

Blood and Tissue (Transmissible Diseases) Regulations 1985

Compare between:

[02 Apr 2011, 01-c0-01] and [22 May 2012, 01-d0-01]

Health Act 1911

Blood and Tissue (Transmissible Diseases) Regulations 1985

1. Citation

These regulations may be cited as the *Blood and Tissue* (*Transmissible Diseases*) Regulations 1985 ¹.

2. Interpretation

- In these regulations —
 blood includes any substance derived from blood.
- (2) A reference in these regulations to the donating of blood shall be read as including a reference to the donating of any substance obtained from the blood, or of any ovum or semen.

[Regulation 2 inserted in Gazette 17 May 1991 p. 2480.]

3. The taking of blood without a declaration

- (1) Subject to this regulation, a person shall not
 - (a) take any blood intended for the rapeutic use; or
 - (b) knowingly accept for therapeutic use any blood donated, unless the person donating the blood made a declaration in the form prescribed by these regulations within the 12 hours preceding the donation of the blood.
- (2) Where the donor of any blood is by reason of injury or illness incapable of making a declaration in the form prescribed by these

regulations, a person who takes, or accepts a donation of, blood from that donor for the apeutic use where the circumstances are such as to be, in the opinion of a person who is a designated officer, or the delegate of a designated officer, for the purposes of the Human Tissue and Transplant Act 1982, medically justifiable shall not be taken to have contravened subregulation (1).

- The taking or accepting of blood that is intended (3)
 - for the use of the donor; or (a)
 - (b) for a use other than a therapeutic use,

shall be taken not to contravene subregulation (1) notwithstanding that no declaration is made in respect of that blood.

[Regulation 3 amended in Gazette 13 May 1988 p. 1596.]

4. **Declaration to be required from donor**

A person who intends to donate blood for the rapeutic use is required to furnish in writing to the person taking the blood at the time of donating that blood a declaration made in the form prescribed by these regulations before a witness who is authorised by these regulations to permit such a declaration to be made in their presence, that declaration having been made within the preceding 12 hours, and shall not donate blood unless such a declaration is furnished.

[Regulation 4 amended in Gazette 13 May 1988 p. 1596.]

5. Person authorised to permit declarations to be made

For the purpose of taking declarations required by these regulations, a person who is within one of the following categories of authorised persons may permit such a declaration to be made before them —

a person who is an authorised witness for a statutory declaration in accordance with the Oaths, Affidavits and Statutory Declarations Act 2005 section 12(6);

- (b) a person who is a designated officer, or the delegate of a designated officer, for the purposes of the *Human Tissue* and *Transplant Act 1982*;
- [(c) deleted]
- (d) a staff member of the Red Cross Blood Transfusion Service,
- [(e) deleted]

and shall state his or her full name on and sign the declaration, date it and endorse on it the time at which it was made and the category of authorisation to which he or she belongs.

[Regulation 5 amended in Gazette 13 May 1988 p. 1596; 1 Apr 2011 p. 1177.]

6. The form of declaration

For the purposes of these regulations, the form of declaration to be furnished shall comply with the form set out in Schedule 1.

[Regulation 6 inserted in Gazette 13 May 1988 p. 1596; amended in Gazette 12 Feb 1999 p. 474.]

7. Offences

A person who contravenes regulation 3(1) or 4 commits an offence and is liable to a penalty of not more than \$1 000 and not less than —

- (a) in the case of a first offence, \$100;
- (b) in the case of a second offence, \$200; and
- (c) in the case of a third or subsequent offence, \$500.

[Regulation 7 inserted in Gazette 13 May 1988 p. 1596.]

Schedule 1 — Blood donor declaration

[r. 6]

[Heading inserted in Gazette 22 Jun 2010 p. 2769.]

There are some people in the community who MUST NOT give blood as it may transmit infections to people who receive it. So before you give blood we need you to answer some questions to ensure that it will be safe for people to be given your blood or blood products. The following questions are a vital part of our effort to eliminate these diseases from the blood supply.

