

OPTN/UNOS Living Donor Committee

Proposal to Establish and Clarify Policy Requirements for Therapeutic Organ Donation

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Proposal to Establish and Clarify Policy Requirements for Therapeutic Organ Donation

Executive Summary

This policy proposal would define a therapeutic organ donor and clarify that only a subset of existing policies are necessary to protect the therapeutic donor and organ recipient, while avoiding potential impediments that could result in the therapeutic donor's native organ not being transplanted.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Living Donor Committee is interested to receive specific feedback on the phrase "therapeutic organ donor." The Committee coined the term "therapeutic organ donor" to describe an individual who has an organ removed, as a component of their treatment for a medical problem, and their removed organ is suitable for transplant into a transplant candidate. Domino donors are one type of therapeutic organ donor who have their organs removed so that they can receive a replacement organ. The term "therapeutic organ donor" may not be found in the medical literature and is not currently defined or used in OPTN policy.

Members are required to submit a Living Donor Registration form for all living donors. The Living Donor Registration form includes ten categories for donor type including paired donation, non-directed donation and domino donation. Since therapeutic donor is a new proposed category of living donor it is not one of the categories on the current form. Under the current system, a therapeutic donor could be reported as a non-directed donor. The Committee is interested to receive specific feedback regarding if the current reporting system should be modified to allow specific reporting on therapeutic donors.

Proposal to Establish and Clarify Policy Requirements for Therapeutic Organ Donation

Affected Policies: 1.2 (Definitions), 6.5.F (Allocation of Domino Donor Hearts), 14.1.A (Living Donor Psychosocial Evaluation Requirements); 14.2.A ILDA Requirements for Living Donor Recovery Hospitals; 14.3 (Informed Consent Requirements); 14.4.B (Living Donor Medical Evaluation Requirements); 14.6.B (Placement of Non-directed Living Donor Kidneys); 14.6.C (Transplant Hospital Acceptance of Living Donor Organs); 14.9 (Requirements for Therapeutic Living Donation; 14.9.A (Informed Consent Requirements for Therapeutic Donors); 14.9.B (Psychosocial and Medical Evaluation Requirements for Therapeutic Donation); and 14.9.C (Recovery of Therapeutic Donor Organs); 14.6.D (Acceptance of Therapeutic Donor Organs); 14.9.E (Reporting and Data Submission Requirements for Therapeutic Donors).

Sponsoring Committee: Living Donor Committee

Public Comment Period: August 14 – October 14

What problem will this proposal solve?

This proposal would define a therapeutic organ donor as a living donor who has his or her organ removed as treatment for a medical problem and whose organ is suitable for transplant into another individual. Therapeutic donors may or may not receive a replacement organ. Domino donors are one type of therapeutic organ donors who have their organ removed so that they can receive a replacement organ. Most current living donor policies are not appropriate or applicable for a therapeutic organ donor. The proposed policy modification will limit the requirements for these donors to a subset of existing policies for evaluations, disclosures and medical testing necessary to protect the potential organ recipient, while avoiding potential impediments or complications that could result in the therapeutic donor's native organ not being transplanted.

Why should you support this proposal?

The proposal would improve the care of therapeutic donors, protect therapeutic donor organ recipients, and could increase the number of organs available for transplant. Most current living donor policies are not appropriate or applicable for a therapeutic organ donor. Under the proposal, recovery centers would only need to meet a subset of existing policies or establish and follow center-specific protocols to address the unique circumstances of therapeutic donors.

How was this proposal developed?

The Living Donor Committee (the Committee) coined the term “therapeutic organ donor” to describe an individual who has an organ removed, as a component of their treatment for a medical problem, and their removed organ is suitable for transplant into a transplant candidate. Potential therapeutic donors may have conditions such as:

- renal cell carcinoma (with the tumor removed after recovery and before transplant);
- ureteral trauma (transected ureter)
- maple syrup urine disease (most common type of domino liver donor)

Domino donors are one type of therapeutic donor. A domino donor is an individual undergoing organ transplantation whose native organ is suitable for transplant to another transplant candidate. Though rare, an example of a domino donor is a patient with lung disease who donates their heart to a heart transplant candidate in the process of receiving their own heart-lung transplant. The term domino donor is found in current OPTN policy but it is not specifically defined.

