Maternity - Rh (D) Immunoglobulin (Anti D)

Summary This guideline provides direction to NSW maternity service providers, emergency departments and general practitioners regarding the use of Rh (D) Immunoglobulin (Anti-D). Rh (D) Immunoglobulin is used as a prophylactic treatment and or treatment for potential sensitising events for Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation).

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Distributed to Public Health System, Divisions of General Practice, Ministry of Health, Private Hospitals and Day Procedure Centres, Tertiary Education Institutes

Audience General practitioners;all clinicians in Maternity Services;Emergency Departments

NSW GOVERNMENT Health

GUIDELINE SUMMARY

MATERNITY – Rh (D) IMMUNOGLOBULIN (ANTI-D)

PURPOSE

This guideline provides direction to NSW maternity service providers, emergency departments and general practitioners regarding the care of rhesus (Rh) (D) negative women and the use of Rh (D) Immunoglobulin (Anti-D).

Rh (D) Immunoglobulin is used as prophylaxis treatment and or treatment for potential sensitising events for Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation).

KEY PRINCIPLES

All pregnant women should be typed for ABO and Rh (D) as early as possible during each pregnancy.

All Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation), should be provided with information both verbal and written on their rhesus status and Rh (D) Immunoglobulin.

All Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation), should be offered Rh (D) Immunoglobulin prophylactically and or for potential sensitising events.

All Rh negative women should sign the consent/decline to treatment form.

USE OF THE GUIDELINE

The guideline for the use of Rh (D) Immunoglobulin should be used by general practitioners and all staff working in NSW Health Maternity Services or Emergency Departments who are providing care to Rh negative women who are pregnant or recently pregnant (up to 10 days post pregnancy cessation).

- Midwives
- Nurses
- Obstetricians
- Medical Officers
- General Practitioners

REVISION HISTORY

Version	Approved by	Amendment notes
September-2015 GL2015_011	Deputy Secretary, Population and Public Health	Replaces GL2014_017. Additional guidance provided on when to do a feto-maternal haemorrhage test.
August-2014 GL2014_017	Deputy Secretary, Population and Public Health	Replaces PD2006_074. Provides greater guidance around recommendations however clinical information remains the same. Additions are an algorithm as a quick guide for clinical staff and a statewide patient consent form.
29-Aug-2006 PD2006_074	Director-General	Revised policy replacing PD2005_524
22-Feb-2005 PD2005_524	Director-General	New policy

ATTACHMENTS

1. Guideline: Maternity – Rh (D) Immunoglobulin (Anti-D)

NSW KIDS + FAMILIES

MATERNITY + RH(D) IMMUNOGLOBULIN (ANTI D)

GUIDELINE

NSW GOVERNMENT Health

healthy, safe and well

CONTENTS

1 INTRODUCTION

1.1 Purpose

This guideline provides direction to NSW maternity service providers, emergency departments and general practitioners regarding the care of rhesus (Rh) (D) negative women and the use of Rh (D) Immunoglobulin (Anti-D). Table 1 gives a summary of the recommendations for the use of Rh (D) Immunoglobulin.

1.2 Background

Rh (D) Immunoglobulin (Anti-D) is used to protect against Haemolytic Disease of the Newborn (HDN) which has the potential to occur in neonates born to women with Rh (D) negative blood. HDN prevention in neonates is vital owing to the potentially serious complications that can occur.

1.3 Product information, ordering and distribution

1.3.1 Table 1: Product information

Product	Presentation	Dose	Administration	
Rh(D) Immunoglobulin-VF	Single vial	**250 IU**	Slow deep intramuscular injection	Table 2 page 3
Rh(D) Immunoglobulin-VF	Single vial	**625 IU**	Slow deep intramuscular injection	Table 2 page 3 Table 3 page 4
Rhophylac®	Single-use prefilled 2 mL syringe	**1500 IU**	Intravenous or intramuscular injection	Table 2 page 3 Table 3 page 4
NOTE: At times a substitute product may be provided from supplier				

For detailed product information see:

Rh (D) Immunoglobulin - CSL product information at http://www.csl.com.au/s1/cs/auhq/1196562765747/Web_Product_C/1196562710368/ProductDetail.htm

Rhophylac® - CSL product information at http://www.csl.com.au/s1/cs/auhq/1196562765747/Web_Product_C/1255926737064/ProductDetail.htm

Australian Rh (D) Immunoglobulin-VF and Rhophylac® is produced by CSL Limited and is distributed by the Australian Red Cross Blood Service to registered Australian Hospital Providers.