Even though there are a lot of questions they are all important and you need to answer every question on the form honestly and to the best of your ability. Answering these questions honestly is important because THERE ARE PENALTIES INCLUDING FINES AND/OR IMPRISONMENT FOR GIVING FALSE OR MISLEADING ANSWERS TO ANY OF THE QUESTIONS.

All donations of blood are tested for the presence of Hepatitis B and C, HIV 1 and 2 (AIDS virus), syphilis and HTLV I and II. Should your blood test be positive for any of these diseases or show a significantly abnormal result you will be notified.

DECLARATION

Thank you for answering the following questions.

If you are uncertain about how you should answer any of the questions please discuss your concerns with the interviewer.

You will be asked to sign this declaration in the presence of the interviewer once you have answered all the questions.

Please respond by placing a cross or a tick in the relevant box. Do not circle.

To the best of your knowledge have you:

In the last 12 months had an illness with swollen glands and a rash, with or without a fever?	□ Yes□ No
Ever thought you could be infected with HIV or have AIDS?	□ Yes□ No

Blood and Tissue (Transmissible Diseases) Regulations 1985 Blood donor declaration Schedule 1

3.	Ever "used drugs" by injection or been injected, even once, with drugs not prescribed by your doctor or dentist?	□ Yes□ No
4.	Ever had treatment with clotting factors such as Factor VIII or Factor IX?	□ Yes□ No
5.	Ever had a test which showed you had Hepatitis B, Hepatitis C, HIV or HTLV?	□ Yes□ No
6.	In the last 12 months have you engaged in sexual activity with someone you might think would answer "yes" to any of questions 1-5?	□ Yes□ No
7.	Since your last donation or in the last 12 months have you had sexual activity with a new partner who currently lives or who has previously lived overseas?	□ Yes□ No
With	in the last 6 months have you:	
8.	Had a tattoo (including cosmetic tattooing), body and/or ear piercing, electrolysis or acupuncture?	□ Yes□ No
	- · · · · · · · · · · · · · · · · · · ·	
With	in the last 12 months have you:	
With 9.	hin the last 12 months have you: Had male to male sex (that is, oral or anal sex) with or without a condom?	□ Yes□ No
	Had male to male sex (that is, oral or anal sex) with	□ Yes□ No
9.	Had male to male sex (that is, oral or anal sex) with or without a condom? Had sex (with or without a condom) with a man who you think may have had oral or anal sex with	
9. 10.	Had male to male sex (that is, oral or anal sex) with or without a condom? Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man? Been a male or female sex worker (e.g. received	□ Yes□ No
9. 10. 11.	Had male to male sex (that is, oral or anal sex) with or without a condom? Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man? Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)? Engaged in sexual activity with a male or female	□ Yes□ No
9. 10. 11. 12.	Had male to male sex (that is, oral or anal sex) with or without a condom? Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man? Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)? Engaged in sexual activity with a male or female sex worker?	□ Yes□ No □ Yes□ No □ Yes□ No
9. 10. 11. 12.	Had male to male sex (that is, oral or anal sex) with or without a condom? Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man? Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)? Engaged in sexual activity with a male or female sex worker? Been injured with a used needle (needlestick)? Had a blood/body fluid splash to eyes, mouth, nose	 □ Yes □ No □ Yes □ No □ Yes □ No □ Yes □ No
9. 10. 11. 12. 13. 14.	Had male to male sex (that is, oral or anal sex) with or without a condom? Had sex (with or without a condom) with a man who you think may have had oral or anal sex with another man? Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)? Engaged in sexual activity with a male or female sex worker? Been injured with a used needle (needlestick)? Had a blood/body fluid splash to eyes, mouth, nose or to broken skin?	 □ Yes □ No

Compare 02 Apr 2011 [01-c0-01] / 22 May 2012 [01-d0-01]

page 5

Blood and Tissue (Transmissible Diseases) Regulations 1985 Blood donor declaration Schedule 1

17.	Had (yellow) jaundice or hepatitis or been in	
	contact with someone who has?	□ Yes□ No

In making this declaration I understand that —

- as scientific knowledge advances, I may be asked to undergo further blood tests; and
- my donation is a gift, which may be used for therapeutic purposes and in some instances for the manufacture of diagnostic agents and research; and
- there are penalties, including fines and imprisonment, for providing false or misleading information.

