



Part - B

STANDARD OPERATING PROCEDURE (S O P) SUGGESTED BY COMMITTEE AND FORMS

(REPORT AND RECOMMENDATION OF THE COMMITTEE FOR LIVE DONATION ORGAN TRANSPLANT, PGIMER, CHANDIGARH.

This is in compliance to order dated 16.05.2019 passed by the Hon'ble Punjab and Haryana High Court (CWP-15590-2016 and CWP-10247-2016) and the request sent by Director Health & Family Welfare, U.T. Chandigarh vide Endst. No.GH-III/2019/12980 dated 14.06.2019 and instruction forward by the office of Director PGIMER, Chandigarh to the Chairman of the appointed committee. Prof. Arunanshu Behera vide letter No.EKB-003568 dated 18.06.2019 the committee which looked into issue of cadaver donation had been reconvened to consider and deliberate upon the matter and issues of live organ donation.)

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SOP

(This standard operating procedure is in reference to committee recommendations numbers 1-11)

This SOP is in conformity with the intent and spirit of THOA 2011 (amended THOA 1994) and RULES 2014 notified by the government of India. This is an effort to make the process for registration of recipient and donor for live organ transplantation transparent and accountable to monitoring agencies (NOTTO/ROTO) and provide basis for data mining for validation and vetting processes of the data that is being received from the donor, from the recipient, from the transplant center , from the authorization committee and lastly from the treating team/surgeons. NOTTO will monitor the whole data keeping job they have been provided under the Act and Rules.

This committee merely recommends assigning codes and ID numbers which can be added to the existing forms 1-9 for various applications. These codes and IDs will enable data mining to pin point breaches under the law/act at a level where it has happened. The digital process and biometric verification that this committee recommends can easily be affected by NOTTO/ROTO in consultation with NIC (national informatic center) in a process similar to that applied in other verification centers like Aadhar verification centers and PSKs (Passport Sewa kendras), driving licensing issuing authority and similar services.

The codes to recipient and donor are specific and generated by providing AADHAAR or PAN verification through biometrics by the NOTTO/ROTO.

The codes and the IDs that are required for this SOP for the NOTTO for future data mining are as follows:

1. ID code for the donor (12 digits, computer generated) to be provided at the time of registration of donor in NOTTO database with respect to a directed donation

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 e.g.

- A second and and third donor if required later can register for same recipient ID code
2. ID code for the recipient (12 digits, computer generated) to be provided at the time of registration of recipient in NOTTO database with respect to a directed donation/recipient code.
e.g.

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*The provision of unique code is in conformity with THOA provision to protect the identity of the donor and the recipient for data protection in case of tissue and organ donation. This code will help in data mining of records in future.

3. The patient/donor will approach for biometrics with his Aadhar number, PAN number, registered mobile number for authentication and present the authentication certificate to the transplant center concerned and authorization committee concerned for approval of the process of transplantation.
4. For the above process to continue further, the following codes and IDs are to be given for the entities mentioned as below:
 - a. Type of live donor transplant need to be given a code (alphabetic)

Near related	A
Spouse	B
Related	C
Unrelated	D
SWAP	E
Domino	F
Others (transplant between a foreign national in India)	G

- b. Each organ that is to be transplanted needs to be given a code (double digit numerical code)

Heart	01
Lung	02
Liver	03
Kidney	04
Pancreas	05
Intestine	06
Other tissue (specified)	07

*more organs can be coded later

5. Each center will be given a code (4 digit, numerical)

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6. For purpose of data mining and record keeping, a 4 digit (alphanumeric) be given to all authorization committee whether at the level of ROTTO/SOTTO/District/Hospital based.

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7. Registered mobile number of the donor and recipient be entered as additional input into the specific forms of application provided under RULES 2014.
8. The NOTTO/ROTO must keep a database of a designated transplant coordinator who will assist the secretariat of authorization committee. The database must include the same parameters that can be verified with Aadhar number, PAN number, registered mobile number which will enable them to make an entry for data uploading at various steps with a unique password on their registered mobile number which can be used to generate the password through SMS (similar to OTPs) valid for 1 hour. The Aadhar number will be the user ID ; the PAN number will be the password and the OTP in registered mobile number will be the second password for data entry.
9. The NOTTO/ROTO must keep a database of all transplant surgeons. The database must include the same parameters that can be verified with Aadhar number, PAN number, registered mobile number which will enable them to make an entry for data uploading at various steps with a unique password on their registered mobile number which can be used to generate the password through SMS (similar to OTPs) valid for 1 hour. The Aadhar number will be the user ID; the PAN number will be the password and the OTP in registered mobile number will be the second password for data entry.
10. The process of consent by the recipient/donor and authorization process will be carried out after receiving a written report given to the secretariat of authorization committee by the designated transplant coordinator who will carry the step forward and handover approval/rejection to the designated transplant team. There will be no involvement of transplant team In the completion of this process except for care/treatment and investigation that is required under THOA.