1.4 Relevant NSW Health Policy Directives and Guidelines

This guideline should be read in conjunction with the following policy directives:

PD2012_016 Blood - Management of Fresh Blood Components

(http://www0.health.nsw.gov.au/policies/pd/2012/PD2012_016.html)

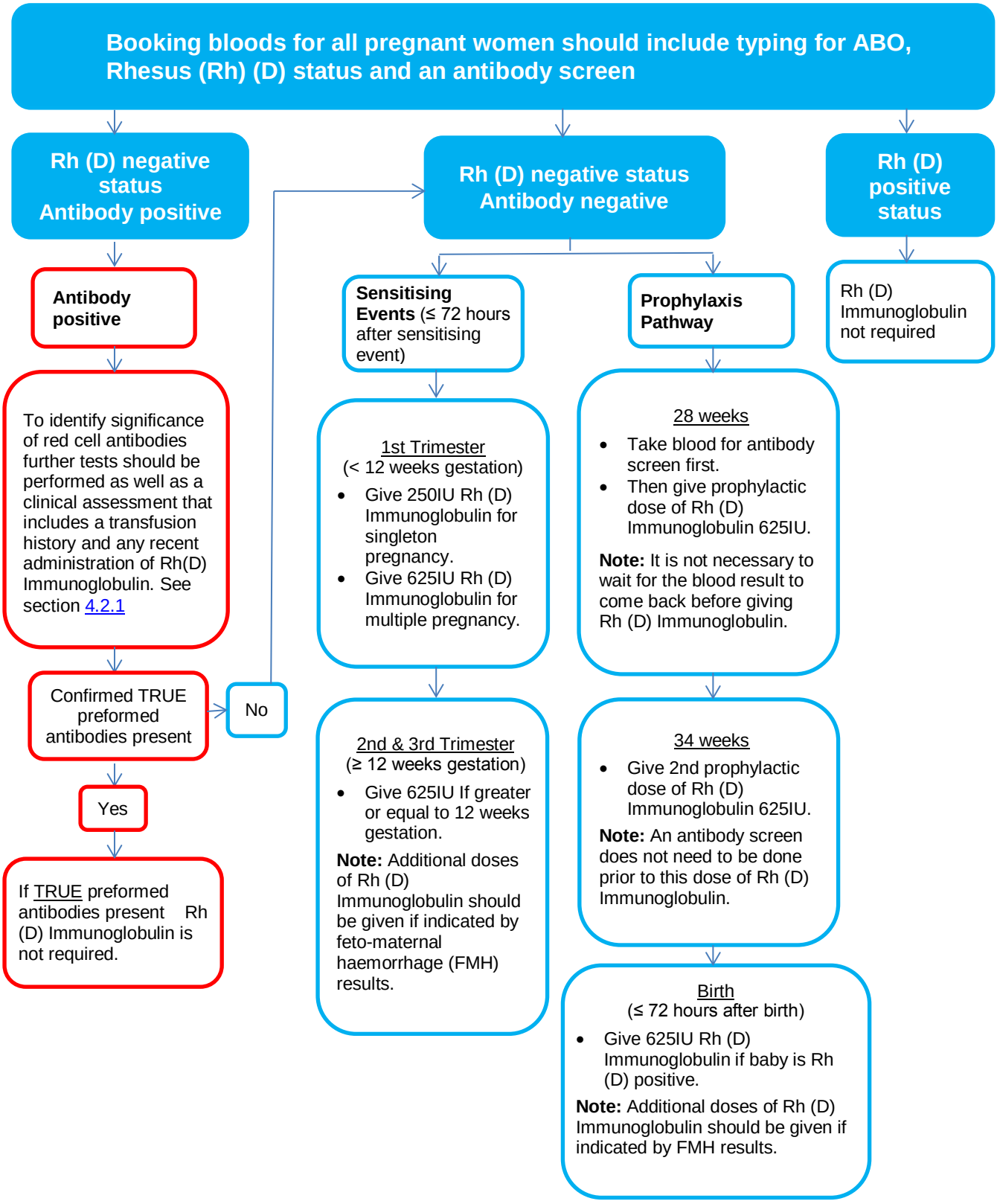
PD2005_406 Consent to medical treatment – Patient Information
(http://www.health.nsw.gov.au/policies/PD/2005/pdf/PD2005_406.pdf)

