Reporting of Deceased Donor HLA Types to NHSBT-ODT

This SOP replaces SOP5038/2

Copy Number

Effective

11/12/17

Summary of Significant Changes

Change to ODT website location. Change to Duty Office email address and department title to Hub Operations.

Purpose

Describes the process for the reporting of deceased donor HLA types to NHSBT-Organ Donation and Transplantation

Responsibilities

NTLCs to enter the HLA type onto NTxD and report any consistency failure to the submitting laboratory

H&I scientist(s) to resolve any HLA consistency failure and provide the NTLC with further instruction as necessary

Definitions

NTLC - National Transplant Liaison Coordinator (ODT Hub Operations)

Items Required

FRM4365 - HLA Report

<u>DAT2885</u>:- Minimum Resolution for Donor and Patient HLA Types (Minimum Typing Requirements for Reporting Donor and Recipient Types)

HLA Conversion Chart for Organ Allocation

These forms/information sheets accessible at:

www.odt.nhs.uk/transplantation/pathology-services/histocompatibility-and-immunogenetics

Reporting of Deceased Donor HLA Types to NHSBT-ODT

1. PROCEDURE FOR REPORTING OF <u>DONOR OFFER HLA TYPE</u> (donor laboratory)

Complete FRM4365 HLA Report

Ensure that the current version of this report form is used.

In-house generated report forms may be used, but must mimic the format and content of FRM4365 exactly

- 1.1 Enter identification and contact details of the laboratory submitting the HLA type.
- 1.2 Enter the HLA type:

The type must be reported in compliance with the minimum typing resolution requirements (<u>DAT2885</u>: Minimum Typing Requirements for Reporting Donor and Recipient Types).

- The type may be reported using serological or molecular nomenclature or a combination of both.
 If molecular nomenclature is reported alone, the database will automatically 'map' alleles to the antigens used in the organ allocation process
 (HLA Conversion Chart for Organ Allocation)
- Ensure that serological nomenclature is reported in the 'HLA broad' and/or 'HLA split specificity' boxes and molecular nomenclature is reported in the 'HLA allele(s)' boxes.
- Ensure that valid WHO nomenclature is used for all HLA loci.
- 1.4 Indicate that the type is an 'OFFER TYPE' by ticking the 'Donor Centre: offer type' box. This is essential in order to alert ODT Hub Operations that this type is to be used in the organ allocation process.

Do not tick the 'revised type' or 'retype' boxes when submitting an offer type.

- 1.5 Enter date and time
- 1.6 Enter method(s) of typing technique used.
- 1.7 Note any information that may be useful for other laboratories in the 'Comments' box, including HLA-DPB type if known.
 Information given in this area is not entered onto the database, recorded by the NTLCs or considered in the organ allocation process.
- 1.8 Enter ODT donor identification number, if known
- 1.9 Click on 'Make Read Only' and 'Submit Form'. The form will automatically be emailed to the ODTHub Operations Mailbox odthub.operations@nhsbt.nhs.uk. The form may also be faxed to ODT Hub Operations but laboratories are requested to send the form using secure email wherever possible.
- 1.10 The H&I scientist must then telephone ODT Hub Operations to confirm that the email or fax has been received.
- 1.11 If the NTLC has not contacted the laboratory to report a failure of the automated consistency checks on the HLA type, twenty minutes following submission of the HLA report form, the donor laboratory H&I scientist must telephone ODT Hub Operations to confirm that the HLA type has successfully passed the consistency checking procedure and the organ allocation process has been initiated.

Reporting of Deceased Donor HLA Types to NHSBT-ODT

HLA TYPE AUTOMATED CONSISTENCY CHECKING PROCESS

The automated process checks consistency according to the following 5 rules;

Rule 1: There is consistency between HLA broad/split antigens/alleles.

(Example 1, Appendix 1)

Valid WHO nomenclature is used

(Example 2, Appendix 1)

If there is inconsistency between broad antigens/ split antigens/ alleles or invalid WHO nomenclature is used the HLA type cannot be entered into the database.

Rule 2: No more than 2 antigens/alleles can be reported at a single locus

If more than 2 antigens or alleles are reported at a single locus, the HLA type cannot be entered into the database.

Action:

- ODT Hub Operations contacts the laboratory that issued the donor HLA type and requests that the type is reviewed so that it can be entered into the database
- The laboratory resolves the error and submits the <u>revised</u> HLA type to ODT following the process described in Section II for submission of revised types.
- If the laboratory H&I scientist is unable to resolve the error, the scientist will then contact their own Head of Laboratory (or designated deputy) for advice and resolution.
- The laboratory will submit the revised HLA type to ODT following the process described in Section 2 for submission of revised types, and confirm that the organ allocation process has been successfully initiated.

