

## REJECTION

### Executive Summary

**For reporting allograft rejection, more precise classification has been introduced with addition of further Banff classification variables and categorisation of the type of rejection. This is to capture more accurately the types of acute rejection, distinguishing from chronic features of rejection and better reflect current definitions used internationally.**

The ANZDATA Advisory Committee and Transplant Working Group agreed to this new data collection element and are to implement this within the Online Electronic Data Collection tool (<https://services.anzdata.org.au>) and the A4 Rejection (RE) Paper Form from Survey 71 - 2020.

### Background

To allow more accurate reporting of graft rejection types, ANZDATA transitioned to the collection of Banff classification (i.e. i, t, v, g and ptc) in 2018 for allograft rejection reporting. With current reporting varying and substantial disagreement between reported rejection types and Banff classification (when available). The response to treatment for allograft rejection was also limited in the reporting of ongoing chronic features.

At the request of the Transplant Working Group and in line with international definitions of allograft rejection, the Registry has expanded data collection to allow for more precise Banff classification and grading of rejection types.

These changes include:

- Remove “Acute” from the title, with the new title as “**Rejection Form**”
- Replace text to say “**Report new rejection episodes once only.** Continuous ongoing rejection episodes previously reported should not be reported again.”
- Remove Box 2a – current rejection subtypes (Cellular, Glomerular, Vascular and Humoral) and replace with “**Antibody Mediated**” and “**T-Cell Mediated**”
- Add Banff parameters (**c4d, cg, ci, ct, cv, mm, ah, ti, i-IFTA**) to the currently reported parameters (**g, i, t, v, ptc**).
- Remove “Humoral Rejection”, replace with “**Antibody Mediated Rejection as per current Banff Criteria**”.

### Data Element

The data elements relating to ‘**REJECTION**’ classification is being introduced for collection as at 31-December, at the end of a survey period, for ‘Survey 71 - 2020’.

These variables will be added to the Rejection group of data elements within the AnzdataRejection database table and subsequently be variables for completion for those patients with an allograft rejection episode(s) during a survey period.

Ideally all variables would be collected, as many histology services already routinely report these. There is likely to be some missing data where services don’t report all items routinely, however this should improve with time.

## Collection of Data Element

Figure 1 – Paper Form - IF BIOPSY PERFORMED

IF BIOPSY PERFORMED									
What type of rejection did the biopsy show? <b>Please complete all boxes</b>									
Antibody Mediated	<input type="text"/>								
T-cell Mediated	<input type="text"/>								
Presence of Donor Specific Antibody (DSA)	<input type="text"/>								
	1 = Nil 2 = Mild 3 = Moderate 4 = Severe								
	1 = Pre-transplant 2 = De Novo 3 = Pre-transplant & De Novo 4 = No DSA detected								
BANFF CLASSIFICATIONS (Enter either Grade 0, 1, 2, 3 for each box)									
g	i	t	v	ptc	c4d	cg	ci	ct	cv
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
mm	ah	ti	i-IFTA						
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>						

Figure 2 – Screen View - REJECTION

Add Rejection Episode

Rejection Date \*

Was a Biopsy Performed? \*

What type of rejection did the biopsy show?

Antibody Mediated

T-Cell Mediated

Banff Classifications (if known)

g  i  t  v  ptc

c4d  cg  ci  ct  cv

mm  ah  ti  i-IFTA

## Attachment - REJECTION FORM (RE)

See full Rejection Form (RE) attached for comprehensive data reporting.



# ANZDATA Registry Rejection Form

# Form RE

This Form is additional to the main data form

<u>REGISTRY NO</u>	<u>CURRENT HOSPITAL</u>	<u>SURNAME</u>	<u>GIVEN NAMES</u>
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In this survey period, indicate the number of rejection episodes

<b>DATE OF THIS REJECTION</b>	<b>WAS A BIOPSY PERFORMED</b>	<b>IF NO BIOPSY</b>
<input type="text"/>	<input type="checkbox"/> C = Yes (Clinical Suspicion) P = Yes (Protocol) D = Yes (Delayed Graft Function) N = No (Go to Question 2b)	On clinical grounds (including response to treatment) was this rejection considered <input type="checkbox"/> 1 = Possible 2 = Probable 3 = Definite

**IF BIOPSY PERFORMED**

What type of rejection did the biopsy show? **Please complete all boxes**

Antibody Mediated	<input type="text"/>	1 = Nil 2 = Mild 3 = Moderate 4 = Severe	<b>BANFF CLASSIFICATIONS</b> (Enter either Grade 0,1,2,3 for each box) g   i   t   v   ptc                    c4d   cg   ci   ct   cv <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
T-cell Mediated	<input type="text"/>		
Presence of Donor Specific Antibody (DSA)	<input type="text"/>	1 = Pre-transplant 2 = De Novo 3 = Pre-transplant & De Novo 4 = No DSA detected	mm   ah   ti   i-IFTA <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

**PRIMARY TREATMENT OF THIS REJECTION**

Sequential codes may be used eg:

<input type="text"/>	A = Nil	<input type="text"/>
<input type="text"/>	B = Introduction Or Increased Dose Of Steroids	<input type="text"/>
<input type="text"/>	C = Introduction Or Increased Dose Of Steroids And Polyclonal / Monoclonal Therapy (See Q.55 On The Main Form) *	<input type="text"/>
<input type="text"/>	D = Polyclonal / Monoclonal Therapy Alone (See Q.55 On The Main Form) *	<input type="text"/>
<input type="text"/>	E = Introduction Or Increased Dose Of Cyclosporin A	<input type="text"/>
<input type="text"/>	F = Introduction Or Increased Dose Of Tacrolimus	<input type="text"/>
<input type="text"/>	G = Introduction Or Increased Dose Of Mycophenolate Mofetil	<input type="text"/>
<input type="text"/>	H = Introduction Or Increased Dose Of Sirolimus	<input type="text"/>
<input type="text"/>	I = Plasmapheresis	<input type="text"/>
<input type="text"/>	J = Intravenous Immunoglobulin *	<input type="text"/>
<input type="text"/>	Z = Other (Specify)	<input type="text"/>

**Monoclonal/Polyclonal Therapy**

\* For all Monoclonal / Polyclonal therapies, enter agent & number of doses given.

Agent Code	Doses Given	Type of Agent
<input type="text"/>	<input type="text"/>	5 = Intravenous Immunoglobulin
<input type="text"/>	<input type="text"/>	6 = Basilixmab
<input type="text"/>	<input type="text"/>	7 = Rituximab
<input type="text"/>	<input type="text"/>	8 = Polyclonal Anti T Cell
<input type="text"/>	<input type="text"/>	9 = Other Monoclonal (Specify)

**RESPONSE OF THIS REJECTION TO TREATMENT**

<input type="text"/>	A = Resolution of rejection with return of graft function to pre-rejection levels or better B = Resolution of rejection with improvement of graft function but not to pre-rejection levels C = Resolution of rejection but with no improvement of graft function with serum creatinine less than 250 umol/L D = Resolution of rejection but with no improvement of graft function with serum creatinine greater than 250 umol/L E = Inadequate control of rejection with failure of graft within one month F = Rejection not resolved but no graft failure within one month
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**COMMENTS**