1.5 Abbreviations

1.5.1 Table 2: Abbreviations

Abbreviations	
Rh	Rhesus
FMH	Feto-maternal haemorrhage
mL	Millilitre
DAT	Direct antibody test (also known as the Coombs test). For the purpose of this guideline DAT will be used
BMI	Body Mass Index

2 RHESUS (D) STATUS IN PREGNANT WOMEN: CARE PATHWAY



NOTE: If Rh (D) Immunoglobulin has not been administered within 72 hours of either a sensitising event or birth a dose offered within 9 - 10 days may still provide protection[1].

3 USE OF Rh (D) IMMUNOGLOBULIN[1]

3.1 Table 3: Use of Rh (D) Immunoglobulin

POTENTIAL SENSITISING EVENTS*		PROPHYLAXIS	
1st Trimester (< 12 weeks gestation)	**2nd and 3rd Trimester** (≥ 12 weeks gestation)	**Antenatal**	**Postnatal**
Indication: Potential sensitising event.	**Indication:** Potential sensitising event.	**Indication:** All Rh (D) negative women at 28 and 34 weeks gestation with no preformed anti-D antibodies.	**Indication:** All Rh (D) negative women who give birth to a Rh (D) positive baby unless it has been clearly documented that the woman already has preformed antibodies (alloimmunisation).
Product & Dose Rh (D) immunoglobulin-VF **250 IU** for singleton pregnancies **625 IU** for multiple pregnancies	**Product & Dose** Rh (D) immunoglobulin-VF **625 IU** with additional doses to be given as indicated by results from the assessment of feto-maternal haemorrhage**.**	**Product & Dose** Rh (D) Immunoglobulin-VF **625 IU**.	**Product & Dose** Rh (D) Immunoglobulin-VF **625 IU** with additional doses to be given as indicated by the results from the assessment of feto-maternal haemorrhage.
Route of administration: Given slowly by deep intramuscular injection	**Route of administration:** Given slowly by deep intramuscular injection	**Route of administration:** Given slowly by deep intramuscular injection	**Route of administration:** Given slowly by deep intramuscular injection

NOTE: In some circumstances, intravenous administration of Rh (D) Immunoglobulin may be warranted in which case the intravenous preparation of Rh (D) Immunoglobulin (RHOPHYLAC®) should be used.

***POTENTIAL SENSITISING EVENTS**
Including:

- ectopic pregnancy
- termination of pregnancy
- miscarriage
- ultrasound guided procedures such as:
  - chorionic villus sampling
  - amniocentesis
  - cordocentesis
  - fetoscopy
- abdominal trauma that causes uterine activity and or abdominal pain
- antepartum haemorrhage
- external cephalic version
- birth

NOTE: Rh (D) Immunoglobulin prophylaxis is a completely separate administration from Rh (D) Immunoglobulin required for potentially sensitising events regardless of when Rh (D) Immunoglobulin has previously been administered**.**

CONTRAINDICATIONS
Rh (D) Immunoglobulin should not be given to women:

- with preformed anti-D antibodies (alloimmunisation), except where the preformed antibodies are due to antenatal administration of Rh (D) Immunoglobulin;
- who are Rh (D) positive;
- who are Immunoglobulin A deficient, unless they have been tested and shown not to have circulating anti-IgA antibodies;
- with a history of anaphylactic or other severe systemic reaction to Immunoglobulins.

