ACCRÉDITATION SANS FRONTIÈRES (ASF)
NON-GOVERNMENTAL, NON-PROFIT

ASF Health Standards Version 11

Standard 13: Organ and Tissue Transplant

Core standard · applicability by facility type shown for each criterion

DOCUMENT NUMBER	ASF-HS11-S13
REVISION	01
DATE OF THIS REVISION	10 November 2026
STATUS	Approved for use
OWNER	Accréditation Sans Frontières (ASF)
APPROVED BY	Prof. Giorgi Pkhakadze, MD, MPH, PhD, Chair, Public Health Institute of Georgia
APPLIES TO SURVEYS STARTING AFTER	[date to be confirmed]
REVIEW	Every year, or earlier if the law, a cited guideline or the standard itself changes. Next scheduled review: 1 November 2027.
CONTROLLED COPY	The copy on france-asf.fr is the controlling copy. A printed copy is valid only for the revision shown on its cover.

REVISION HISTORY

Revision	Date	Change	Approved by
01	10 November 2026	First issue of the paper standard. Adapted from the web version of Standard 13 in ASF Health Standards Version 11.	Prof. Giorgi Pkhakadze

APPROVAL

Prof. Giorgi Pkhakadze, MD, MPH, PhD
Chair, Public Health Institute of Georgia

Date: 10 November 2026

Complete on its own, without internet access. References are listed in section 11. The current revision is at france-asf.fr.

Contents

1 Introduction

2 About ASF and this standard

3 How to use this standard

4 Scope

5 Ratings and colours

6 Abbreviations

7 Terms and definitions

8 Standard 13 at a glance: criteria, responsibilities, training

9 Criteria 13.1 to 13.6 (each on its own page)

10 Questions and answers

11 References

12 Document register

Criterion pages: 13.1 Donor Consent Obtained Through a Process Independent of the Transplant Team · 13.2 Organ Allocation Follows a Transparent, Documented Protocol · 13.3 No Financial Incentive to Donor or Family · 13.4 Recipient Evaluation and Informed Consent Process · 13.5 Organ and Tissue Traceability, End to End · 13.6 Post-Transplant Follow-Up and Outcome Tracking.

1 Introduction

This document is Standard 13 of ASF Health Standards. It sets out how a facility carries out organ and tissue transplantation safely and fairly: donor consent independent of the transplant team, transparent allocation, no financial incentive to donors or families, recipient evaluation and informed consent, end-to-end traceability, and systematic follow-up after transplant.

A standard is a set of numbered criteria. Each criterion says what must be in place (the criterion statement), how it is rated for each setting, what the assessor will check and what evidence the facility must show. The guidance in this document explains what each criterion means in practice, so that a reader who has only this paper can understand and meet it.

Purpose of this document. Standard 13 makes sure that every donation is freely given, every organ is allocated fairly and traced safely, and every recipient is evaluated, consented and followed up.

Who should read it. Transplant surgeons, physicians, nurses, coordinators, the donation and consent team, the transplant lead, the clinical governance lead, the chief executive, and the assessors who verify the facility. Each criterion names the positions responsible for it (section 8.2).

The standard is a tool to improve care, not a list of paperwork. Templates and forms named in this document are reference drafts. You may adapt them, replace them with your own, or upload your own documents, provided they meet the same criterion.

2 About ASF and this standard

Accréditation Sans Frontières (ASF) is a non-governmental, non-profit accreditation body. It was legally established in Paris in 2020. ASF develops health standards that are practical, affordable and open to all facilities, including those working with limited resources, in crisis, or in transition.

ASF believes accreditation should be accessible in every sense: geographically, so that facilities in remote areas can take part; financially, so that cost is not a barrier; and in language and format, so that staff can read and use the standard in their own working environment.

Each standard is an independent document. Standard 13 has been written so that it can be read and used on its own. It repeats the definitions, abbreviations and references it needs. A reader who has only this document can understand every criterion in it.

3 How to use this standard

If you deliver transplant services, read section 4 to confirm which criteria apply to your facility type, then section 5 to find the rating for your setting. Read each criterion from 13.1 to 13.6, paying attention to the rating, the guidance and the evidence. Prepare the evidence named in each criterion, covering the period stated.

If you are an assessor, use the sample and the checks in each criterion. The pass rule and the immediate-fail rule decide each criterion. A criterion is met only when all its checks are passed and no immediate-fail event is found.