Rule 3. Bw4/Bw6 antigen associations must be consistent with HLA B locus antigens/alleles

Unsuccessful consistency checking according to rule 3 generates the following error message:

The reported HLA type displays an unlikely Bw4/Bw6 association with reported B locus antigens. Please check HLA type.

(Example 3, Appendix 1)

Rule 4. DR51/51N/52/53/53N antigen associations must be consistent with HLA-DR locus antigens/alleles

Unsuccessful consistency checking according to rule 4 generates the following error message:

The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type.

(Example 4, Appendix 1)

Rule 5. DRB3/4/5 allele associations must be consistent with HLA-DR locus antigens/alleles and DR51/51N/52/53/53N antigens.

Unsuccessful consistency checking according to rule 5 generates the following error message:

The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type.

(Examples 5, 6,7 Appendix 1)

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Unsuccessful consistency checking according to rules 3, 4 or 5:

Action:

- ODT Hub Operations contacts the laboratory that issued the donor HLA type and requests that the type is reviewed.
- The laboratory resolves the error and submits the <u>revised</u> HLA type to ODT following the process described in Section II for submission of revised types.
- If the laboratory H&I scientist is unable to resolve the error, the scientist will then contact their own Head of Laboratory (or designated deputy) for advice and resolution.
- The laboratory will submit the revised HLA type to ODT following the process described in Section 2 for submission of revised types and confirm that the organ allocation process has been successfully initiated. If the HLA type is correct but an unusual antigen association has been identified, the Head of Laboratory (or designated deputy) will contact ODT Hub Operations and authorize initiation of the allocation process with the HLA type as reported. The NTLC will record the name of this person.

Please note that all donor HLA types will be manually checked by NHSBT-ODT Scientific Support staff during normal working hours within 5 working days of submission. Any inconsistencies detected by the consistency checking process will be followed up with the Head of the Laboratory reporting the donor type, and be included in the papers for the Clinical Audit Risk and Effectiveness Group of NHSBT- Organ Donation and Transplantation and in the 'Donor Discrepancy Monitoring Report'.

Reporting of Deceased Donor HLA Types to NHSBT-ODT

2. REPORTING OF REVISED DONOR HLA TYPE

2.1 Donor Laboratory Revised HLA type:

- If the offer type is revised the donor laboratory must immediately inform ODT Hub Operations by telephone.
- The revised HLA type should be entered onto the HLA report form FRM4365 Deceased Donor HLA Report Form and emailed or faxed to ODT Hub Operations. The 'Donor Centre: Revised Type' box on the report form must be ticked.
 Do not tick the 'offer type' or 'retype' boxes when submitting a revised type. The H&I scientist must then telephone ODT Hub Operations to confirm that the email/fax has been received.
- Twenty minutes following submission of the form, the laboratory must telephone
 ODT Hub Operations to confirm that the type has been received and that the organ allocation process has been successfully initiated.

The allocation algorithm will be repeated with the revised type if the type is received within 18 hours of original offer type. ODT Hub Operations will inform all organ recipient centres (where relevant) of the revision. The ODT Hub Operations Standard Operating Procedure will be followed if re-allocation of an organ is necessary.

2.2 Recipient Laboratory Revised HLA type:

- If there is a discrepancy between the HLA type performed at the recipient centre laboratory and the type submitted by the donor centre laboratory, the recipient H&I scientist must contact the donor H&I scientist to discuss and resolve the discrepancy. The NTLCs do not have the relevant knowledge to advise on or resolve a discrepancy identified in an HLA type. It is the responsibility of the scientists to resolve any such discrepancy.
- Where the offer type is to be revised the donor centre must inform ODT Hub Operations by telephone. The revised HLA type should be entered onto the <u>FRM4365</u> Deceased Donor HLA Report Form and emailed/faxed to <u>ODT Hub Operations</u>. The <u>'Donor Centre: Revised Type'</u> box on the report form <u>must be ticked</u>.
 Do not tick the 'offer type' or 'retype' boxes when submitting a revised type.
- The recipient centre must then email/fax a <u>FRM4365</u> Deceased Donor HLA Report Form ticking the <u>'Recipient centre Revised type'</u> box to ODT.
 Do not tick the 'offer type' or 'retype' boxes when submitting a revised type.
- The procedure for 'Donor Centre Revision' as given above will then be initiated.