For women with severe thrombocytopenia or a coagulation disorder that contraindicates intramuscular injection, the intravenous preparation of Rh (D) Immunoglobulin should be used.

4 ADMINISTRATION OF Rh (D) IMMUNOGLOBULIN

Prophylactic Rh (D) Immunoglobulin and Rh (D) Immunoglobulin administered for potentially sensitising events should be viewed as a completely separate administration. Prophylactic Rh (D) Immunoglobulin is not an alternative to Rh (D) Immunoglobulin administered for potentially sensitising events and vice versa. Prophylactic Rh (D) Immunoglobulin should be given irrespective of whether Rh (D) Immunoglobulin has been administered for a potentially sensitising event. Similarly, potential sensitising events that occur after administration of Prophylactic Rh (D) Immunoglobulin should be covered with an additional dose of Rh (D) Immunoglobulin 625IU/mL; unless feto-maternal haemorrhage (FMH) test indicates that a larger dose is required[2].

If Rh (D) Immunoglobulin has not been administered within 72 hours of either a sensitising event or birth a dose offered within 9 - 10 days may still provide protection[1].

4.1 Table 2: Rh (D) Immunoglobulin Dosage

Rh (D) Immunoglobulin dosage as determined by size of FMH
This table is a guide:
It should only be used when laboratory results do not indicate number of vials to be administered.

Estimated FMH (mL)	Rh (D) Immunoglobulin vials (625IU/mL) required
3mL	1
6mL	1
12mL	2
18mL	3
24mL	4

If FMH is > 15mL always consult with Haematology and consider intravenous administration of Rh (D) Immunoglobulin (RHOPHYLAC®)

For further information see *Guidelines for Laboratory Assessment of Fetomaternal Haemorrhage*, 2002, Australian & New Zealand Society of Blood Transfusion website:
http://www.anzsbt.org.au/publications/documents/ANZSBTguide_Nov02a.pdf

4.2 Routine testing

4.2.1 First antenatal visit

ABO and Rh (D) typing for all pregnant women should occur as early as possible during each pregnancy and preferably at the first antenatal appointment. All current results should be reviewed with historical records and any discrepancies identified should be fully investigated and resolved[2].

Antibody screening should be undertaken in conjunction with ABO and Rh (D) typing. Detection at the first antenatal visit of any antibody is abnormal and further clinical assessment should occur [2] and includes:

- Test to identify the presence of clinically significant red cell antibodies
- Assessment of the clinical significance of the antibody detected
- Previous transfusion history

- History of recent administration of Rh (D) Immunoglobulin *(if Anti D antibody detected*)

Note: If the woman is identified as being antibody positive she should have antibody levels measured every 4 weeks and the results between tests compared. Further testing should be considered if there is a rise in antibody levels between measurements[2].

4.2.2 Testing at 28 weeks gestation

All Rh (D) negative women should have an antibody screen at 28 weeks[2].

For Rh (D) positive women, her individual circumstances and assessment by a clinician will determine the need for the decision to repeat the antibody screen at 28 weeks [2].

The blood sample for the antibody screen should be drawn prior to Rh (D) negative women receiving the Rh (D) Immunoglobulin injection. Antibody screening at 28 weeks gestation should still occur even in the event of Rh (D) Immunoglobulin administration for an earlier sensitising event. The date of administration of the Rh (D) Immunoglobulin should be clearly stated on the request form to assist with interpretation of the result[2].

As most Rh (D) negative women will not be sensitised, it is acceptable for Rh (D) Immunoglobulin to be administrated immediately after the blood sample has been taken, and before results are available[2].

Further antibody screening in Rh (D) negative women without preformed antibodies is not required [2].

