



New South Wales

# Human Tissue Regulation 2020

under the

Human Tissue Act 1983

[*The following enacting formula will be included if this Regulation is made:*]

Her Excellency the Governor, with the advice of the Executive Council, has made the following Regulation under the *Human Tissue Act 1983*.

Minister for Health and Medical Research

## Explanatory note

The object of this Regulation is to remake, with minor changes, the *Human Tissue Regulation 2015*, which is repealed on 1 September 2020 by section 10(2) of the *Subordinate Legislation Act 1989*.

This Regulation provides for the following—

- (a) the organisms and substances that are prescribed contaminants,
- (b) the classes of medical practitioners who are eligible to be appointed as designated specialists,
- (c) the certificate required to be completed by a person donating blood,
- (d) the amount of blood or blood products that will give rise to a presumption that a person is carrying on a business of supplying blood or blood products,
- (e) the means by which a senior available next of kin of a deceased person may give consent to the removal of tissue from the person,
- (f) savings and formal matters.

This Regulation is made under the *Human Tissue Act 1983*, including sections 4(1) (definition of **prescribed contaminant**), 5(2)(b), 20D (definitions of **certificate** and **prescribed witness**), 20F(6) (definition of **prescribed contaminant**), 21A(b), 23(3)(b), 24(3), 34(1)(b2) and 39 (the general regulation-making power).

This Regulation comprises or relates to matters set out in Schedule 3 to the *Subordinate Legislation Act 1989*, namely matters of a machinery nature and matters that are not likely to impose an appreciable burden, cost or disadvantage on any sector of the public.

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# public consultation draft

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Human Tissue Regulation 2020 [NSW]  
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## Human Tissue Regulation 2020

under the

Human Tissue Act 1983

### 1 Name of Regulation

This Regulation is the *Human Tissue Regulation 2020*.

### 2 Commencement

This Regulation commences on 1 September 2020 and is required to be published on the NSW legislation website.

**Note.** This Regulation replaces the *Human Tissue Regulation 2015*, which is repealed on 1 September 2020 by section 10(2) of the *Subordinate Legislation Act 1989*.

### 3 Definition

(1) In this Regulation—

*the Act* means the *Human Tissue Act 1983*.

**Note.** The Act and the *Interpretation Act 1987* contain definitions and other provisions that affect the interpretation and application of this Regulation.

(2) Notes included in this Regulation do not form part of this Regulation.

### 4 Prescribed contaminants

For the purposes of the definitions of *prescribed contaminant* in sections 4(1) and 20F(6) of the Act, the following organisms or substances are prescribed or declared—

- (a) hepatitis B virus,
- (b) hepatitis B surface antigen,
- (c) hepatitis C virus,
- (d) hepatitis C antibody,
- (e) Human Immunodeficiency Virus (HIV),
- (f) Human Immunodeficiency Virus (HIV) antibody,
- (g) Human T-Lymphotropic Virus Type-I (HTLV-I),
- (h) Human T-Lymphotropic Virus Type-I (HTLV-I) antibody,
- (i) treponema pallidum,
- (j) treponema pallidum-related antibody.

### 5 Classes of designated specialists

(1) For the purposes of section 5(2)(b) of the Act, a person who holds a specialist registration in one of the following specialties is prescribed—

- (a) anaesthesia,
- (b) emergency medicine,

- (c) intensive care medicine,
  - (d) obstetrics and gynaecology,
  - (e) physician,
  - (f) surgery.
- (2) In this clause—
- health profession** has the same meaning as in the *Health Practitioner Regulation National Law (NSW)*.
- specialist registration** means a person who holds a specialist registration in a recognised specialty in a health profession in accordance with Division 2 of Part 7 of the *Health Practitioner Regulation National Law (NSW)*.

## 6 Certificates

- (1) For the purposes of the definition of **certificate** in section 20D(1) of the Act, the prescribed form of the certificate is set out in Schedule 1.
- (2) For the purposes of section 20D(2) of the Act, the following persons, if employed where the blood is to be removed, are **prescribed witnesses**—
- (a) medical practitioners,
  - (b) nurses,
  - (c) persons employed to work as donor services nursing assistants at the Australian Red Cross Society,
  - (d) persons who have been nominated by their employer, and approved by the Secretary in writing, as appropriate persons to witness signatures.
- (3) A certificate signed for the purposes of section 20D of the Act must be retained, for a period of not less than 10 years from the date on which it was signed, by—
- (a) the person who removed the blood, or
  - (b) if the person who removed the blood did so in the person's capacity as an employee or agent of some other person or body—that other person or body.
- Maximum penalty—2 penalty units.