Reading a criterion. Each criterion has: the criterion statement; the three ratings (humanitarian, transition and fragile, standard); the rating rule; the guidance; what good looks like; common mistakes; why it matters; the sample; the checks, with method, evidence and pass condition; the immediate-fail event; the documents with who writes, approves and checks them; the positions responsible; and the references.

Document codes. Each document has a code made of a topic prefix, a type and a number, for example ENV-SOP-001 (environment, procedure, 001). The type is one of FRM (form, a record kept as evidence), REG (register), PLN (plan),

POL (policy), SOP (standard operating procedure) or GDL (guide). The codes identify documents only. The full list is in section 12.

4 Scope

Standard 13 covers donor consent, organ allocation, payments and incentives, recipient evaluation and consent, traceability of organs and tissues, and post-transplant follow-up. The applicability is shown in section 4.

The standard applies in three settings. The rating for each criterion is given for each setting, and the facility uses the rating for its own setting: **humanitarian settings** (emergency or crisis, very limited resources), **transition and fragile settings** (a health system in change or under strain), and **standard settings** (full resources).

WHERE STANDARD 13 APPLIES

Standard 13 applies when the facility takes, allocates or transplants organs or tissues. For each facility type the table shows whether organ and tissue transplant is a default service (expected) or an optional service (offered only if the facility provides it). The applicability of all 70 standards is in **Annex 1: Applicability of ASF Health Standards by facility type** (ASF-HS11-ANX01), published on france-asf.fr.

Criterion	Applies to
13.1 Donor Consent Obtained Through a Process Independent of the Transplant Team	**default** in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
13.2 Organ Allocation Follows a Transparent, Documented Protocol	**default** in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
13.3 No Financial Incentive to Donor or Family	**default** in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
13.4 Recipient Evaluation and Informed Consent Process	**default** in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
13.5 Organ and Tissue Traceability, End to End	**default** in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.
13.6 Post-Transplant Follow-Up and Outcome Tracking	**default** in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic.

5 Ratings and colours

Rating	Colour	Meaning
Must		Required in every setting. Criteria that can directly affect a patient's life are always Must, and no setting lowers them.
Medium		Required, adapted to what a transition setting can realistically do.

Rating	Colour	Meaning
Minimum		The lowest acceptable level in a humanitarian setting, where resources are very limited.

In standard settings every criterion is Must.

TRAINING LEVELS

Level	Colour	Meaning
Essential		Must be completed by the people named in the role table.
Recommended		Good practice. Not checked as a requirement.
Optional		May be used for development.

6 Abbreviations

Abbreviation	Meaning
ASF	Accréditation Sans Frontières (Accreditation Without Borders), a non-governmental, non-profit accreditation body
FRM	Form. A record that is filled in and kept as evidence
GDL	Guide. Reference guidance for staff
POL	Policy. A written statement of what the facility will do and why
REG	Register. A running record of entries, such as allocations, payments or outcomes
SOP	Standard operating procedure. A step-by-step description of how a task is done
ISCO	International Standard Classification of Occupations (ISCO-08)

DOCUMENT CODE PREFIXES

Prefix	Topic
TXP	Transplant documents

7 Terms and definitions

Term	Definition
Chain of custody	The documented record of who held an organ or tissue, when, and under what conditions, from donor to recipient.
Direct costs	Costs that are incurred for a specific donation and are documented with receipts, such as travel. They are not payments for the donation.
Eligibility criteria	The clinical conditions a recipient must meet before being listed for transplant.

Term	Definition
Graft	The transplanted organ or tissue.
Informed consent	Agreement given by a person who understands the procedure, its risks, its alternatives and its expected outcomes.
Lost to follow-up	A recipient who has missed scheduled visits and cannot be contacted by the team.
Immediate fail	One event that means a criterion is not met, whatever else is in place.
Setting	The context in which a facility works: humanitarian, transition and fragile, or standard.

8 Standard 13 at a glance

Standard 13: Organ and Tissue Transplant is a service standard of ASF Health Standards. It applies when the facility takes, allocates or transplants organs or tissues, and covers consent, allocation, payment, evaluation, traceability and follow-up around each transplant.

The standard has nine criteria. Each is shown below and explained on its own page in section 9.