Further information on the protocol for antibody screening in Rh D negative women during pregnancy is given in the Guidelines for Blood Grouping & Antibody Screening in the Antenatal and Perinatal Setting published by the Australian & New Zealand Society of Blood Transfusion (March 2007) available at:

http://www.anzsbt.org.au/publications/documents/Antenatal_Guidelines_Mar07.pdf

4.2.3 Testing at birth

At birth, cord blood should be collected from all babies of Rh (D) negative mothers to determine:

- ABO blood type
- Rh (D) status
- Direct antiglobulin levels (Direct Antiglobulin Test (DAT))

As soon as possible after birth and preferably within 72 hours all Rh (D) negative women should have a:

- Antibody screen
- FMH test to determine the dose of Rh (D) Immunoglobulin to be given[2].

4.3 Feto-maternal Haemorrhage (FMH) Testing

Prior to the administration of Rh D Immunoglobulin Feto-maternal Haemorrhage (FMH) testing should be done:

- For all potentially sensitising events that occur after the first trimester
- After birth

To check for clearance of fetal cells repeat FMH testing should occur 48 hours after IV administration or 72 hours after IM administration of Rh Immunoglobulin:

- If initial FMH result detects fetal blood > 4 mL
- In any woman with a positive FMH and a Body Mass Index (BMI) ≥ 30 at booking

Note: Repeat FMH testing should occur in conjunction with repeat antibody testing irrespective of BMI

4.4 Treatment

4.4.1 Potential sensitising events

Potential sensitising events include[1,3]:

- Ectopic pregnancy
- Miscarriage
- Termination of pregnancy
- Ultrasound guided procedures including:
  - Chorionic villus sampling
  - Amniocentesis
  - Cordocentesis
  - Fetoscopy
- Abdominal trauma that causes uterine activity and or abdominal pain
- External cephalic version
- Antepartum haemorrhage
- Birth.

In the event of potentially sensitising events during the first trimester of pregnancy where Rh (D) Immunoglobulin is recommended it should be administered as soon as possible after the sensitising event and ideally within 72 hours[1].

More detail on the clinical indications for the use of Rh (D) Immunoglobulin in potentially sensitising events is available from the Australian Red Cross Blood Service / Royal Australian & New Zealand College of Obstetricians & Gynaecologists publication *Guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in obstetrics.*

In the event of potentially sensitising events that occur after the first trimester, blood should be taken prior to the administration of Rh (D) Immunoglobulin to determine the extent of possible FMH. Additional doses of Rh (D) Immunoglobulin should be administered as indicated from the results of testing. There are a variety of methods to assess FMH[3]. For further information see *Guidelines for Laboratory Assessment of Fetomaternal Haemorrhage*, 2002, Australian & New Zealand Society of Blood Transfusion website:

http://www.anzsbt.org.au/publications/documents/ANZSBTguide_Nov02a.pdf

4.4.2 Antenatal prophylaxis

Rh (D) Immunoglobulin should be administered at 28 and 34 weeks gestation **only if the mother is Rh (D) negative** and has **no preformed** anti-D antibodies[1]. If Rh (D)

Immunoglobulin has been given for a potentially sensitising event, antenatal prophylaxis should still be administered[1].

Prior to administration of Rh (D) Immunoglobulin the administrating clinician and the clinician providing verification should check against the pathology result form to confirm:

- Right patient
- Blood group
- Most recent red cell antibody status.

Note: As most Rh (D) negative women will not be sensitised, it is acceptable at the 28 week prophylactic administration for Rh (D) Immunoglobulin to be administrated immediately after the blood sample for the antibody screen has been taken, and before results are available[2].

Note: Rh (D) immunoglobulin should not be administered to women who have been identified with true preformed antibodies (alloimmunised)[1].

4.4.3 Prophylaxis following birth

Prior to postnatal administration of Rh (D) Immunoglobulin two clinicians should:

- Check mother's blood group and Rh (D) antibody status
- Check baby's blood group and Rh (D) status
- Confirm requirement for Rh (D) Immunoglobulin to be administered to the mother when:
    - Mother is Rh (D) negative and has no true preformed antibodies
    - Baby is Rh (D) positive.

Unless it is clearly documented that the mother already has performed antibodies (alloimmunisation), the mother should receive 625 IU Rh (D) Immunoglobulin plus additional doses as indicated from the FMH test[1].