The following steps are enumerated in descending order:

Step 1: Donor and recipient provides details as in FORM 1 for registration as donor and recipient in a manner suggested by the committee. The in turn receive donor and recipient code in print format which they will present to their transplant doctor.



Step 2: The transplant doctors will proceed as per clinical need and if he accepts the patient for transplant, he will refer the recipient and the donor to either the secretariat of authorization committee/ internal scrutiny committee (if employed by the hospital to function as a secretariat to authorization committee for verification

and required formalities). The transplant coordinators will assist the patients in this aspect. By effect of THOA rules, all hospitals and centers must employ the services of transplant coordinator.



Step 3: The transplant coordinator will enter the details into NOTTO/ROTTTO registry with all the input that is prescribed in THOA rules 2014 along with scanned documents uploaded against donor ID, recipient ID and their Aadhar number.



Step 4: All the forms that is required to be uploaded must be given in printed format to both recipient and donor.



Step 5: The coordinator will present the donor for psychometric analysis with the following

- a. Identification proof and donor ID number given by NOTTO.
- b. The format of informed consent that need to be given and which has already been explained by treating transplant doctors.

The medical practitioner, as a psychometric analysis will provide a confidential report through the coordinator to the authorization committee for their verification and necessary action.



Step 6: The transplant coordinator along with the following approach the authorization committee

- a. Application from treating doctors.
- b. The required forms as mentioned in THOA rules applicable for live donor transplant.
- c. Independent psychometric analysis report(format given).
- d. A HLA/ genetic matching report If required (as per THOA rules 2014).
- e. Identity verification proofs in original and the biometrics report establishing the identity of the donor.

The coordinator will fix the appointment of patients with the authorization committee at their earliest sitting to get an approval from the authorization committee.



Step 7: The authorization committee will approve/ reject the application providing a reason in case of rejection. The form of the report must bear codes already described above and the donor and recipient IDs. This report of the authorization committee must be uploaded digitally as well as in scanned format against the donor and recipient IDs to the NOTTO by the designated transplant coordinator in a process of access given to him/her (described in point 8 above).



Step 8: The approval report of the authorization committee will be conveyed to the transplant team by the coordinator in a print format to proceed for transplantation.



Step 9: The transplant team will proceed for transplantation with report of authorization committee however if it is brought to their notice any discrepancy in facts presented by the donor or recipient which they come across while discharging their normal duties as a medical practitioner can request a second report from the authorization committee.



Step 10: The transplant team must take a informed consent for the donor and the recipient explaining risks involved, the loss of life or severe morbidity that can arise and explain the legal provisions of punishment under THOA. Having taken a informed consent, the transplant procedure will proceed. The informed consent must also give option to the donor to withdraw his consent before surgery of the recipient and himself at any time before surgery.



Step 11: All donor surgery and recipient surgery information must be uploaded in a scanned format to the NOTTO/ ROTTO within 6 weeks of completion of surgery or discharge of the donor whichever is earlier. In case of donor death, such intimation must be uploaded to the NOTTO/ROTTTO sites within 72 hours in the event of donor death.

SUGGESTED UNIVERSAL CODES/CODING FOR DATA KEEPING AND RETREIVAL OF DATA IN FUTURE

Following coding procedure with keys is being suggested by the committee for effective data mining in future by NOTTO/ROTTTO. The process is simple by adding these keys to the bottom of FORMS 1-9. The committee recommends the honourable high court to seek opinion regarding this format independently either from national informatics centre(NIC) or authorities providing in Passport sewakendras (PSKs).

Donor code

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Recipient code

R													
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Centre code

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Relation code

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Organ code

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Authorization committee code

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[* Donor code is a 12 digit numerical; Recipient code is 12 digit numerical; Centre code is 4 digit numerical; Relation code is alphabetical from A -G (A= near related, B= spouse, C= related, D= unrelated, E= SWAP, F= domino, G= others); Organ code is 2 digit numerical(01= heart, 02= lung, 03=liver, 04= kidney, 05= pancreas, 06= intestine, 07= other tissues); Authorization code is 5 digit alphanumerical]

**PSYCHOLOGICAL EVALUATION OF THE DONOR FOR ORGAN
TRANSPLANT**

LIVE DONOR

(* Must be accompanied by a copy of format of informed consent specific for the organ concerned)

AADHAR NO-*

PAN No -*

Registered Mob No-

Passport No....*

Driving licence No. (or other photo ID)

DONOR Registry No. (proposed from NOTTO)

Recipient registry no. (proposed from NOTTO)

CENTRE ID CODE NO. (proposed from NOTTO)

.....
.....

NAME :.....

S/O or D/O or Wife of

Hospital card No.....

Inpatient

No.....

PHOTO of Donor:

.....

RELATION TO RECIPIENT- Near relative/ spouse/ relative other than
Near relative/Swap Donor/Domino Donor/ Un related donor. *strike out
whatever not applicable.

Reason and motivation of the donor: Altruistic / emotional attachments

**PSYCHOLOGICAL HEALTH ASSESMENT SHEET FOR
LIVE DONOR.**

*All boxes from 1 to 11 are to be ticked () as applicable.

