. Linkage to existing registries including the US Scientific Registry of Transplant Recipients, the Organ Procurement Transplant Network, the US Renal Data System, and organ-specific donor registries that are currently operated or being developed by transplant- and organ-specific societies would be critical to donor registry success. It also was recommended that a living donor registry should augment, rather than supplant, preexisting organ-specific donor registries, include both medical and psychosocial follow-up, and be committed to providing the transplant community with ready access to data. Although funding from interested societies, foundations, and industry was considered to be acceptable, pursuit of governmental financial support similar to those that have provided long-term stable funding to the US Scientific Registry of Transplant Recipients, Organ Procurement Transplant Network, and US Renal Data System was thought to be preferable.

**THE FINAL DECISION FOR LIVE ORGAN DONATION**

The transplant team, donor advocate, and the potential donor and recipient pair are the responsible parties who should determine if the benefits of the planned donation outweigh the risks.

The risks of a complication to the live kidney donor are not the same as the risks for being a live donor of a liver, lung, intestine, or pancreas. These highly specialized donor procedures should only be performed at centers with the necessary infrastructure resources and only by surgeons with appropriate expertise.

There must be agreement among the potential donor, recipient, and physicians for living organ transplantation to proceed. Transplant physicians must have decision-making autonomy that prevents undue pressure on the medical team to perform a procedure that they do not believe is medically indicated. While the autonomy of the potential donor must be respected, so also must the medical decision making of the transplant team be respected. Therefore, the team should never feel obliged to perform a transplant from a living donor if it believes that it will do more harm than good.

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JAMA, December 13, 2000—Vol 284, No 22 2925
CONSENSUS STATEMENT ON LIVE ORGAN DONORS

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Session on Living Donor Intestine Transplantation was conducted by Johnathan P. Fryer, MD, Northwestern University Medical School.

Session on Living Donor Pancreas Transplantation was conducted by Robert J. Corry, MD (Chair), University of Pittsburgh Medical Center; David Sutherland, MD (Co-Chair), University of Minnesota; and Mitchell L. Henry, MD (Co-Chair), Ohio State University Hospital.


Funding/Support: This conference was supported by a grant from the National Kidney Foundation, American Society of Transplantation, American Society of Transplant Surgeons, American Society of Nephrology, and United Resource Networks.

Disclaimer: This consensus statement reflects the views of the authors and not necessarily those of the United Network for Organ Sharing and the National Institutes of Health.

Acknowledgment: We thank Jennifer G. Martin and Gigi Politoski of the National Kidney Foundation for administrative support.

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2926 JAMA, December 13, 2000—Vol 284, No. 22