Note: Rh (D) Immunoglobulin should be administered to a mother who is Rh (D) negative if cord blood or other sample cannot be obtained from the baby. In this instance the baby should be considered Rh (D) positive[2].

5 CONSENT TO TREATMENT

Women should be advised that Rh (D) Immunoglobulin is a blood product and provided with a clear explanation of the potential risks and benefits of receiving Rh (D) Immunoglobulin[5]. Written information should also be provided in an approved brochure such as *You and Your Baby; Important Information for Rh (D) Negative Women 2010* published by CSL and The Australian Red Cross Blood Service.

The discussion and the provision of written information should be documented in the medical record[5].

Consent or refusal

- Written consent should be obtained prior to administration of Rh (D) Immunoglobulin prophylaxis by completing the *Rh (D) Immunoglobulin Patient Consent Form* (Appendix 1).

- If a woman declines all or part of the recommended Rh (D) Immunoglobulin prophylactic administration programme this should be documented on the *Rh (D) Immunoglobulin Patient Consent Form* (Appendix 1).
- If a women declines Rh (D) Immunoglobulin recommended for sensitising events this should be documented on the *Rh (D) Immunoglobulin Patient Consent Form* (Appendix 1).

As per Policy Directive PD2012_016 *Blood - Management of Fresh Blood Components* it is not necessary to seek the patient's consent for each of the subsequent stages of the Rh (D) Immunoglobulin treatment program. However, the patient's consent is required and should be documented if a new treatment is proposed which was not previously explained to the patient or where alternative treatments become available or if new risks associated with the treatment are identified.

If a woman declines treatment, this should be recorded along with the reason in both the medical record and on the consent form. For further information about consent to treatment refer to the NSW Health Policy Directive PD2005_406 *Consent to Medical Treatment – Patient Information.*

6 ADDITIONAL RESOURCES

Australian Red Cross Blood Service at http://www.transfusion.com.au/

Australian Red Cross Blood Service and CSL Limited, Biotherapies Division patient brochure *You and Your Baby; Important Information for Rh (D) Negative Women*. This brochure is available free at the time of this guideline publication and can be ordered from:

- Salmat **or**
- *CSL Limited* http://resources.transfusion.com.au/cdm/singleitem/collection/p16691coll1/id/29/rec/6 **or**
- downloaded from: http://resources.transfusion.com.au/cdm/ref/collection/p16691coll1/id/129

The Australian & New Zealand Society of Blood Transfusion at http://www.anzsbt.org.au/

Royal Australian & New Zealand College of Obstetricians & Gynaecologists at http://www.ranzcog.edu.au/

National Blood Authority at http://www.nba.gov.au/

National Health & Medical Research Council at http://www.nhmrc.gov.au/

Royal College of Obstetricians and Gynaecologists (RCOG) (2011) *Green Top Guideline No 22: The Use of Anti-D Immunoglobulin for Rhesus D Prophylaxis,* 3rd edition at http://www.rcog.org.uk/womens-health/clinical-guidance/use-anti-d-Immunoglobulin-rh-prophylaxis-green-top-22

