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Note: The applicant should also refer to the Inspection Checklist for specific deficiencies where these have been observed during the inspection.

# SECTION A. GENERAL INFORMATION AND OVERVIEW

|  |  |
| --- | --- |
| Programme/Institution name: |  |
| City: |  |
| Country: |  |
| Type of inspection:  | □ Initial / □ Reaccreditation / □ Re-inspection  |
| Edition of standards used for inspection:  | □ 6th □ 7th |

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Inspection date: | DD/MM/YYYY | Date of Inspection Report: | DD/MM/YYYY | Date of Summary Report: | [DD/MM/YYYY for office use only] |

|  |
| --- |
| **Accreditation goal (mark as appropriate):** |
| AREA | PATIENT | HSCT | Immune Effector Cells |
| Allogeneic | Autologous  | Allogeneic | Autologous  |
| Clinical | Adult |  |  |  |  |
| Paediatric |  |  |  |  |
| HPC, Marrow Collection | Adult |  |  |  |  |
| Paediatric |  |  |   |  |
| HPC, Apheresis Collection | Adult |  |  |  |  |
| Paediatric |  |  |  |  |
| Processing |   |  |  |  |  |

|  |
| --- |
| **Directors (complete all sections)** |
|  | Clinical (Adults) | Clinical (Paediatrics) | HPC(M) Collection  | HPC(A) Collection  | Cell Processing  |
| Director |  |  |  |  |  |
| Medical Director |  |  |  |  |   |
| Include other information about Directors if necessary: |
|  |

|  |
| --- |
| **Inspectors & Observers:** |
| **ADULTS** |
| Team Leader: |  |
| Clinical : |  |
| Marrow Collection : |  |
| Apheresis Collection : |  |
| Donors : |  |
| Processing : |  |
| Quality Management: |  |
| Observer(s) and their organisation |   |
| **PAEDIATRICS**  |
| Team Leader: |  |
| Clinical: |  |
| Marrow Collection |  |
| Apheresis Collection: |  |
| Donors: |  |
| Processing: |  |
| Quality Management: |  |
| Observer(s) and their organisation: |  |

|  |
| --- |
| **Services provided to other facilities NOT inspected during this audit:**  |
| [Complete this where the inspector is aware of any other relationships with facilities not part of this application e.g. registries, other hospitals. If none, mark as ‘N/A’. ] |

|  |
| --- |
| **Observations on the interaction between clinical, collection and processing facilities:** |
| [Reflect on what evidence you saw of interaction and communication between the different facilities] |
| **Distance between facilities** *(if possible, please describe the distance, duration and mode e.g. 5km, 10 mins, by car)* |
| Collection Facility(s) to Clinical Unit(s) |  |
| Collection Facility(s) to Processing Facility |  |
| Processing Facility(s) to Clinical Unit(s) |  |

|  |
| --- |
| **Additional remarks:** |
|  |

# SECTION B. TEAM LEADER ON –SITE INSPECTION SUMMARY

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| --- |
| Team Leader On-site Inspection Summary:  |
| [Use this section to describe the inspection. Describe the atmosphere, any incidents that came up, and the overall impression of the programme. This last point is sometimes called the “helicopter view” and means to consider all aspects together and not just as individual elements. The FACT-JACIE standards emphasize the total programme and the interactions in place between the different services. Each individual inspector should describe the facility(s) he/she has visited in their respective section of this report. Again, specific elements or deficiencies should be detailed in the Inspection Checklist] |

# SECTION C. OBSERVATIONS

***PERSONS INTERVIEWED DURING THE INSPECTION:*** *This section appears under the heading of each section (see below) and should be completed with the names and roles of the persons interviewed during the course of the inspection*

***MAIN STRENGTHS & AREAS FOR IMPROVEMENT:*** *This section appears below each section (see below) and describes the main strengths and areas for improvements e.g. well trained team, excellent document management, need for more regular audits, etc.*

|  |
| --- |
| **Cellular Therapy Product Administration & Clinical Facilities - ADULT** |
| **Persons interviewed during the Inspection**  *[Insert or delete positions as necessary]* |
| **Position/role** | **Name** |
| Programme Director |  |
| Transplant physician/Consultant/Specialist |  |
| Physician in training |  |
| Quality Manager |  |
| Senior Nurse |  |
| Nurses in training (or newest nurse in the unit) |  |
| Other BMT unit nurses |  |
| Pharmacist |  |
| Intensive Care Lead |  |

|  |
| --- |
| **Numbers of transplants for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Adults | [This section should be completed] | [This section should be completed] |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| [Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist] |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| Strengths | [This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist] |
| Areas for improvement | [This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist] |

|  |
| --- |
| **Cellular Therapy Product Administration & Clinical Facilities - PAEDIATRICS** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Position/role** | **Name** |
| Programme Director |  |
| Transplant physician/Consultant/Specialist |  |
| Physician in training |  |
| Quality Manager |  |
| Senior Nurse |  |
| Nurses in training (or newest nurse in the unit) |  |
| Other BMT unit nurses |  |
| Pharmacist |  |
| Intensive Care Lead |  |