The term “therapeutic organ donor” may not be found in the medical literature and it is not currently defined or used in OPTN policy. Under this proposal, therapeutic donors are considered living donors and their status must be reported to the OPTN only until they are discharged from the hospital following organ donation or through six weeks post-donation if they have not been discharged.

In 2011, a living liver donor recovery hospital contacted UNOS with concerns that the reporting requirements applied to domino donors were burdensome and inapplicable, and this hospital requested that the reporting requirements be reconsidered. Specifically, the hospital questioned if it was required to submit living donor forms (Living Donor Registration [LDR], Living Donor Feedback, and Living Donor Follow-up [LDF]) as well as transplant candidate and recipient forms (Transplant Candidate Registration [TCR], Transplant Recipient Registration [TRR], and Transplant Recipient Feedback [TRF]) for domino donors. This hospital also commented that current policy does not address the assessment of domino donors or placement of domino donor organs.

As it considered these issues, the Committee understood that domino donors are living donors but are also very different from “traditional” living donors. Domino donors are also transplant candidates and ultimately transplant recipients. Domino donors are seeking treatment for a medical problem, and this treatment is to have their organ removed and to receive an organ transplant. For domino donors, the transplant of their native organ to a transplant candidate may be an alternative or option, which they may or may not have considered.

The Committee understood that many of the informed consent, medical evaluation, and follow-up requirements for the typical living organ donor should not be required because they are not applicable or useful for domino donors. The Committee appreciated that any donation-related informed consent, medical evaluation or follow-up requirements for domino donors should be kept to a minimum to avoid potential impediments or complications that could result in the domino donor’s native organ not being available for transplant. The Committee determined that policy requirements for domino donation should be limited to those elements that would be necessary to help reduce or prevent potential disease transmission to the organ recipient.

During the early development of this proposal the Committee sent draft domino donor policy language to the Liver and Intestinal, Thoracic, Operations and Safety, and the Membership and Professional Standards Committees (MPSC) for review. The Liver and Intestinal, Thoracic, and MPSC provided responses which the Committee considered as it prepared a policy proposal for public comment.

In October 2014, the Committee received a request on behalf of the MPSC to clarify whether liver transplant programs needed to have an approved living donor liver component in order to perform domino liver recoveries and transplants. The MPSC Chair had received questions from several liver transplant programs without approved living donor components asking whether they could perform domino liver recoveries and transplants, and they were informed that current policy prohibited them from doing so. As a result of this request, the Committee decided to delay public comment on this proposal so the MPSC could review and discuss the Committee’s proposed policy changes. In December 2014, a representative of the Committee presented draft policy language to the MPSC that included a clarification that liver transplant programs would not be required to have an approved living donor component in order to perform domino liver recoveries and transplants. The MPSC was supportive of the clarification and suggested that the language addressing this clarification be clearly written in order to avoid future confusion or conflicting interpretations of policy.

In June 2014, the OPTN/UNOS Board approved new policies that established minimum thresholds for living liver donor follow-up. In November 2014, the Board approved new requirements for living liver donor informed consent and medical evaluation. To address questions regarding whether these policies apply to domino liver donors, the policies include a stipulation that they do not apply to “any individual who is undergoing transplant whose native organ is suitable for transplant to another transplant candidate,” to explicitly exclude domino donors until such time that policies addressing domino donors could be implemented.

The Committee met in April 2015, and reviewed draft policy language addressing domino donors. The draft policy language reflected the Committee’s response to the MPSC regarding membership requirements. During this meeting, the Committee was informed that there are no living donor program approvals. A transplant program may have a living donor component and if so that component applies to the recovery of living donor organs. Approved transplant programs are authorized to transplant both deceased and living donor organs, and are referred to as a “designated transplant program” throughout policy and bylaws.

During this meeting, a Committee member reported that her hospital recently evaluated a patient for the elective removal of her kidney as treatment for groin pain syndrome. This member reported that the hospital had difficulty determining and understanding which OPTN living donor informed consent and medical evaluation policies would or would not apply for this patient and questioned if the domino donor policy proposal could be expanded to include patients who have an organ removed electively that is then transplanted to a transplant candidate. Several other committee members reported similar problems had occurred at their hospitals, and the Committee recommended revising the policy proposal to include all categories of therapeutic living donors (which would include domino donors). The Committee coined the term, “therapeutic donor” to describe an individual who has an organ removed as a component of their treatment for a medical problem, and their removed organ is suitable for transplant into a transplant candidate.