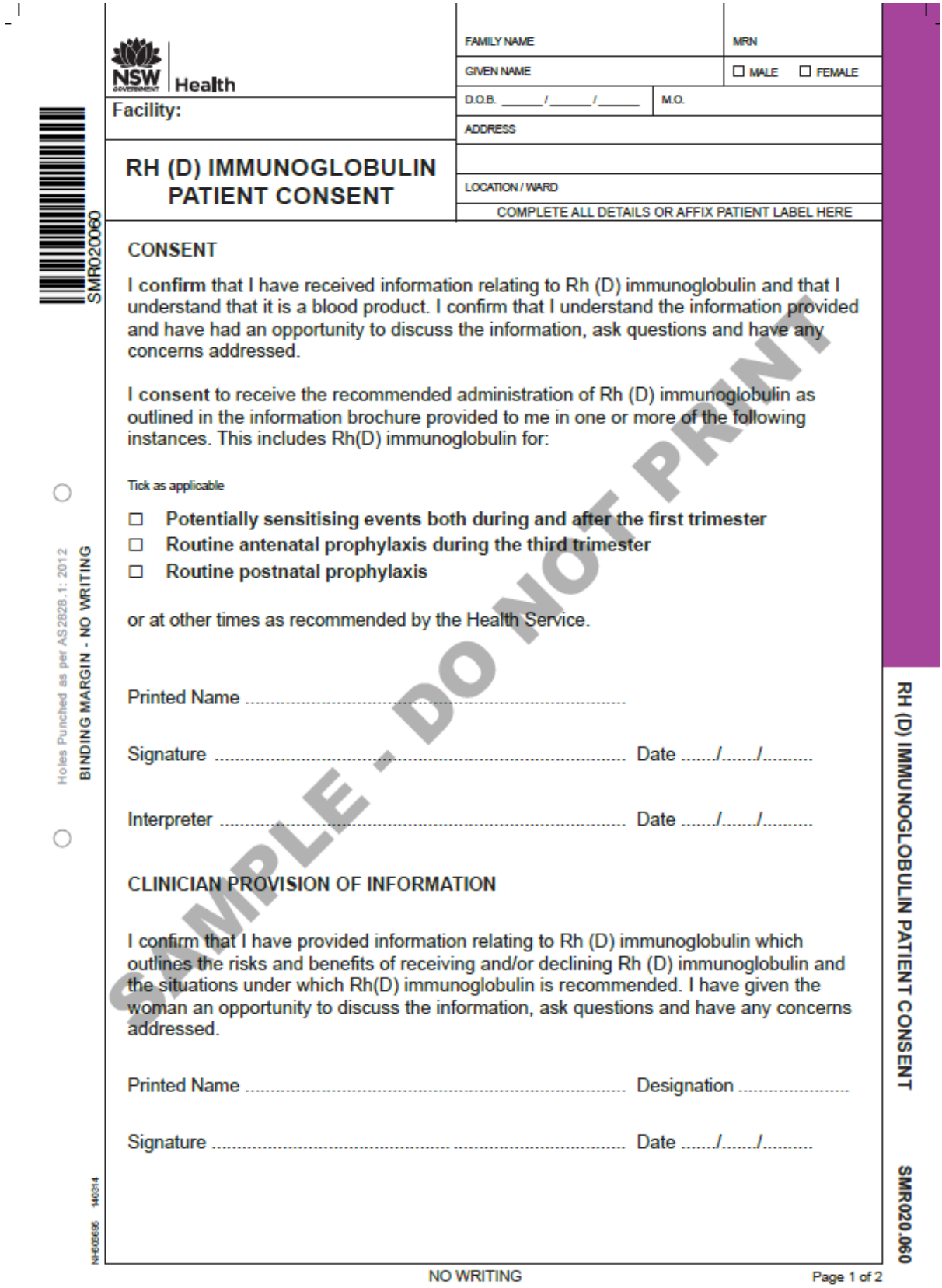
7 REFERENCES

[1] Australian Red Cross Blood Service and The Royal Australian and New Zealand College of Obstetricians & Gynaecologists, (2003), *Guidelines on the prophylactic use of Rh D immunoglobulin (anti-D) in obstetrics.*

[2] Australian & New Zealand Society of Blood Transfusion Ltd and The Royal Australian and New Zealand College of Obstetricians and Gynaecologists, (2007), *Guidelines for Blood Grouping & Antibody Screening in the Antenatal and Perinatal Setting*. Available at http://www.anzsbt.org.au/publications/documents/Antenatal_Guidelines_Mar07.pdf

[3] Australian & New Zealand Society of Blood Transfusion, (2002), *Laboratory Assessment of Fetomaternal Haemorrhage.* Available at: http://www.anzsbt.org.au/publications/documents/ANZSBTguide_Nov02a.pdf

8 APPENDIX 1 RH (D) IMMUNOGLOBULIN PATIENT CONSENT



NSW Health

Facility:

RH (D) IMMUNOGLOBULIN PATIENT CONSENT

FAMILY NAME | MRN

GIVEN NAME | ☐ MALE ☐ FEMALE

D.O.B. _____/_____/_____ | M.O.