|  |
| --- |
| **Numbers of transplants for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Paediatrics | *[This section should be completed]* | *[This section should be completed]* |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| *[Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| Strengths | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| Areas for improvement | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

|  |
| --- |
| **HPC, Marrow Collection - ADULTS** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Position/role** | **Name** |
| Physician who performs harvests |  |
| Nurse who assists with harvests |  |
| Quality Manager |  |

|  |
| --- |
| **Numbers of bone marrow harvests for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Adults | *[This section should be completed]* | *[This section should be completed]* |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| *[Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| Strengths | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| Areas for improvement | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

|  |
| --- |
| **HPC, Marrow Collection - PAEDIATRICS** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Position/role** | **Name** |
| Physician who performs harvests |  |
| Nurse who assists with harvests |  |
| Quality Manager |  |

|  |
| --- |
| **Numbers of bone marrow harvests for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Paediatrics | [This section should be completed] | [This section should be completed] |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| *[Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| Strengths | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| Areas for improvement | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

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| --- |
| **HPC, HPC, Apheresis Collection - ADULT** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Position/role** | **Name** |
| Collection facility director  |  |
| Collection facility medical director  |  |
| Staff involved in collection of cells (nurse, technician) |  |
| Quality Manager |  |

|  |
| --- |
| **Numbers of apheresis procedures for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Adults | *[This section should be completed]* | *[This section should be completed]* |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| *[Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| **Strengths** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| **Areas for improvement** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

|  |
| --- |
| **HPC, Apheresis Collection - PAEDIATRICS** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Position/role** | **Name** |
| Collection facility director  |  |
| Collection facility medical director  |  |
| Staff involved in collection of cells (nurse, technician) |  |
| Quality Manager |  |

|  |
| --- |
| **Numbers of apheresis procedures for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Paediatrics | *[This section should be completed]* | *[This section should be completed]* |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| *[Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| **Strengths** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| **Areas for improvement** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

|  |
| --- |
| **Cellular Therapy Product Processing** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Position/role** | **Name** |
| Laboratory Director  |  |
| Laboratory Medical Director |  |
| Quality Manager |  |
| Laboratory Technician |  |
| Laboratory Trainee |  |

|  |
| --- |
| **Numbers of processing procedures for 12 months up to inspection date** |
|  | Allogeneic | Autologous |
| Procedures | *[This section should be completed]* | *[This section should be completed]* |

|  |
| --- |
| **Brief description of facility(s) inspected:**  |
| *[Limit the description to the unit e.g. how long it has been established, population served, relationships with other organisations, etc. but not specific deficiencies or observations. These should be entered into the Inspection Checklist]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| **Strengths** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| **Areas for improvement** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

|  |
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| **CM7, C7 & D7 Labels (Cell Collection & Cell Processing)** |
| **Inspector who performed check** |
| **Area** | **Name** |
| HPC Marrow Collection Labels  |  |
| HPC Apheresis Labels |  |
| Processing Labels |  |

|  |
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| **SEE INSPECTION CHECKLIST FOR DETAILS OF OBSERVATIONS** |

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| --- |
| **Quality Management** |
| **Persons interviewed during the Inspection [Insert or delete positions as necessary]** |
| **Name** | **Position/role** |
| Physician  |  |
| Technician |  |
| Nurse |  |
| Quality Manager |  |

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| --- |
| **List of facility(s) visited:**  |
| *[List the facilities visited in this visit as part of the Quality Management system]* |

|  |
| --- |
| **Main Strengths & Areas for Improvement** |
| **Strengths** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |
| **Areas for improvement** | *[This section should be for general suggestions. Specific deficiencies should be detailed in the Inspection Checklist]* |

# SECTION D: ACCREDITATION COMMITTEE SUMMARY

The Committee has endorsed the observations made during this inspection which are detailed in this report and which should be responded to by the applicant. In addition, the Committee wishes to highlight the following:

*[INTRODUCE SPECIFIC ITEMS FOR ATTENTION HERE AS BULLET POINTS]*

*[DELETED THE FOLLOWING AS NECESSARY]*

No deficiencies or variances observed at the onsite inspection or in submitted materials.

Overall assessment

Few minor deficiencies noted at the onsite inspection and/or in submitted materials. The JACIE Accreditation Committee will determine the adequacy of the facility’s response and pronounce upon accreditation based on written documentation by the Programme Director of correction of all deficiencies and a satisfactory response to all recommendations.

Significant deficiency or deficiencies documented at the site inspection. The JACIE Accreditation Committee will determine the adequacy of the facility’s response and pronounce upon accreditation based on the Programme Director’s documented correction of all deficiencies and satisfactory response to recommendations.

Significant deficiency or deficiencies observed at the site inspection requiring documentation of correction of deficiencies along with a focussed reinspection of one or more areas of the applicant facility. The same inspector(s) will be responsible for conducting the focussed reinspection. The JACIE Accreditation Committee will review the results of the reinspection and pronounce upon accreditation.

