Preparation Process Dossier (PPD)

Use this dossier to record information to support your application for authorisation of the processing of tissues or cells undertaken in your laboratory. Processing includes all operations involved in the preparation, manipulation, preservation and packaging of tissues or cells intended for human application. If there is an urgent clinical need associated with the preparation process, please provide relevant information in Section G of this form and in the email submission.

This dossier must be completed for each whole process. If you use the same process for more than one tissue type, only one PPD should be submitted. For example, an establishment may use a single PPD when the same process is used to cryopreserve peripheral blood stem cells, cord blood and donor lymphocytes. However, please note that the validation for the preparation process should demonstrate that expected outcomes are achieved for all tissue types.

For guidance on completing this document, please refer to [Preparation Process Dossiers - A guide for processors of tissues and cells for patient treatment](https://www.hta.gov.uk/policies/preparation-process-dossiers-guidance).

Completed PPDs must be submitted to the HTA by email to enquiries@hta.gov.uk with the email subject heading ‘PPD submission – *followed by the* *PPD title*’ or by post to:

HTA, 2nd floor 2 Redman Place,
London E20 1JQ.

If you have any questions please call General Enquiries on 020 7269 1900 and ask to speak to a member of the Regulation Team.

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| **Section A – Establishment information** |

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| **Full name of licensed establishment** |  |
| **HTA licence number** |  |
| **Name of Designated Individual (DI)** |  |
| **Postal address of the licensed premises** |  |
| **Telephone number** |  |
| **Name of PPD contact and e-mail address** |  |
| **Telephone number of PPD contact** |  |
| **Date of submission** |  |

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| **Section B – Preparation process – general information** |

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| **Title of the preparation process** |  |
| **Description of the tissues or cells to which this preparation process is applied** |  |
| **Please provide a brief description of how the processed tissues or cells will be used** |  |
| **Will all mandatory donor serology tests be performed? If not, please provide more information about the donor serology tests that will be performed.***Note: mandatory tests are anti-HIV1/2, HBsAg, anti-HBc, anti-HCV-Ab, anti-T. Pallidum (syphilis), and HTLV-1 (depending on circumstances)***Please give details of any additional donor selection and/or testing requirements that will be applied in relation to this preparation process** | YES **[ ]** NO **[ ]**  Additional non-mandatory testing performed? YES [ ]  NO [ ]  If yes, provide details:Additional donor selection required (e.g. age of donor)?  YES [ ]  NO [ ]  If yes, provide details: |
| **Please provide a brief description or a flowchart of the preparation process****Please append a copy of the SOP to be followed for the preparation process** |  |

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| **Section C – Reagents and materials** |

Please list all reagents and materials used in this preparation process that come into contact with the tissues or cells, providing details of the supplier in each case.

Please expand this table as necessary.

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| **Reagents or materials that come into contact with the tissues/cells** | **Specification****(e.g. UKCA- or CE-marked, clinical grade, reagent grade, etc.)***If not UKCA- or CE-marked, please provide a rationale*  | **Manufacturer or supplier** | **Product code** |
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| **Section D – Quality control testing** |

Please list all quality control tests applied to the processed tissues or cells, including characterisation and microbiology, providing details of the supplier of any test kits where applicable.

Please expand this table as necessary.

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| **Test (manufacturer name and product code, if applicable)** | **CE marked or validated?***If validated in-house, please append validation* | **Description of test article (analyte)** | **Criteria for release** |
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| **Section E – Process validation** |

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| **How has the preparation process been validated to demonstrate that it does not render the tissues or cells clinically ineffective or harmful for the recipient?** | 1. By studies conducted at your establishment? YES **[ ]** NO **[ ]**

If yes, please append a copy of the validation report.Refer to [Preparation Process Dossiers - A guide for processors of tissues and cells for patient treatment](https://www.hta.gov.uk/sites/default/files/PPD%20Guide.pdf) for an example validation report template1. By studies published by others? YES **[ ]** NO **[ ]**

If yes, please append copies of the most relevant publications, and written verification that the process described in this dossier and the published process are equivalent1. By retrospective analysis of clinical results? YES **[ ]** NO **[ ]**

If yes, please attach a summary of the analysis methods and results |
| **If the process is covered by a patent, please provide the patent number**  |  |
| **If the process includes a sterilisation or viral inactivation step, please provide a brief description of the validation and copies of the studies on which the validation is based**  | Please append a copy of the validation report. |
| **Please list all Critical Quality Attributes (CQAs) of the tissues and cells processed using the described methodology**Note: please refer to [Preparation Process Dossiers - A guide for processors of tissues and cells for patient treatment](https://www.hta.gov.uk/sites/default/files/PPD%20Guide.pdf) for more information |  |
| **Please list all Critical Processing Parameters (CPPs) for this preparation process**Note: please refer to [Preparation Process Dossiers - A guide for processors of tissues and cells for patient treatment](https://www.hta.gov.uk/sites/default/files/PPD%20Guide.pdf) for more information. |  |

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| **Section F – Final labelling and accompanying information** |

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| **Do you intend to distribute or export the processed tissues of cells? YES** **[ ]  NO [ ]** **If yes, please attach here a copy of the final label affixed to the primary packaging of tissues or cells that have been processed using this method****Please also attach a copy of the accompanying information sheet supplied to clinical users with the tissues or cells** |
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| **Section G – Additional information** |

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| **Please provide any additional information that the HTA should be aware of with respect to the reviewing/authorisation of your preparation process (e.g. urgent clinical need)** |
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| **Section H – Declaration by the DI** |

**I hereby accept that the information included in this dossier demonstrates that the preparation processes described are validated.**

**DI name (print): ..............................................................................................................**

**\*DI signature: ..................................................................................................................**

**Date (DD Month YYYY):..................................................................................................**

\* Please sign here if a paper-copy PPD is submitted by mail. Submissions by email should be sent from the DI, in which case a signature is not necessary.

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| **Section I – Checklist of documents** |

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| **Document** | **Linked to PPD section** | **Required** | **Included** |
| Completed PPD | - | ✓ | [ ]  |
| SOP for the preparation process | B | ✓ | [ ]  |
| Process flowchart or description of process | B | ✓ | [ ]  |
| Reagent risk assessment and testing details | C |  | [ ]  |
| Validation Report | E | ✓ |  |
| * Your own validation
 | E |  | [ ]  |
| * Published studies by others
 | E |  | [ ]  |
| * Retrospective evaluation
 | E |  | [ ]  |
| Viral inactivation validation | E |  | [ ]  |
| Final labels | F | ✓ | [ ]  |

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| Other accompanying documents (if applicable) : |