Under this proposal, data submission for therapeutic donors would be limited to two forms:

- 1) Living Donor Feedback form which would be required pre-operatively
- 2) Living Donor Registration (LDR) form which is due when they are discharged from the hospital post-donation or at six weeks post-donation if they have not been discharged.

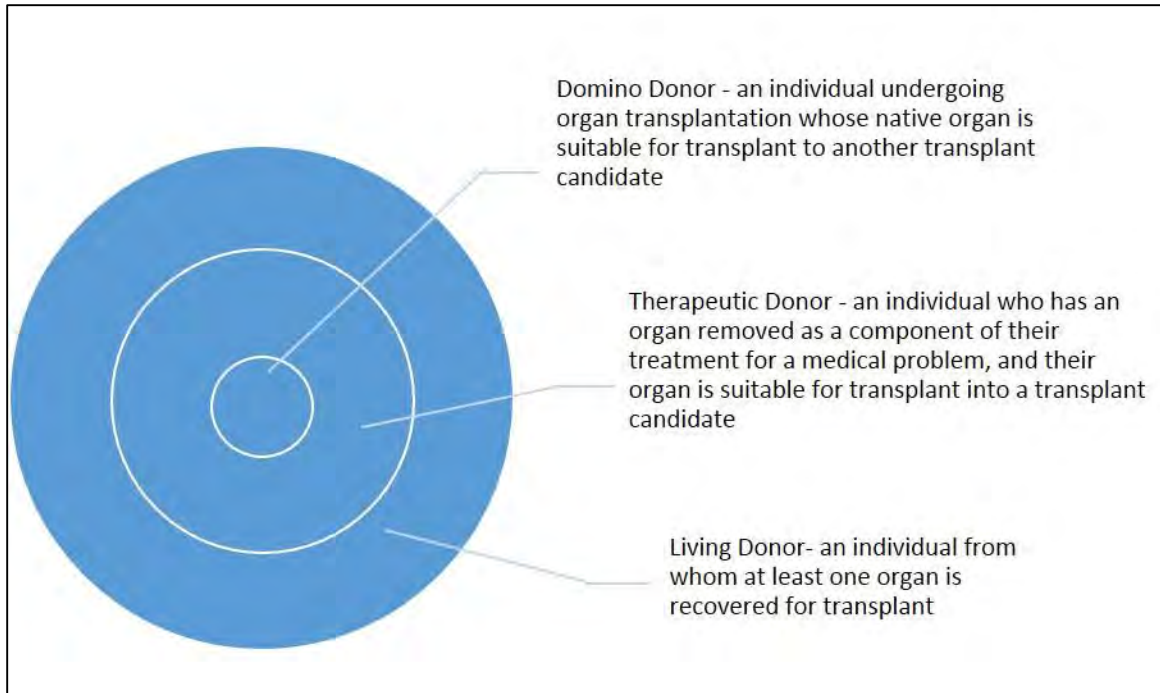
As currently proposed, therapeutic donors would not be subject to follow-up reporting at 6, 12 and 24 months. Domino donors, the subset of therapeutic donors whose native organ is removed because they are receiving a transplant, receive post-transplant follow-up as a transplant recipient and would be subject to transplant recipient follow-up reporting.

In regards to donation-related informed consent and medical evaluation requirements, the Committee favored limiting policy requirements to those policies necessary to prevent potential coercion, valuable consideration and potential disease transmission. Most existing requirements for the informed consent, psychosocial and medical evaluation, and follow-up of living donor would not apply to therapeutic donors.

UNOS staff subsequently modified the draft policy language so it could encompass all categories of therapeutic living donors and clarify membership requirements. As proposed:

- transplant hospitals can recover therapeutic donor organs if they have a designated transplant program for that organ type (living donor approval not required)
- transplant hospitals can transplant therapeutic donor organs that were recovered at a hospital with a designated transplant program for that organ type (living donor approval not required)

The following diagrams and tables compare and contrast living donors, therapeutic donors and domino donors.