Please note that all revised donor HLA types will be followed up by ODT Scientific Support Services and be included in the papers for the Clinical Audit Risk and Effectiveness Group of NHSBT- Organ Donation and Transplantation and in the 'Donor Discrepancy Monitoring Report'.

3. REPORTING OF DONOR HLA RE-TYPE (CONFIRMATORY TYPE)

- Following a transplant the <u>FRM4365</u> Deceased donor HLA Report form should be used to email/fax the results of confirmatory HLA types or retypes. The 'HLA re-type' box <u>must be</u> ticked.
 - Do not tick the 'offer type' or 'revised type' boxes when submitting a retype.
- No immediate action will be taken by ODT Hub Operations on receipt of a re-type.
 HLA retypes are entered onto the database and are taken into account for the definitive HLA type used in survival analysis.

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 1

Rule1: There is consistency between HLA broad/split antigens/alleles.

HLA type submitted:

ŀ	HLA broad	HLA spli	it HLA	HLA broad	HLA split	HLA	
	specificity	specificit	y allele(s)	specificity	specificity	allele(s)	
HLA -A	2		02	9	25	25]
-B	8		08	35		35	Bw6
-DR	103		01:03	3	17	03	DR52
-Cw	4		04	7		07	
-DQB1	1	5	05:01-04	2		02:01-04	
-DRB3	01-0	3		-DRB4			
alleles				alleles			
-DRB5							
alleles							

The NTLC will be unable to enter this type as there is inconsistency between A9/A25/A*25

	HLA bro		•	HLA llele(s)	HLA broad specificity	HLA split		.A le(s)	
HLA -A	2	,		02	9	24		24]
-B	8			80	35		3	35	Bw6
-DR	103		C	1:03	3	17	C)3	DR52
-Cw	4			04	7		C)7	
-DQB1	1	5	05	:01-04	2		02:0	1-04	
-DRB3	01-0)3			-DRB4				
alleles					alleles				
-DRB5									
alleles									

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 2

Rule1: Valid WHO nomenclature is used

HLA type submitted:

	HLA broa	ad HLA s specifici	•	HLA broad specificity	HLA split specificity	HLA allele(s)	
HLA -A	Specificity	Specifici	01	Specificity	specificity	02	\neg
-B			08			62	Bw6
-DR			04				DR53
-Cw			03:03/11/13			07	
-DQB1			0301			03:02	
-DRB3				-DRB4	01		
alleles				alleles			
-DRB5							
alleles							

The NTLC will be unable to enter this type as **B*62** is invalid nomenclature

	HLA broad specificity	HLA spli specificit		HLA broad specificity	HLA split specificity			_
HLA -A			01			0	2	
-B			80			15:01/0 07/20	04-	Bw6
-DR			04					DR53
-Cw			03:03/11/13			0	7	
-DQB1			03:01			03:	:02	
-DRB3 alleles				-DRB4 alleles	01			
-DRB5 alleles								

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 3

Rule 3:

Bw4/Bw6 antigen associations must be consistent with HLA B locus antigens/alleles

HLA type submitted:

	HLA broad	HLA sp	lit HLA	HLA broad	HLA split	HL	.Α	
	specificity	specifici	ity allele(s)	specificity	specificity	[,] alle	le(s)	
HLA -A	2		02	11			11	
-B	16	39	39	12	44		44	Bw6
-DR	1		01:01/02/04-10	4			04	DR53
-Cw			05				12	
-DQB1	1	5	05	3	7	03:01/	09/10/13	
-DRB3				-DRB4	01/02:	01N		
alleles				alleles				
-DRB5								
alleles								

B44 is not consistent with Bw6.

Auto generated error message:

The reported HLA type displays an unlikely Bw4/Bw6 association with reported B locus antigens. Please check HLA type.

	HLA broad specificity	HLA sp specific			HLA broad specificity	HLA split specificity			
HLA -A	2		02		11		•	11	
-B	16	39	39		12	44	4	14	Bw4,6
-DR	. 1		01:01/02/04-10		4		()4	DR53
-Cw	,						,	12	
-DQB1	1	5	05		3	7	03:01/0	09/10/13	
	-		•	_	•				•
-DRB3					-DRB4	01/02:	01N		
alleles					alleles				
-DRB5									_
alleles									

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 4

Rule 4: DR51/51N/52/53/53N antigen associations must be consistent with HLA DR locus antigens/alleles

HLA type submitted:

	LA broad	HLA spli			HLA broad	HLA split			
	specificity	specifici	ty allele(s)	_	specificity	specificity	allele	e(s)	
HLA -A	1				2				
-B	7				17	57			Bw4,6
-DR	2	15			4				DR53
-Cw	6				7				
-DQB1	1	6			3	7			
_				_					
-DRB3					-DRB4				
alleles					alleles				
-DRB5									
alleles]					

DR15(2) is not consistent with DR53

Auto generated error message:

The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type

	HLA broad specificity			HLA broad specificity	HLA split specificity	HLA allele(s)	
HLA -A	1		02	2			
-B	7			17	57		Bw4,6
-DR	2	15		4			DR51,53
-Cw	6			7			
-DQB1	1	6		3	7		
-DRB3 alleles -DRB5				-DRB4 alleles			
alleles							

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 5

Rule 4: DR51/51N/52/53/53N antigen associations must be consistent with HLA DR locus antigens/alleles

HLA type submitted:

	HLA broad	∣ HLA sp	olit HLA	HLA broad	HLA split	HLA	
	specificity	specifici	ty allele(s)	specificity	specificity	allele(s)	
HLA -A			01			23	
-B			80			49	Bw4,6
-DR			03:01/04			04	DR52
-Cw			07				
-DQB1			02			03:01/09/10	
							_
-DRB3	01	1		-DRB4			
alleles				alleles			
-DRB5							
alleles							

DRB1*04 is not consistent with DR52

Auto generated error message:

The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type

	HLA broad specificity	HLA spli		HLA broad specificity	HLA split specificity	HLA allele(s)	
HLA -A			01			23]
-B			80			49	Bw4,6
-DR	2		03:01/04			13	DR52
-Cw	,		07				
-DQB1			02			03:01/09/10	
				_			
-DRB3				-DRB4			
alleles				alleles			
-DRB5							
alleles							

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 6

Rule 5:

DRB3/4/5 allele associations must be consistent with HLA DR locus antigens/alleles and DR51/51N/52/53/53N antigens

HLA type submitted:

	HLA broad	l HLA split	HLA		HLA broad	HLA split	HL	.A	
	specificity	specificity	allele(s)		specificity	specificity	alle	le(s)	_
HLA -A			02						
-B			15:01/04				5	57	Bw4,6
-DR			03:01/04				0	7	DR52,53
-Cw			12:03/6				05:0	1/3/4	
-DQB1			03:01/4				03	:03	
				_					
-DRB3			01		-DRB4	01:03:01:	02N		
alleles					alleles				
-DRB5									
alleles									

DRB4*01:03:01:02N is not consistent with DR53

Auto generated error message:

The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type

	HLA broad specificity	HLA split specificity			HLA broad specificity	HLA split specificity	HL. allel		
HLA -A			02						
-B			15:01/04				5	7	
-DR			03:01/04				0	7	DR52,53N
-Cw			12:03/6				05:0	1/3/4	
-DQB1			03:01/4				03:	03	
				_					
-DRB3			01		-DRB4	01:03:01:	02N		
alleles					alleles				
-DRB5									
alleles									

Reporting of Deceased Donor HLA Types to NHSBT-ODT

Appendix 1

Examples of Non valid and Revised HLA types

Example 7

Rule 5:

DRB3/4/5 allele associations must be consistent with HLA DR locus antigens/alleles and DR51/51N/52/53/53N antigens

HLA type submitted:

	HLA broad specificity	HLA sp		HLA broad specificity	HLA sp		.A le(s)		
HLA -A	1		01	11	<u> </u>	11			
-B	22	55	55	17	57	57		Bw4,6	1
-DR	3	17	03:01/04	4		04		52	
-Cw	3	9	03:03/11/12	6		6			
-DQB1	2		02	3	7	03:01/09	/10/1		
-DRB3 alleles -DRB5 alleles				-DRB4 alleles	0	1			

DR4 DRB1*04 is not consistent with DR52 DR17(3) DRB1*0301 is not consistent with DRB4*01 DRB4*01 is not consistent with DR52

Auto generated error message:

The reported HLA type displays an unlikely DR51/52/53 or DRB3*/4*/5* association with reported DR locus antigens. Please check HLA type

	HLA broad specificity	HLA sp		HLA broad specificity	HLA sp		A le(s)	
HLA -A	1		01	11		11		
-B	22	55	55	17	57	57	,	Bw4,6
-DR	3	17	03:01/04	4		04	ļ	52,53
-Cw	3	9	03:03/11/12	6		6		
-DQB1	2		02	3	7	03:01/09)/10/13	
-DRB3 alleles -DRB5	01-03			-DRB4 alleles	0	1		