1. Does the patient have any diagnosable psychiatric illness, as per the current nosological system?

yes	no
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2. Substance use history, which the donor has not revealed earlier.

yes	no
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3. Review of prior counselling, medications which the donor has not revealed earlier.

yes	no
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4. Level of education- post graduate/graduate/middle level/primary/none.

Is the donor intelligent to understand his situation as a donor?

yes	no
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5. **Comprehension ability:** Is the person able to comprehend the information provided and take your assessment of his situation correctly?

yes	no
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6. **Expectation from the donation.** Any monetary gain the donor expects from donation which is not permissible under THOA?

yes	no
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7. Does the recipient expect only a successful outcome? Would he still donate out of his commitment to donate even there is risk of unsuccessful outcome in recipient?

yes	no
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8. Does the person understand fully the risks to his personal health when he is donating either part or whole of organ when he is alive?

yes	no
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9. Is the Motivation for donation voluntary?

yes	no
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10. Confirm Relationship with the transplant candidate (recipient) from donor: Relationship as stated in application for confirmed?

yes	no
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11. confirmation of his consent to donate considering his attachment to the recipient, his personal beliefs , his social and religious beliefs. Do you find him suitable as per his personality traits,, current and past history of exposure to stress and coping abilities?

yes	no
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Advice given by Psychological assessment consultant for authorization committee to consider:

A. RE- CHECKING OF DONOR DETAILS REQUIRED?

Not required	Required
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B.RE- EVALUATION PSYCHOMETRY REQUIRED ?

Not required	Required
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C.REFERRED TO AUTHORIZATION COMMITTEE WITH COMMENTS

PROCEED	NOT to proceed
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***cross as X whatever box not applicable from A to C.**

Instruction to Psychologist: (make separate entry in box provided mentioning points being addressed to as mentioned bellow)

- Point 1.** If, yes, what is the level of severity of the illness
If required use validated scales like PHQ-9/BDI to rate the severity of depression, and GAD-7 to rate the level of anxiety
To what likely it is going to interference with organ transplant- will it impair the donor's cooperation with the pre-transplant, immediate transplant and long-term post transplant recommendations and recovery?
- Point 2.** If, yes, what is the level of severity of drug dependence that may have affected his decisions. Use or abuse, dependence, attempts to abstain, lapses, relapses, last intake
- Point 3.** Make a comment if you feel it is going to affect outcome.
- Point 4.** Does the patient require formal assessment of intelligence quotient?incase it is required make entry in box.
- Point 5 .** any specific observation that may hinder a transplant under **THOA** must be recorded in the box.
- Point 6 .** Is there any benefit to self monetarily, he expects from his action?
Is the person *willing to sign a statement attesting that the donor is not providing the organ for monetary gain?*
- Point 7.** what does the person expect with respect to the outcome of the recipient after donation.
- Point 8.** Is the person fully informed of the risks and benefits to the donor, *as demonstrated by the donor's expression of understanding of these risks and benefits?*
Is the person fully informed of the risks, benefit and alternative treatment available to the recipient, *within the constraints of the transplant center's obligation to maintain confidentiality of recipient medical information.*
Explore the prospective donor's awareness of any potential short- and long-term risks for surgical complications and health outcomes, both for the donor and the transplant candidate; recovery and recuperation time; availability of alternative treatments for the transplant candidate; financial ramifications (including possible insurance risk). Determine that the donor understands that data on long-term donor health and psychosocial outcomes continue to be sparse. Assess the prospective donor's understanding,

acceptance and respect for the specific donor protocol, e.g. willingness to accept potential lack of communication from the recipient; willingness to undergo future donor follow-up Social support: Evaluate significant other, familial, social and employer support networks available to the prospective donor on an ongoing basis as well as during the donor's recovery from surgery.

Financial suitability: Determine whether the prospective donor is financially stable and free of financial hardship; has resources available to cover financial obligations for expected and unexpected donation-related expenses; is able to withstand time away from work or established role, including unplanned extended recovery time; has disability and health insurance.

Point 9. The psychologist must consider at this point Why does the person want to donate? , is the donation voluntary? Is the voluntary behaviour consistent with the persons past behaviors, apparent values, beliefs, moral obligations or lifestyle, and whether it would be free of coercion, inducements, ambivalence, impulsivity or ulterior motives (e.g. to atone or gain approval, to stabilize self-image, to remedy psychological malady) Asses whether the reasons are due to Altruistic reason , emotional attachment to recipient or Coercion .

Point 10. Review the nature and degree of closeness (if any) to the recipient, e.g. how the relationship developed; and whether the transplant would impose expectations or perceived obligations on the part of either the donor or the recipient.

Point 11. while evaluating pay special attention to :a) current and past history of exposure to stress and reaction to the same: physical, psychological or sexual abuse, current stressors (e.g. relationships, home, work), recent losses

b) coping abilities: assess repertoire of coping skills used to manage previous life or health-related stressors

c) personality traits: specifically evaluate for the traits of altruism, impulsivity, self-harm