This form, when completed, will be classified as '**For official use only**'.
For guidance on how your information will be treated by the TGA see: Treatment of information provided to the TGA at <https://www.tga.gov.au/treatment-information-provided-tga>.

Request for advice - Biologicals

Our advice provided is nonbinding and without prejudice, and you should seek your own independent legal advice to ensure that all of the legislative requirements are met.

If advice from us is sought, please forward the completed form to bloodandtissues@tga.gov.au.

Supporting information may need to be provided to justify the classification of your biological, including references and data generated by you.

The purpose of this form is to guide you through the classification of biologicals and capture sufficient information about your product for us to provide advice, where this is sought.

A number of advice categories are available. Please select and complete the relevant sections of the form as follows (you may select more than one):

Section A of this form must be completed for all requests

☐ **Is my product regulated as a 'Biological'?**

Complete Section B of this form

☐ **Is my product fully regulated or exempt from certain regulatory requirements?**

Complete Section C of this form

☐ **Is the processing for my product considered 'minimal manipulation'?**

Complete Section D of this form

☐ **Is the intended use of my product 'homologous'?**

Complete Section E of this form

☐ **How will my product be classified under the biological framework?**

Complete Section F of this form

Section A: General Applicant and Product Information

Applicant

Company	
Address	

Contact person

Name	
Position	
Mailing address	
Phone	
Email	

Product information

Title	Your response
Proposed product name	
Brief description of the active substance(s)	
Brief description of the finished product	
Proposed clinical indication (including route of administration)	
Your understanding of the classification of your biological (with regard to the advice being requested)	

Section B: Is my product regulated as a biological?

Refer to What is regulated as a biological prior to completing this section. If unsure, please provide your interpretation with justification in the request to us.

	Question (Guidance)	Decision	Comments/ Justification
B1	Is my product a therapeutic good?	☐ Yes – Proceed to Question B2 ☐ No – Refer information on other product regulating agencies	
B2	Does it meet the definition of a biological?	☐ Yes – Proceed to Question B4 ☐ No – Proceed to Question B3	
B3	Is the product referenced in 'Things that regulated as Biologicals'?	☐ Yes – Proceed to Question B4 ☐ No – Refer Medicines and TGA classifications and Medical devices & IVDs.	
B4	Is it excluded from TGA regulation?	☐ Yes – Your product is not regulated by the TGA ☐ No – Proceed to Question B4	
B5	Is it declared as 'not to be a biological'?	☐ Yes – Your product is regulated as therapeutic goods but not regulated as biologicals. ☐ No – Your product is regulated as a biological.	
B6	Your understanding of the classification of your biological		

Section C: Is my product fully regulated or exempt from certain regulatory requirements?

Refer to Exempt autologous HCT products prior to completing this section. If unsure, please provide your interpretation with justification in the request to us.

	Question (Guidance)	Decision	Comments/ Justification
C1	Is your product for autologous use?	☐ Yes – Proceed to Question C2 ☐ No – Your product is regulated as a biological	
C2	Is it manufactured and used by the medical or dental practitioner with primary responsibility for clinical care?	☐ Yes – Proceed to Question C4 ☐ No – Proceed to Question C3	
C3	Is it manufactured and used by a person or persons under the professional supervision of the practitioner with primary responsibility for clinical care?	☐ Yes – Proceed to Question C4 ☐ No – Your product is regulated as a biological	
C4	Is it for a single indication in a single clinical procedure?	☐ Yes – Proceed to Question C5 ☐ No – product is regulated as a biological	
C5	Are the original cells and tissues minimally manipulated?	☐ Yes – Proceed to Question C6 ☐ No - Your product is regulated as a biological	
C6	Is the product for 'homologous use'?	☐ Yes – Exemptions apply ☐ No – Your product is regulated as a biological	
C7	Your understanding of the classification of your biological		

Section D: Does the method of preparation for my product meet the definition for 'minimal manipulation?

Refer to Method of preparation: Interpretation of minimal manipulation prior to completing this section. If unsure, please provide your interpretation with justification in the request to us.

If advice is requested from us you will need to clearly outline all steps in the manufacturing process, the current understanding of the mechanism of action, the characteristics of the HCT that relate to the intended use, and justification for why each step meets the definition of minimal manipulation or not.

	Question (Guidance)	Decision	Comments/ Justification
D1	Do any of the manufacturing step/s alter the biological characteristics of the original cells or tissues?	☐ Yes – Processing is considered **more than** minimal manipulation ☐ No – Proceed to Question D2	
D2	Do any of the manufacturing step/s alter the physiological functions of the original cells or tissues?	☐ Yes – Processing is considered **more than** minimal manipulation ☐ No – Proceed to Question D3	
D3	Do any of the manufacturing step/s alter the structural properties of the original cells or tissues?	☐ Yes – Processing is considered **more than** minimal manipulation ☐ No – Processing is considered **minimal manipulation**	
D4	Your understanding of the classification of your biological		

Section E: Is the intended use of my product considered homologous?

Refer to Intended use: Interpretation of homologous use prior to completing this section. If unsure, please provide your interpretation with justification in the request to us.

If advice is requested from us you will need to clearly outline the current understanding of the mechanism of action, the basic functions of the HCT, the intended use (based on your labelling material and associated supporting documents), and justification for why the use is considered homologous or not.

	Question (Guidance)	Decision	Comments/ Justification
E1	Is the intended use of the processed cells and tissues to perform the same basic function of human cells and tissues as in donor?	☐ Yes – Intended use is considered homologous use ☐ No – Intended use is considered non-homologous use	
E2	Your understanding of the classification of your biological		

Section F: How will my product be classified under the biologicals framework?

Refer to Classification of Biologicals prior to completing this section. If unsure, please provide your interpretation with justification in the request to us.

	Question (Guidance)	Decision	Comments/ Justification
F1	Is your product mentioned as class 1 in Schedule 16 of the *Therapeutic Goods Regulations 1990*?	☐ Yes – Your product will be regulated as a 'Class 1' biological ☐ No – Proceed to Question F2	
F2	Could your product be appropriate to be classified as a class 1 biological?	☐ Yes – Contact us at bloodandtissues@health.gov.au ☐ No – Proceed to Question F3	
F3	Is your product mentioned as a specific class of biologicals in Schedule 16 of the *Therapeutic Goods Regulations 1990* (currently only class 4 biologicals)?	☐ Yes – Your product will be regulated as that class of biological (class 4 biological) ☐ No – Proceed to Question F4	
F4	Is your product minimally manipulated?	☐ Yes – Proceed to Question F5 ☐ No – Your product will be regulated as a 'class 3' biological	
F5	Is the intended use of the product homologous?	☐ Yes – Your product will be regulated as a 'class 2 biological ☐ No – Your product will be regulated as a 'class 3' biological.	
F6	Your understanding of the classification of your biological		