8.1 CRITERIA AND RATINGS

No.	Criterion	Humanitarian	Transition	Standard
13.1	Donor Consent Obtained Through a Process Independent of the Transplant Team	Minimum	Must	Must
13.2	Organ Allocation Follows a Transparent, Documented Protocol	Minimum	Must	Must
13.3	No Financial Incentive to Donor or Family	Minimum	Must	Must
13.4	Recipient Evaluation and Informed Consent Process	Minimum	Medium	Must
13.5	Organ and Tissue Traceability, End to End	Minimum	Medium	Must
13.6	Post-Transplant Follow-Up and Outcome Tracking	Minimum	Medium	Must

8.2 RESPONSIBILITIES

Each criterion names the positions responsible for it. The facility sets its own reporting lines, and each position should have written terms of reference. ISCO-08 codes are shown for each role and are recorded in the staff register.

No.	Criterion	Positions responsible or involved
13.1	Donor Consent Obtained Through a Process Independent of the Transplant Team	Manager (ISCO 1342) · Nurse (ISCO 2221)
13.2	Organ Allocation Follows a Transparent, Documented Protocol	Manager (ISCO 1342) · Secretary (ISCO 3344)
13.3	No Financial Incentive to Donor or Family	Manager (ISCO 1342) · Secretary (ISCO 3344)
13.4	Recipient Evaluation and Informed Consent Process	Manager (ISCO 1342) · Nurse (ISCO 2221)
13.5	Organ and Tissue Traceability, End to End	Nurse (ISCO 2221) · Manager (ISCO 1342)
13.6	Post-Transplant Follow-Up and Outcome Tracking	Manager (ISCO 1342) · Secretary (ISCO 3344)

8.3 TRAINING FOR STANDARD 13

Training is shown by course. Essential training must be completed by the people named. Recommended training is good practice. The colours follow section 5.

Course	Essential for	Recommended for	Criteria	Status
Healthcare Ethics for ASF Accreditation (A-07)	Manager, Nurse	None	13.1, 13.2, 13.3	In development
Transplant Recipient Evaluation and Informed Consent (TXP-01)	Manager, Nurse	None	13.4	In development
Organ and Tissue Traceability End to End (TXP-02)	Manager, Nurse	None	13.5	In development
Post-Transplant Follow-Up and Outcome Tracking (TXP-03)	Manager, Nurse	None	13.6	In development

Evidence of training may be a verified micro-credential in the GMJ Academy micro-credential portfolio, or a training certificate kept in the staff file.

13.1 Donor Consent Obtained Through a Process Independent of the Transplant Team

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	Must	Must

Applies to: default in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Donor or donor-family consent for organ or tissue donation is obtained through a process independent of the transplant team requesting the organ, with the independence structurally built in — not a theoretical separation undermined by the same staff being involved in both roles.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: donor or donor-family consent is obtained by a process independent of the transplant team that needs the organ.

GUIDANCE

Donation must be a free choice made by the donor or their family. The consent discussion is held by a person who is not part of the transplant team that will use the organ, so that the family is not pressured by the people who benefit from the decision.

Independence has to be built into the process: separate people, a written procedure and a record of who led the discussion. Two roles held by the same person on the same case are not independent, whatever the policy says.

WHAT GOOD LOOKS LIKE

- The consent team is trained in the donation process and in respectful refusal, and the family is offered a private space to decide.

COMMON MISTAKES

- The transplant surgeon who needs the organ asks the family for consent.
- Consent taken by a member of the requesting team, with no independent person present.

> **Why it matters.** Donation must be a free choice, made by the donor or their family, and not pressured by the team that will use the organ. A consent process separate from the treatment team protects that choice.

WHAT THE ASSESSOR CHECKS

Sample. Review donor consent records for all donations in the last 12 months.

---

1 Donor or family consent is obtained by a process independent of the transplant team.

Method. Check each consent for the person who took it and their role in the transplant team.

Evidence to show. Donor consent independent of the transplant team (TXP-POL-001).

Pass when. No consent was taken by a member of the requesting transplant team.

2 **Consent is recorded with the donor's known wishes or the family's decision.**

Method. Check each consent record for the wishes or decision recorded.

Evidence to show. Donor consent record (TXP-FRM-001).

Pass when. Every consent records the wishes or decision.

3 **Consent is taken at a time and place that does not put the family under pressure.**

Method. Check each consent record for the time, the place and the person who led the discussion.