## 7 Presumption that person is carrying on blood supply business

For the purposes of section 21A(b) of the Act—

- (a) the prescribed quantity of blood is 1 litre, and
- (b) the prescribed quantity of blood products is, in relation to any particular kind of blood product, the quantity of blood products of that kind that can be derived or extracted from 1 litre of blood.

## 8 Removal of tissue after death

- (1) For the purposes of sections 23(3)(b) and 24(3) of the Act, the consent of a senior available next of kin of a deceased person may be given verbally if—
- (a) an audio or audio visual recording is made of the consent, and
  - (b) the senior available next of kin has consented to the making of that audio or audio visual recording.
- Note.** See section 23 of the Act for other manners in which consent may be given.
- (2) For the purposes of section 34(1)(b2) of the Act, tissue may be retained for a period not exceeding 72 hours if the tissue was removed from the body of a person during medical, dental or surgical treatment performed as a matter of urgency in order to save the life of the person or to prevent serious damage to the health of the person.

**9 Savings**

Any act, matter or thing that, immediately before the repeal of the *Human Tissue Regulation 2015*, had effect under that Regulation continues to have effect under this Regulation.

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Human Tissue Regulation 2020 [NSW]  
Schedule 1 Blood donor certificate

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## Schedule 1 Blood donor certificate

(Clause 6(1))

(Human Tissue Act 1983, section 20D)

### Questions

(Please circle your answers)

- |    |  |                    |
|----|--|--------------------|
| 1  | To the best of your knowledge, have you ever thought you could be infected with HIV or have AIDS?  | Yes/No             |
| 2  | To the best of your knowledge, have you ever had a test which showed you had hepatitis B, hepatitis C, HIV or HTLV?  | Yes/No             |
| 3  | To the best of your knowledge, in the last 5 years, have you “used drugs” by injection or been injected with drugs not prescribed by a doctor or dentist?  | Yes/No             |
| 4  | In the last 12 months, have you had an illness with both a rash and swollen glands, with or without a fever?   | Yes/No             |
| 5  | In the last 12 months, have you engaged in sexual activity with someone who—<br>(a) you think could be infected with HIV or have AIDS?<br>(b) had a test which showed they had hepatitis B, hepatitis C, HIV or HTLV?<br>(c) ever “used drugs” by injection or has been injected with drugs not prescribed by a doctor or dentist?<br>(d) had an illness with both a rash and swollen glands, with or without a fever? | Yes/No             |
| 6  | In the last 12 months, have you had sexual activity with a new partner who currently lives or has previously lived overseas?   | Yes/No             |
| 7  | In the last 12 months, have you had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man?  | Yes/No             |
| 8  | In the last 12 months, have you had male-to-male sex (that is, oral or anal sex) with or without a condom?   | Yes/No/I am female |
| 9  | In the last 12 months, have you been a sex worker (eg received payment for sex in money, gifts or drugs)?  | Yes/No             |
| 10 | In the last 12 months, have you engaged in sexual activity with a sex worker?  | Yes/No             |
| 11 | In the last 12 months, have you been imprisoned in a prison or held in a lock-up or detention centre?  | Yes/No             |
| 12 | In the last 12 months, have you had a blood transfusion?   | Yes/No             |
| 13 | In the last 12 months, have you had (yellow) jaundice or hepatitis or been in contact with someone who has?  | Yes/No             |
| 14 | In the last 4 months, have you been injured with a used needle (needlestick)?  | Yes/No             |
| 15 | In the last 4 months, have you had blood or other bodily fluid come into contact with your eyes, mouth, nose or to broken skin?  | Yes/No             |
| 16 | In the last 4 months, have you had a tattoo, body and/or ear piercing or acupuncture?  | Yes/No             |

I declare that I have understood the information on this form and have answered the questions in the declaration honestly and to the best of my knowledge. I understand that there are penalties, including fines and imprisonment, for providing false or misleading information.

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# public consultation draft

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Human Tissue Regulation 2020 [NSW]  
Schedule 1 Blood donor certificate

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**Donor (please print)**

Surname/family name

Given name

Date of birth

**Please ONLY sign in the presence of the interviewer**

Signature

Date