Donor Characteristics

	Living Donors	Therapeutic Donors	Domino Donors
Currently defined in OPTN Policy	Yes	No	No
Currently referenced in OPTN Policy	Yes	No	Yes
Has an organ removed as a component of their treatment for a medical problem	No	Yes	Yes
Donates an organ	Yes	Yes	Yes
Receives an organ transplant	No	No	Yes

Current and Proposed Policy Requirements

	Living Donors	Therapeutic Donors (includes Domino Donors)
Provide an Independent Donor Advocate	Yes, all requirements in Policy 14.2	No
Informed Consent	Yes, all requirements in Policy 14.3	Yes, but as proposed the requirements would be limited to only four specific elements from Policy 14.3
Psychosocial Evaluation	Yes, all requirements in Policy 14.1	Yes, but as proposed the requirements would be limited to one element from Policy 14.1
Medical Evaluation	Yes, all requirements in Policy 14.4	Yes, but as proposed the requirements would be limited to three elements from Policy 14.4
Reporting	Yes, all living donor requirements in Policy 18.1	Yes, but limited to submitting the Living Donor Feedback (LDF) and Living Donor Registration (LDR) forms
Identification of Transmissible Disease	Yes, all requirements in Policy 15.4	Yes, but limited to Policy 15.4.A

In June 2015, a subcommittee of the full Committee reviewed the revised draft policy language and supported sending the proposal for public comment. Later in June 2015, the Committee reviewed and supported (voted by e-mail) sending the proposal for public comment.

Alternatives Considered

The Committee considered several options for naming this type of donor and determined that “therapeutic donor” was the best option. The term therapeutic organ donor may not be found in the medical literature and it is not found in current OPTN policy.

For all therapeutic donors, the Committee recommended that the organ recovery hospital should be required to submit the Living Donor Feedback and the Living Donor Registration (LDR) forms. These forms are used to match the organ donor with the recipient and to remove the recipient from the waiting list. Following submission of the LDR form the hospital would be required to contact the OPTN contractor to have future living donor feedback forms discontinued (future Living Donor Follow-up (LDF) forms would not generate at 6 months, 1-year and 2-years post donation). The Committee questioned if this could be an automated process so the hospital would not need to contact the OPTN. The proposal does not include a provision for an automated process because it would require programming which would be low priority due to the small number of donors impacted and due to the existing IT backlog.

Programs without an active living kidney donor program are able to create a Living Donor Registration form and Living Donor Feedback form in UNetSM.

The Committee considered but did not propose additional data collection on therapeutic donors and therapeutic donor organ recipients in this proposal.

As currently proposed, a recovery hospital could develop and follow a protocol which could allow the recovery of an organ for transplant from a therapeutic donor that would be prohibited from recovery and transplant (based on stricter OPTN policies) from a living donor.

How well does this proposal address the problem statement?

The proposed policy would only affect a small number of donors and transplant recipients each year.

Since 2006, no domino donor heart transplants have been reported to the OPTN. Eight to twelve domino liver donor transplants were performed in each of the past 4 years.

Year	Number of Domino Liver Donors	Number of Domino Heart Donors
2014	12	0
2013	8	0
2012	10	0
2011	11	0

The OPTN does not currently collect data on other types of therapeutic organ donors (i.e. patients treated for renal cell carcinoma or ureteral trauma), so the volume of some types of therapeutic donation is not known.

Which populations are impacted by this proposal?

The proposal would affect a small number of therapeutic organ donors and transplant candidates.

How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* New minimum requirements for the evaluation of therapeutic donors could lead to an increase in the number of transplant.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* The proposal would establish minimum requirements for the informed consent, psychosocial and medical evaluation and follow-up of therapeutic donors, which promotes the safety of both the donor and recipient.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Living Donor Committee will request yearly updates on the number of therapeutic donations to assess whether the new policy has had an adverse effect on the number of these donations. Current OPTN data collection identifies domino liver donors as therapeutic donors, but kidney donors who donate as therapeutic donors may be recorded in the OPTN data simply as non-directed donors. The Committee

could ask the UNOS Help Desk to notify Committee support staff whenever they receive a request to discontinue follow-up forms for a therapeutic donor to better determine the frequency of this type of organ donation.