ADDRESS

LOCATION / WARD

COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE

SMR020060

BINDING MARGIN - NO WRITING

Holes Punched as per AS2828.1: 2012

SAMPLE - DO NOT PRINT

CONSENT

I confirm that I have received information relating to Rh (D) immunoglobulin and that I understand that it is a blood product. I confirm that I understand the information provided and have had an opportunity to discuss the information, ask questions and have any concerns addressed.

I consent to receive the recommended administration of Rh (D) immunoglobulin as outlined in the information brochure provided to me in one or more of the following instances. This includes Rh(D) immunoglobulin for:

Tick as applicable

- ☐ **Potentially sensitising events both during and after the first trimester**
- ☐ **Routine antenatal prophylaxis during the third trimester**
- ☐ **Routine postnatal prophylaxis**

or at other times as recommended by the Health Service.

Printed Name .....

Signature ..... Date ...../...../.....

Interpreter ..... Date ...../...../.....

CLINICIAN PROVISION OF INFORMATION

I confirm that I have provided information relating to Rh (D) immunoglobulin which outlines the risks and benefits of receiving and/or declining Rh (D) immunoglobulin and the situations under which Rh(D) immunoglobulin is recommended. I have given the woman an opportunity to discuss the information, ask questions and have any concerns addressed.

Printed Name ..... Designation .....

Signature ..... Date ...../...../.....

NH020696 140314

RH (D) IMMUNOGLOBULIN PATIENT CONSENT SMR020.060

NO WRITING

Page 1 of 2

NSW Health

Facility:

FAMILY NAME	MRN
GIVEN NAME	☐ MALE ☐ FEMALE
D.O.B. _____/_____/_____	M.O.
ADDRESS	
LOCATION / WARD	
COMPLETE ALL DETAILS OR AFFIX PATIENT LABEL HERE	

RH (D) IMMUNOGLOBULIN PATIENT CONSENT

REFUSAL (delete if not required)

I decline to receive the recommended administration of Rh (D) immunoglobulin as outlined in the information brochure provided to me in one or more of the following instances. This includes Rh (D) immunoglobulin for:

Tick as applicable

- ☐ **Potentially sensitising events both during and after the first trimester**
- ☐ **Routine antenatal prophylaxis during the third trimester**
- ☐ **Routine postnatal prophylaxis**

Reason/s for objection:

.....

.....

.....

.....

Printed Name .....

Signature ..... Date ...../...../.....

Interpreter ..... Date ...../...../.....

CLINICIAN DECLARATION WHEN Rh(D) IMMUNOGLOBULIN IS DECLINED

I have fully explained to the above woman the risks to future pregnancies as well as the risk to the mother of serum antibodies which may make future cross-matches/transfusions more difficult or limited.

Printed Name ..... Designation .....

Signature ..... Date ...../...../.....

Page 2 of 2

NO WRITING

9 ATTACHMENT 1: IMPLEMENTATION CHECKLIST

LHD/Facility:			
Assessed by:		**Date of Assessment:**	
IMPLEMENTATION REQUIREMENTS	**Not commenced**	**Partial compliance**	**Full compliance**
1. All Rh (D) negative women are provided with written and verbal information on their Rh status and the use of Rh (D) Immunoglobulin	❑	❑	❑
	Notes:		
2. All Rh (D) negative women sign the written consent form documenting their consent or refusal to Rh (D) Immunoglobulin	❑	❑	❑
	Notes:		
3. All Rh (D) negative women who consent to antenatal prophylatic Rh (D) Immunoglobulin receive Rh (D) Immunoglobulin according to the recommended schedule	❑	❑	❑
	Notes:		
4. That education is provided to ensure that all staff are aware that Rh (D) Immunoglobulin prophylaxis is a completely separate administration from Rh (D) Immunoglobulin required for potentially sensitising events regardless of when Rh (D) Immunoglobulin has previously been administered.	❑	❑	❑
	Notes:		
5.	❑	❑	❑
	Notes:		
6.	❑	❑	❑
	Notes:		