Significant deficiencies observed during the site inspection requiring a full reinspection of the applicant facility. The same inspector(s) will be responsible for conducting the focussed reinspection. The JACIE Accreditation Committee will review the results of the reinspection and pronounce upon accreditation.

Non-accreditation. Reapplication and submission of documents required.

|  |
| --- |
| Conditions: |
| [Complete where any conditions are attached to the eventual accreditation e.g. laboratory accreditation limited to service provided to a specific hospital] |

|  |
| --- |
| Date for submission of evidence of corrections: |
| 6 months from receipt of this report. |

|  |
| --- |
| ADDITIONAL COMMENTS: |
| N/A |

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| --- |
| GENERAL ISSUES ARISING FROM THIS INSPECTION: |
| N/A |

# SECTION E: POST INSPECTION *[FOR JACIE OFFICE USE ONLY]*

|  |
| --- |
| **1st review** |
| **Date Summary Report** | DD/MM/YYYY | **Date Evidence of Correction Received** | DD/MM/YYYY | **Date Review Completed** | DD/MM/YYYY  |

|  |
| --- |
| **General observation of the corrections**  |
| [xxx xxxx] |

|  |
| --- |
| **Cellular Therapy Product Administration & Clinical Facilities - ADULT** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|   |

|  |
| --- |
| **Cellular Therapy Product Administration & Clinical Facilities - PAEDIATRICS** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|  |

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| --- |
| **HPC, Marrow Collection - ADULT** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|  |

|  |
| --- |
| **HPC, Marrow Collection - PAEDIATRICS** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|  |

|  |
| --- |
| **HPC, Apheresis Collection - ADULT** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|   |

|  |
| --- |
| **HPC, Apheresis Collection - PAEDIATRICS** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|   |

|  |
| --- |
| **Cellular Therapy Product Processing** |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|  |

|  |
| --- |
| Quality Management |
| Name of Inspector |  |
| Date Review completed | DD/MM/YYYY |
| Observation and Comments |
|   |

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| --- |
| Conclusion |
| Date all Evidence are compliant | DD/MM/YYYY | (if only clinical) Date Collection Facility JACIE Accredited | DD/MM/YYYY | (if only clinical) Date Processing Facility JACIE Accredited | DD/MM/YYYY  |
| Accreditation Outcome (JAC Chair Decision) | AccreditedYes/No | Accreditation Outcome date: | DD/MM/YYYY |
| If no, please write process taken |   |

General Directions Given to Programmes for Correcting Cited Deficiencies:

Where issues have been identified, the following steps must be completed:

1. You must document in writing how your programme has corrected each of the deficiencies. Correction of deficiencies may take the form of a new protocol or procedure, a revised protocol or procedure, new forms developed and put into use, new staff, new training processes, etc.
Enter this information into the corresponding section of the Inspection Checklist aligning the corrections information with the remarks of the inspector and/or the Accreditation Committee (see image).

1. Labels: corrections to labels should be detailed in a separate document. This could be a simple Word document. Entitle this document as “Labelling response and corrections” and refer to the type of label which has been corrected or amended. For example, “C7.5.1 Apheresis label at completion of collection”.

1. Your documentation of correction of each deficiency must include a description of how your programme will comply with the citation and copies of any policies, procedures, protocols or documents that demonstrate the corrective action has been implemented.

1. Please indicate as new or show clearly any changes in policies, protocols or procedures so that reviewers can easily understand your corrections and changes.

1. If there are any long-term solutions to deficiencies, such as new construction being required to provide adequate space, the plans for such corrections should be included with your response, although the actual construction is not required to have been completed. Please include as much detail as possible.

1. Where the summary reports state “It is unclear that...” or “There is no evidence that...”, you should submit the evidence (such as a policy, protocol, procedure or an audit report) that the practice at your facility is already in compliance, or that you have made the necessary changes to ensure compliance.

1. Please organise your response according to the deficiencies as stated in the enclosed summary report, and be as clear as possible in your responses. Highlight specific sections of procedures or protocols that you wish to call to our attention.

1. Review our designation of the facilities you wish to have accredited for each of the services your programme provides. If any facility designation is incorrect, please notify in writing of the correct designations as soon as possible. Also, include any significant staff changes that have occurred since your submission.

1. Your complete response is expected within 3 and 9 months (depending on outcome) of receipt of this letter. Please notify us if you anticipate that additional time will be required for you to complete your response.

If you disagree with any of the findings of the on-site inspection team or the reviewers, submit a written statement outlining the reasons that you disagree, along with as much documentation as possible to support your opinion. This may be submitted separately or as part of your overall response and will be presented to the JACIE Accreditation Committee for review.

Your response should be submitted to the JACIE Accreditation Office where your response will be evaluated. If the response is determined to be satisfactory, accreditation will be awarded for the services and facilities as described above. If any questions remain after our review, these will be submitted to the JACIE Accreditation Committee for final determination.