Evidence to show. Donor consent record (TXP-FRM-001).

Pass when. Every consent record shows the time, the place and that the discussion was led by the independent consent team.

Pass. The criterion is met when every check above is passed.

Immediate fail. . The transplant surgeon who needs the organ asks the family for consent. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
TXP-FRM-001	Donor consent record	Manager	Chief executive	Manager
TXP-POL-001	Donor consent independent of the transplant team	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Donor consent independent of the transplant team	— Must
Nurse (ISCO 2221)	Completes the Donor consent record	— Must

REFERENCES FOR THIS CRITERION

- WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: donor consent obtained independently of the transplant team, and the free choice of donation. https://pubmed.ncbi.nlm.nih.gov/21235034/

13.2 Organ Allocation Follows a Transparent, Documented Protocol

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: default in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Organ allocation decisions follow a written, transparent protocol based on clinical criteria, applied consistently, with any deviation from the standard protocol specifically documented and justified — not informal decisions vulnerable to undue influence.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: organ allocation follows a written, transparent protocol based on clinical criteria, and every departure is justified.

GUIDANCE

Organs are scarce. Allocation follows a written protocol based on clinical criteria such as urgency, tissue match and likely benefit. Each allocation records the criteria used, and any departure from the protocol is written down with its reason and reviewed.

A transparent rule protects patients on the waiting list and protects staff from pressure. Undocumented exceptions are the main route for undue influence.

WHAT GOOD LOOKS LIKE

- The allocation panel publishes its criteria, and each allocation is reviewed by a second clinician.

COMMON MISTAKES

- A kidney allocated outside the protocol with no criteria recorded.
- Exceptions agreed informally and never written down.

> **Why it matters.** Organs are scarce. Allocating them by a written, transparent rule, based on clinical need, is the only fair way to decide who receives one.

WHAT THE ASSESSOR CHECKS

Sample. Review organ allocation decisions for the last 12 months, including any decision that departed from the protocol.

---

1 Allocation follows the written protocol and its clinical criteria.

Method. Check each allocation against the protocol criteria.

Evidence to show. Organ allocation protocol (TXP-POL-002).

Pass when. Every allocation follows the protocol criteria.

2 **Each allocation is recorded with the criteria used.**

Method. Check each allocation record for the criteria and the date.

Evidence to show. Allocation decision register (TXP-REG-001).

Pass when. Every allocation records the criteria used.

3 **Any departure from the protocol is recorded with the reason and reviewed.**

Method. Check each departure for the reason and the review.

Evidence to show. Allocation decision register (TXP-REG-001).

Pass when. Every departure has a reason and a review.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A kidney allocated to a friend of a senior clinician with no criteria recorded. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
TXP-REG-001	Allocation decision register	Secretary	Chief executive	Manager
TXP-POL-002	Organ allocation protocol	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Organ allocation protocol	— Must
Secretary (ISCO 3344)	Keeps the Allocation decision register	— Must

REFERENCES FOR THIS CRITERION

- WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: allocation of organs by written, transparent criteria based on clinical need. https://pubmed.ncbi.nlm.nih.gov/21235034/

13.3 No Financial Incentive to Donor or Family

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Must**	**Must**

Applies to: default in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** No financial payment or material incentive, beyond legitimate reimbursement of documented direct costs, is offered to a donor or donor family in connection with organ or tissue donation, with staff trained to recognise and refuse any such arrangement.

Rating rule. Minimum in humanitarian settings. Must in transition and fragile settings. Must in standard settings: no payment or material incentive is offered to a donor or family beyond documented direct costs.

GUIDANCE

No payment, gift or material benefit is offered to a donor or a donor family in connection with donation. The facility may reimburse documented direct costs, such as travel for the family, against a receipt and an approval given before payment.

Payment for organs is exploitation and is prohibited in most countries. A clear reimbursement rule, with receipts and approval, keeps legitimate costs separate from any incentive.

WHAT GOOD LOOKS LIKE

- Staff are trained to recognise and refuse any offer of payment, and the payment log is reviewed each quarter.

COMMON MISTAKES

- A family paid for funeral costs as a reward for donation, with no receipt.
- Reimbursements paid first and approved afterwards.

> **Why it matters.** Paying a donor or their family for an organ is exploitation and is banned in most places. Only legitimate costs, such as travel, may be covered, and only with a record.