I have also been advised by the interviewer that —

- there are some possible risks associated with donating blood; and
- I must follow the instructions of the staff to minimise those risks.

I hereby declare that I have answered the above questions honestly and to the best of my knowledge.		
Donor's signature:	Witness' signature:	
Print full name:	Print full name:	
Donation number:	Category of authorisation:	
	Date and time of declaration:	

[Schedule 1 inserted in Gazette 22 Jun 2010 p. 2769-71.]

Notes

This is a compilation of the *Blood and Tissue (Transmissible Diseases)* Regulations 1985 and includes the amendments made by the other written laws referred to in the following table $\frac{1a}{2}$. The table also contains information about any reprint.

Compilation table

Citation	Gazettal	Commencement
Blood and Tissue (Transmissible Diseases) Regulations 1985	8 Feb 1985 p. 517-19	8 Feb 1985
Blood and Tissue (Transmissible Diseases) Amendment Regulations 1986	12 Sep 1986 p. 3350	12 Sep 1986
Blood and Tissue (Transmissible Diseases) Amendment Regulations 1988	13 May 1988 p. 1596-7	13 May 1988
Blood and Tissue (Transmissible Diseases) Amendment Regulations 1991	17 May 1991 p. 2480-1	17 May 1991
Blood and Tissue (Transmissible Diseases) Amendment Regulations 1999	12 Feb 1999 p. 474-7	12 Feb 1999

Reprint of the *Blood and Tissue (Transmissible Diseases) Regulations 1985* as at 11 Oct 2002 (includes amendments listed above)

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Blood and Tissue (Transmissible Diseases) Amendment Regulations 2010	22 Jun 2010 p. 2769-71	r. 1 and 2: 22 Jun 2010 (see r. 2(a)); Regulations other than r. 1 and 2: 4 Jul 2010 (see r. 2(b))
Blood and Tissue (Transmissible Diseases) Amendment Regulations 2011	1 Apr 2011 p. 1177	r. 1 and 2: 1 Apr 2011 (see r. 2(a)); Regulations other than r. 1 and 2: 2 Apr 2011 (see r. 2(b))
Blood and Tissue (Transmissible <u>Diseases</u>) Amendment <u>Regulations 2012 r. 1 and 2</u>	22 May 2012 p. 2163-6	22 May 2012 (see r. 2(a))

On the date as at which this compilation was prepared, provisions referred to in the following table had not come into operation and were therefore not included in this compilation. For the text of the provisions see the endnotes referred to in the table.

Compare 02 Apr 2011 [01-c0-01] / 22 May 2012 [01-d0-01]

Provisions that have not come into operation

Citation	Gazettal	Commencement
Blood and Tissue (Transmissible Diseases) Amendment	22 May 2012 p. 2163-6	1 Jul 2012 (see r. 2(b))
<i>Regulations 2012</i> r. 3-5 ²		

On the date as at which this compilation was prepared, the *Blood and Tissue* (Transmissible Diseases) Amendment Regulations 2012 r. 3-5 had not come into operation. They read as follows:

Regulations amended

These regulations amend the *Blood and Tissue (Transmissible* Diseases) Regulations 1985.

Regulation 2A inserted

After regulation 1 insert:

Regulations operate as local laws

Under section 343A of the Act, these regulations apply as if they were local laws made by each local government.

Schedule 1 replaced

Delete Schedule 1 and insert:

Schedule 1 — Blood donor declaration

[r. 6]

There are some people who MUST NOT give blood as it may transmit infections to those people who receive it. To determine if your blood or blood products will be safe to be given to people in need, we would like you to answer some questions. These questions are a vital part of our efforts to eliminate diseases from the blood supply.

