HSC.21350 Clinical Transplant Registries and Transplant Data Retention **Phase II**

The institution participates in and retains records of patient and donor transplant information in the United Network for Organ Sharing (UNOS) Clinical Transplant Registry or its equivalent.

NOTE: The laboratory and/or transplant coordinator must retain records on transplant recipients, including a history of prior transfusion, pregnancy, and prior transplants as well as HLA antibody history, date of transplant(s) and outcome. In addition, there must be records of donor and recipient age, race, sex, ABO, and HLA types. The source of the donor organ or donor hematopoietic stem cells must be recorded. This information can be retained as part of an institutional registry.

REFERENCES

1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

HSC.21366 Record Review **Phase II**

There are records of periodic review and verification of patient histocompatibility data.

NOTE: Histocompatibility tests performed for organ transplantation (HLA typing, HLA antibody sensitization, unacceptable antigens during prior transplants or sensitization, and any pretransplant screening results) must be reviewed and verified when patients are placed on organ waiting lists. Changes or additions to the waiting lists must be verified. These records must be readily available for review and retained for at least two years.

REFERENCES

1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.

****REVISED** 12/26/2024***

HSC.21382 Discrepancy Resolution **Phase II**

The laboratory has a defined process to resolve HLA typing discrepancies within and between laboratories.

NOTE: There must be records of the steps taken to resolve discrepancies.

This requirement applies to HLA testing performed by all testing methods, including next generation sequencing.

REFERENCES

1) Organ Procurement and Transplantation Network (OPTN) Bylaws. Appendix C. Membership Requirements for Histocompatibility Laboratories. US Department of Health and Human Services. December 5, 2022.
2) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.

HSC.21390 Donor Confidentiality **Phase II**

The laboratory ensures confidentiality of all donor records, including releasing or sharing donor information for clinical purposes.

NOTE: For example, if identifiable donor information will be shared with the recipient, appropriate donor informed consent must be obtained, donor information must be redacted, or other appropriate action taken.

Refer to the Laboratory General Checklist for specific requirements on patient privacy and patient data accessibility.

REFERENCES

1) Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee ISCT and EBMT (JACIE). FACT-JACIE International Standards for Hematopoietic Cellular Therapy Product Collection, Processing, and Administration. 8th Edition, December 14, 2021.

REAGENTS

Inspector Instructions:

	• Reagent inventory log • Sampling of procedures for reagent and patient sample storage and handling • Sampling of typing/screening tray records for completeness • Validation studies for modified reagents
	• What are your laboratory's criteria for mixing components from one lot number of reagent kit with components from another lot number of kit? • How do you ensure that all reagents are acceptable and in date? • How does your laboratory manage and control reagent inventory?

Additional requirements are in the REAGENTS section of the All Common Checklist.

HSC.21612 Reagent Tracking **Phase II**

The laboratory records the reagent lot numbers and shipments used for each assay.

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2004(Oct 1): 1038 [42CFR493.1256(a)]

HSC.21675 Reagent Kit Components **Phase II**

Combinations of reagents from different lots are checked against old reagent lots or with suitable reference material before or concurrently with being placed in service.

Evidence of Compliance:

✓ Records of checks performed on combinations of reagents from different lots

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HSC.21800 Reagent and Specimen Storage **Phase II**

Optimal storage conditions for reagent and specific types of patient specimens are defined and followed.

NOTE 1: Written procedures must include storage and retention requirements for specific types of patient specimens, including lymphocytes, RNA, DNA, and sera.

NOTE 2: Use of continuous monitoring and alert systems and back-up storage plans must be specified as applicable.

Evidence of Compliance:

✓ Records of storage and retention at defined conditions

REFERENCES

1) Department of Health and Human Services, Centers for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register.* 2023(Dec 28):[42CFR493.1278(a)(1) and (a)(2)].