WHAT THE ASSESSOR CHECKS

Sample. Review all payments and reimbursements linked to donation for the last 12 months.

1 No payment or incentive is offered to a donor or donor family.

Method. Check the payment log for any payment to a donor or family.

Evidence to show. No financial incentive (TXP-POL-003).

Pass when. No sampled payment is an incentive.

2 Each reimbursement is for a documented direct cost.

Method. Check each reimbursement for the receipt and the cost category.

Evidence to show. Payments and reimbursement register (TXP-REG-002).

Pass when. Every reimbursement has a receipt and a documented direct cost.

3 Each reimbursement is approved before payment.

Method. Check each reimbursement for the approval before the payment date.

Evidence to show. Payments and reimbursement register (TXP-REG-002).

Pass when. Every reimbursement was approved before payment.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A family paid for the donor's funeral costs as a reward for donation, with no receipt. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
TXP-REG-002	Payments and reimbursement register	Secretary	Chief executive	Manager
TXP-POL-003	No financial incentive	Chief executive	Governing body members	Chief executive

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the No financial incentive	— Must
Secretary (ISCO 3344)	Keeps the Payments and reimbursement register	— Must

REFERENCES FOR THIS CRITERION

- WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: prohibition of payment or incentive to donors and families, with reimbursement limited to documented direct costs. https://pubmed.ncbi.nlm.nih.gov/21235034/

13.4 Recipient Evaluation and Informed Consent Process

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Transplant recipients undergo a documented evaluation against clinical eligibility criteria, with informed consent covering realistic outcomes, risks, and the source of the organ or tissue where legally and clinically relevant — not a general surgical consent treated as sufficient.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: every transplant recipient is evaluated against clinical eligibility criteria and gives informed consent that covers realistic outcomes and risks.

GUIDANCE

Every recipient is evaluated against documented clinical eligibility criteria before being listed for transplant. Informed consent covers realistic expected outcomes, the risks of surgery and immunosuppression, the alternatives, and the source of the organ or tissue where that is legally and clinically relevant.

A general surgical consent is not enough for a transplant. The recipient must understand the lifelong nature of the treatment and what success and failure look like.

WHAT GOOD LOOKS LIKE

- Recipients receive written information in their own language and time to ask questions before they sign consent.

COMMON MISTAKES

- A recipient listed with no documented evaluation and no discussion of transplant risks.
- A general surgical consent form used as the transplant consent.

> **Why it matters.** A transplant recipient must be fit for the procedure and understand its risks. A documented evaluation and informed consent make sure the decision is sound.

WHAT THE ASSESSOR CHECKS

Sample. Review evaluation and consent records for 15 transplant recipients.

---

1 Each recipient is evaluated against documented clinical eligibility criteria.

Method. Check each evaluation for the criteria checked and the outcome.

Evidence to show. Recipient evaluation and consent (TXP-SOP-001).

Pass when. Every recipient has a documented evaluation.

2 **Consent covers realistic outcomes, risks and alternatives.**

Method. Check each consent for the three elements.

Evidence to show. Recipient evaluation and consent record (TXP-FRM-002).

Pass when. Every consent covers all three elements.

3 **Recipients are added to the waiting list only after the evaluation is complete.**

Method. Check each waiting-list entry against the date the evaluation was completed.

Evidence to show. Recipient evaluation and consent (TXP-SOP-001).

Pass when. Every waiting-list entry follows a completed evaluation.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A recipient listed for transplant with no documented evaluation and no consent discussion of risks. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
TXP-SOP-001	Recipient evaluation and consent	Manager	Chief executive	Chief executive
TXP-FRM-002	Recipient evaluation and consent record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Recipient evaluation and consent	— Medium
Nurse (ISCO 2221)	Completes the Recipient evaluation and consent record	— Medium

REFERENCES FOR THIS CRITERION

- WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: recipient evaluation and informed consent for transplantation. https://pubmed.ncbi.nlm.nih.gov/21235034/

13.5 Organ and Tissue Traceability, End to End

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Every organ or tissue is traceable through a documented chain of custody from donor to recipient, including handling, testing, and transport, with no gap in the record at any point in that chain.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: every organ or tissue is traceable from donor to recipient through a documented chain of custody.

GUIDANCE

Every organ or tissue is traceable through a documented chain of custody from donor to recipient. Each handling, testing and transport step is recorded with the time, the person and the condition, so that an unsafe donation can be found and stopped.