All of the questions are important to answer. Answer each question on the form as honestly as you can and to the best of your knowledge. THERE ARE PENALTIES INCLUDING FINES AND IMPRISONMENT FOR ANYONE PROVIDING FALSE OR MISLEADING INFORMATION.

All donations of blood are tested for the presence of hepatitis B and C, HIV (the AIDS virus), HTLV and syphilis. If your blood test proves positive for

	of these conditions, or for any reason the test shows ormal result, you will be informed.	a significantly
Pleas	se respond by placing a cross or a tick in the relevan	t box. Do not circle.
To th	ne best of your knowledge, have you ever:	
1	Thought you could be infected with HIV or have AIDS?	□ Yes □ No
2.	"Used drugs" by injection or been injected, even once, with drugs not prescribed by a doctor or dentist?	□ Yes □ No
3.	Had treatment with clotting factors such as Factor VIII or Factor IX?	□ Yes □ No
<u>4.</u>	Had a test which showed you had hepatitis B, hepatitis C, HIV or HTLV?	□ Yes □ No
In th	e last 12 months have you:	
<u>5.</u>	Had an illness with swollen glands and a rash, with or without a fever?	□ Yes □ No
6.	Engaged in sexual activity with someone you might think would answer "yes" to any of questions 1-5?	□ Yes □ No
<u>7.</u>	Had sexual activity with a new partner who currently lives or who has previously lived overseas?	□ Yes □ No
8.	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
9.	Had male to male sex (that is, oral or anal sex) with or without a condom? (Females please tick "I am female")	☐ Yes ☐ No I am female ☐
<u>10.</u>	Been a male or female sex worker (e.g. received payment for sex in money, gifts or drugs)?	□ Yes □ No
<u>11.</u>	Engaged in sexual activity with a male or female sex worker?	□ Yes □ No
<u>12.</u>	Been imprisoned in a prison or been held in a lock-up or detention centre?	□ Yes □ No
13.	Had a blood transfusion?	□ Yes □ No

Compare 02 Apr 2011 [01-c0-01] / 22 May 2012 [01-d0-01]

<u>14.</u>	Had (yellow) jaundice or hepatitis or been in contact with someone who has?	□ Yes □ No
In th	e last 6 months have you:	
<u>15.</u>	Been injured with a used needle (needlestick)?	☐ Yes ☐ No
<u>16.</u>	Had a blood/body fluid splash to eyes, mouth, nose or to broken skin?	☐ Yes ☐ No
<u>17.</u>	Had a tattoo (including cosmetic tattooing), body and/or ear piercing, electrolysis or	- W - W
	acupuncture (including dry-needling)?	□ Yes □ No

Thank you for answering these questions. If you are uncertain about any of your answers, please discuss them with your interviewer.

We would like you to sign this declaration in the presence of your interviewer to show that you have understood the information on this form and have answered the questions in the declaration to the best of your knowledge.

Your donation is a gift to be used to treat patients. In some circumstances, your donation may be used for the purposes of research, teaching, quality assurance or the making of essential diagnostic reagents (including commercial reagents). A part of your donation will also be stored for possible future testing and research; samples that are no longer required will be destroyed. Approval from an appropriate Human Research Ethics Committee is required before any research is undertaken on your donation or any part of it.

You may be asked to undergo further testing, which you have the option to decline.

Should you become aware of any reason why your blood should not be used for transfusion after your donation, please call us. In particular, if you develop a cough, cold, diarrhoea or other infection within a week after donating, please report it immediately.

I agree to have blood taken from me under the conditions above and —

- I have been provided with "Information about the risk of donating blood". I have read and understood this information and have had the opportunity to ask questions. I accept the risks associated with donation and agree to follow the instructions of the staff to minimise these risks.
- I declare that I have understood the information on this form and 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.

page 10

Blood and Tissue (Transmissible Diseases) Regulations 1985

Donor	Witness
Surname/ Family name:	Surname/ Family name:
Given name:	Given name:
Date of birth:	Signature:
Signature:	Date:
Date:	Time:
	Donation number:

Compare 02 Apr 2011 [01-c0-01] / 22 May 2012 [01-d0-01]