How will the OPTN implement this proposal?

This proposal is expected to affect few transplant hospitals, living donors and transplant candidates. The proposal should not require communication or education beyond the typical actions. This proposal will not require programming in UNetSM.

How will members implement this proposal?

Hospitals will need to follow new informed consent, medical evaluation and data submission requirements specific to therapeutic donors.

Will this proposal require members to submit additional data?

This proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

Specific monitoring of the proposed language will not be incorporated into the current routine site survey of OPTN members because of the small number of therapeutic donors per year and the inability to specifically differentiate therapeutic donors from other non-directed donors using OPTN data. However, members are expected to comply with the requirements in the proposed language and are required to provide documentation as requested for OPTN review.

Policy Language

Proposed new language is underlined and (example) and language that is proposed for removal is struck through (~~example~~).

The symbol [...] indicates that there are no other changes to that policy section.

1 **Policy 1.2 (Definitions)**

2 **Therapeutic organ donor**

3 An individual who has an organ removed as a component of medical treatment, and who may or may not
4 receive a replacement organ. The organ that was removed can be transplanted into another person.
5 Domino heart and liver donors are considered therapeutic organ donors.

6 **~~6.5.F Allocation of Domino Donor Hearts~~**

7 ~~If a transplant program recovers the native heart of a heart-lung recipient, then the transplant program~~
8 ~~that recovers this heart may transplant it into a second candidate registered at the same transplant~~
9 ~~program.~~

10 ~~If, however, the transplant program does not transplant the recovered, native heart into one of its~~
11 ~~candidates, then the heart will be allocated according to *Policy 6.5: Heart Allocation*~~

12 ~~*Classifications and Rankings.* For the purposes of allocating these hearts, the DSA of allocation is the~~
13 ~~DSA where the native heart of the heart-lung transplant recipient is recovered~~

14 **14.1 Psychosocial Evaluation Requirements for Living Donors**

15 **14.1.A Living Donor Psychosocial Evaluation Requirements**

16 ~~Living donor psychosocial evaluation requirements do not apply to any individual who is undergoing~~
17 ~~transplant whose native organ is suitable for transplant to another transplant candidate.~~

18 [...]

19 **14.2 Independent Living Donor Advocate (ILDA) Requirements**

20 **14.2.A ILDA Requirements for Living Donor Recovery Hospitals**

21 ~~Living donor ILDA requirements do not apply to any individual who is undergoing transplant whose native~~
22 ~~organ is suitable for transplant to another transplant candidate.~~

23 [...]

24 **14.3 Informed Consent Requirements**

25 ~~Living donor informed consent requirements do not apply to any individual who is undergoing transplant~~
26 ~~whose native organ is suitable for transplant to another transplant candidate.~~

27 [...]

28 **14.4.B Living Donor Medical Evaluation Requirements**

29 ~~Living donor medical evaluation requirements do not apply to any individual who is undergoing transplant~~
30 ~~whose native organ is suitable for transplant to another transplant candidate.~~

31 [...]

32 **14.6.B Placement of Non-directed Living Donor Kidneys Organs**

33 Prior to determining the placement of a non-directed living donor kidney organ, including non-directed
 34 organs from therapeutic organ donors, the recovery hospital must obtain the match run of its waiting
 35 list candidates from its local OPO or the Organ Center. When a non-directed living donor kidney
 36 organ is allocated placed, the recovery hospital must document how the organ is allocated placed and
 37 the rationale for placement allocation.

38 **14.6.C Transplant Hospital Acceptance of Living Donor Organs**

39
 40 ~~Transplant hospitals that perform living donor transplants must only accept and transplant living donor~~
 41 ~~organs recovered at OPTN member recovery hospitals that are approved to perform living donor recovery~~
 42 ~~for that organ type.~~

43
 44 ~~If the OPTN does not have approval criteria for a living donor recovery hospital for a particular organ type,~~
 45 ~~then that perform living donor transplants must only accept and transplant living donor organs recovered~~
 46 ~~at OPTN member transplant hospitals with current designated transplant program for that organ type.~~

47
 48 A transplant hospital must only accept and transplant living donors organs according to Table 14-10
 49 below.