Without a complete record, a contaminated or mislabelled organ cannot be traced, and other recipients cannot be warned. The chain of custody is the safety net for the whole service.

WHAT GOOD LOOKS LIKE

- Each organ or tissue is labelled at donation with a unique identifier that follows it to the recipient.

COMMON MISTAKES

- A donor organ arriving with no label and no record of transport temperature.
- Handovers recorded with no names or times.

> **Why it matters.** An organ or tissue must be traceable from donor to recipient, through every step of handling, testing and transport. Without a chain of custody, an unsafe donation cannot be found or stopped.

WHAT THE ASSESSOR CHECKS

Sample. Review chain of custody records for 15 organ or tissue donations from donor to recipient.

1 Handling, testing and transport are recorded at each step.

Method. Check each record for the handling, testing and transport entries.

Evidence to show. Organ handling and transport record (TXP-FRM-003).

Pass when. Every step is recorded with time and person.

2 Each handover is signed by the person giving the organ or tissue and the person receiving it.

Method. Check each handover entry for both signatures and the time.

Evidence to show. Organ handling and transport record (TXP-FRM-003).

Pass when. Every handover is signed by both people, with the time recorded.

3 **Any gap or break in the chain of custody is investigated and recorded.**

Method. Check the record for any break and the investigation that followed.

Evidence to show. Organ handling and transport record (TXP-FRM-003).

Pass when. Every break has an investigation and its outcome recorded.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A donor organ arrives with no label and no record of transport temperature. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
TXP-FRM-003	Organ handling and transport record	Manager	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Nurse (ISCO 2221)	Completes the Organ handling and transport record	— Medium
Manager (ISCO 1342)	Checks the criterion at each review	— Medium

REFERENCES FOR THIS CRITERION

- WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: traceability of organs and tissues from donor to recipient. https://pubmed.ncbi.nlm.nih.gov/21235034/

13.6 Post-Transplant Follow-Up and Outcome Tracking

HUMANITARIAN SETTINGS	TRANSITION AND FRAGILE SETTINGS	STANDARD SETTINGS
Minimum	**Medium**	**Must**

Applies to: default in Hospital. **Not applicable to:** Ambulatory clinic, Primary health clinic, Long-term care, Telemedicine, Home care, Fitness and wellness, Dental clinic, Aesthetic and procedure clinic. Each setting shows its rating above.

> **Criterion.** Transplant recipients are followed systematically after the procedure, with graft and patient outcomes tracked and reported, not lost to follow-up once the recipient is discharged from the immediate post-operative period.

Rating rule. Minimum in humanitarian settings. Medium in transition and fragile settings. Must in standard settings: recipients are followed up systematically, and graft and patient outcomes are tracked and reported.

GUIDANCE

Recipients are followed up on a defined schedule after transplant. Graft function and patient outcomes are recorded in an outcome register and reported. Recipients who miss a visit are traced, and the tracing attempts are recorded.

Transplant is a lifelong treatment. Outcome tracking shows whether the service is succeeding, and early follow-up catches rejection and infection before they become serious.

WHAT GOOD LOOKS LIKE

- Outcomes are shared with the transplant team and with each recipient at every review.

COMMON MISTAKES

- A recipient discharged after transplant and lost to follow-up within six months.
- Graft failure recorded in the clinical notes but not in the outcome register.

> **Why it matters.** After a transplant, the graft and the patient must be followed for years. Tracking outcomes shows whether the service is succeeding, and catches problems early.

WHAT THE ASSESSOR CHECKS

Sample. Review follow-up records for all recipients transplanted in the last 2 years.

1 Each recipient is followed up at the defined schedule.

Method. Check each recipient record for the follow-up visits against the schedule.

Evidence to show. Post-transplant follow-up and outcome tracking (TXP-SOP-003).

Pass when. Every recipient is followed up on schedule.

2 Graft and patient outcomes are recorded and reported.

Method. Check the outcome register for each recipient and the report.

Evidence to show. Graft and patient outcome register (TXP-REG-004).

Pass when. Every recipient has outcomes recorded and reported.

3 Recipients lost to follow-up are traced.

Method. Check each recipient lost to follow-up for the tracing attempts.

Evidence to show. Post-transplant follow-up and outcome tracking (TXP-SOP-003).

Pass when. Every recipient lost to follow-up has tracing attempts recorded.