50
 51 **Table 14-10: Transplant Hospital Requirements for Accepting and Transplanting Living Donor Organs**

<u>If this type of living donor organ is being recovered:</u>	<u>Then the recovery hospital must:</u>
<u>Kidney</u>	<u>Meet the requirements according to the OPTN Bylaws E.5: Kidney Transplant Program that Perform Living Donor Recovery</u>
<u>Liver</u>	<u>Meet the requirements according to the OPTN Bylaws F.6: Liver Transplant Program that Perform Living Donor Recovery</u>
<u>Other organ types excluding kidney or liver</u>	<u>Have current designated transplant program approval for that organ type</u>

53
 54 **14.9 Requirements for Therapeutic Donors**

55 Although therapeutic donors are considered living donors, the requirements in *Policy 14: Living Donation*
 56 are limited only to Policies 14.9 A through 14.9 E below for therapeutic donors.

57 **14.9.A Informed Consent Requirements for Therapeutic Donors**

58 Recovery hospitals must provide *all* of the following disclosures to therapeutic donors:

- 59 1. The recovery hospital will take all reasonable precautions to provide confidentiality for the donor
 60 and recipient.
 61
 62 2. It is a federal crime for any person to knowingly acquire, obtain, or otherwise transfer any human
 63 organ for anything of value including, but not limited to, cash, property, and vacations.
 64
 65 3. Health information obtained during the evaluation for donation is subject to the same regulations
 66 as all health records and could reveal conditions that must be reported to local, state, or federal
 67 public health authorities.
 68

69 4. Any new information discovered during the therapeutic donor's first two years of post-donation
70 care that indicates risk of potential transmission of infectious disease or malignancy to the
71 recipient of the therapeutic donor's native organ:

- 72
- 73 a) May need to be reported to local, state, or federal public health authorities
- 74 b) Will be disclosed to the recipient's transplant hospital
- 75 c) Will be reported through the OPTN Improving Patient Safety Portal
- 76

77 Documentation of the informed consent must be maintained in the donor medical record.

78

79 **14.9.B Psychosocial and Medical Evaluation Requirements for Therapeutic Donors**

80 Recovery hospitals must evaluate therapeutic donors according to all of the following requirements:

- 81 1. Perform an evaluation for the presence of behaviors that may increase risk for disease
82 transmission as defined by the U.S. Public Health Service (PHS) Guideline
- 83
- 84 2. Screen the therapeutic donor for all of the following according to Policy 14.4: Medical Evaluation
85 Requirements for Living Donors, Table 14-6: Requirements for Living Donor Medical Evaluations:
 - 86 a) Transmissible diseases screening
 - 87 b) Endemic transmissible diseases
 - 88 c) Cancer screening
 - 89
- 90 3. Develop and comply with written protocols for the therapeutic donor exclusion criteria considering
91 incorporating as appropriate the elements of Table 14-9: Living Donor Exclusion Criteria
- 92
- 93 4. Register and verify the blood type of the therapeutic donor according to Policy 14.5: Registration
94 and Blood Type Verification of Living Donors before Donation

95 Documentation of the psychosocial and medical evaluation must be maintained in the donor medical
96 record.

97 **14.9.C Recovery of Therapeutic Donor Organs**

98

99 Transplant hospitals can recover therapeutic donor organs if the hospital has current designated
100 transplant program approval for that organ type.

101

102 **14.9.D Acceptance of Therapeutic Donor Organs**

103 Transplant hospitals must only accept therapeutic donor organs recovered at transplant hospitals that
104 have a current designated transplant program approval for that organ type.

105

106

107 **14.9.E Reporting and Data Submission Requirements for Therapeutic Donors**

108 **Table 14-11: Reporting Requirements for Therapeutic Donation**

<u>Recovery hospitals must:</u>	<u>According to:</u>
<u>Report potential and proven disease transmission</u>	<u>Policy 15.4.A: Transplant Program Requirements</u>
<u>Submit the living donor feedback and Living Donor Registration (LDR) forms for the therapeutic donor</u>	<u>Policy 18.1: Data Submission Requirements</u>

109 #