Pass. The criterion is met when every check above is passed.

Immediate fail. . A recipient discharged after transplant and lost to follow-up within six months. This fails the criterion on its own, whatever else is in place.

EVIDENCE AND DOCUMENTS

Code	Document	Writes	Approves	Checks
TXP-SOP-003	Post-transplant follow-up and outcome tracking	Manager	Chief executive	Chief executive
TXP-REG-004	Graft and patient outcome register	Secretary	Chief executive	Manager

POSITIONS RESPONSIBLE

Position	Why it applies	Training
Manager (ISCO 1342)	Maintains the Post-transplant follow-up and outcome tracking	— Medium
Secretary (ISCO 3344)	Keeps the Graft and patient outcome register	— Medium

REFERENCES FOR THIS CRITERION

- WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: follow-up and outcome tracking after transplantation. https://pubmed.ncbi.nlm.nih.gov/21235034/

10 Questions and answers

Does Standard 13 apply to every facility?
No. It applies to hospitals and transplant services that take, allocate or transplant organs and tissues. Section 4 shows, for each facility type, whether the service is a default or an optional service.

Who must ask a donor family for consent?
Under 13.1 consent is obtained through a process that is independent of the transplant team that needs the organ.

Can a donor family be paid?
No. Under 13.3 no payment or material incentive is offered. Documented direct costs may be reimbursed, with a receipt and an approval given before payment.

How are organs allocated?
Under 13.2 allocation follows a written, transparent protocol based on clinical criteria. Any departure from the protocol is documented, justified and reviewed.

Does a facility that only refers patients abroad need this standard?
Only if it takes, allocates or transplants organs or tissues itself. Referral alone is not covered by these criteria, but any donation the facility handles must still meet the consent and traceability rules.

Do I have to use the forms on this page?
No. They are reference drafts. Adapt them, write your own, or upload your own, provided the same criterion is met and the evidence can be shown.

The criterion text is the authority. These answers summarise it.

11 References

CITED FOR CRITERIA

1. WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: donor consent obtained independently of the transplant team, and the free choice of donation. https://pubmed.ncbi.nlm.nih.gov/21235034/ (criterion 13.1)
2. WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: allocation of organs by written, transparent criteria based on clinical need. https://pubmed.ncbi.nlm.nih.gov/21235034/ (criterion 13.2)
3. WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: prohibition of payment or incentive to donors and families, with reimbursement limited to documented direct costs. https://pubmed.ncbi.nlm.nih.gov/21235034/ (criterion 13.3)
4. WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: recipient evaluation and informed consent for transplantation. https://pubmed.ncbi.nlm.nih.gov/21235034/ (criterion 13.4)
5. WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: traceability of organs and tissues from donor to recipient. https://pubmed.ncbi.nlm.nih.gov/21235034/ (criterion 13.5)
6. WHO (2010). WHO Guiding Principles on Human Cell, Tissue and Organ Transplantation. Adopted by the World Health Assembly, resolution WHA63.22. Geneva: World Health Organization. Published version: . Used for: follow-up and outcome tracking after transplantation. https://pubmed.ncbi.nlm.nih.gov/21235034/ (criterion 13.6)

INTERNATIONAL STANDARDS CITED

1. International Labour Organization (2008). International Standard Classification of Occupations, ISCO-08. Geneva: ILO.

12 Document register

Every document code used in Standard 13, with its type and the criteria that use it. The codes identify the documents; a facility may use its own document if it meets the same criterion.

Code	Document	Type	Criteria
TXP-FRM-001	Donor consent record	Form (record)	13.1
TXP-FRM-002	Recipient evaluation and consent record	Form (record)	13.4
TXP-FRM-003	Organ handling and transport record	Form (record)	13.5
TXP-POL-001	Donor consent independent of the transplant team	Policy	13.1
TXP-POL-002	Organ allocation protocol	Policy	13.2
TXP-POL-003	No financial incentive	Policy	13.3
TXP-REG-001	Allocation decision register	Register	13.2
TXP-REG-002	Payments and reimbursement register	Register	13.3
TXP-REG-004	Graft and patient outcome register	Register	13.6
TXP-SOP-001	Recipient evaluation and consent	Procedure (SOP)	13.4
TXP-SOP-003	Post-transplant follow-up and outcome tracking	Procedure (SOP)	13.6