*The assessment is to be completed by institutions when interested in cooperating with the European Clinical Research Infrastructure Network (ECRIN Nutrition).*

*Please tick appropriate boxes or fill in text and mail the completed form after signature to:*

***Yvonne Masson****: [Yvonne.masson@clrermont.inra.fr](mailto:Yvonne.masson@clrermont.inra.fr)*

***Or***

***Anne Tourault****: [anne.tourault@clermont.inra.fr](mailto:anne.tourault@clermont.inra.fr)*

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| --- | --- | --- | --- | --- | --- |
| General information | | | | | |
| 1 | Name of centre or unit |  | | | |
| 2 | Contact information | CEO/head of centre or unit | | Main contact for clinical trial management | |
| Name Address Tel/Fax Email |  | Name Address Tel/Fax Email |  |
| 3 | Web site |  | | | |

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| 1 | **Quality Policy** | |
| 1.1 | Does your centre agree to conduct clinical trials in nutrition in collaboration with ECRIN following the principles of the ECRIN Nutrition Quality Policy?  Yes  No | |
| 1.2 | Comments |  |

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| 2 | **Regulations** | |
| 2.1 | When collaborating with ECRIN Your centre commit to conduct Clinical trials according to the Declaration of Helsinki (Fortaleza Brazil October 2013) as well as with the principles of Good Clinical Practice E6 (R1) version 4 as defined by the International Conference on Harmonisation (ICH), and with the applicable national and local regulatory requirements.  Yes  No | |
| 2.2 | Comments |  |

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| 3 | **Audit** | |
| 3.1 | When collaborating with ECRIN your centre accept that Research activities conducted on site can be selected for audit for Good Clinical Practice compliance and adherence to SOPs.  Yes  No | |
| 3.2 | Comments |  |

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| 4 | **Monitoring** | |
| 4.1 | The centres ensure the accuracy, completeness, legibility, and timeliness of the data reported to the sponsor and comply with procedures for data recording/reporting, to permit monitoring, auditing and inspection and to retain the trial related essential documents.  Yes  No | |
| 4.2 | Comments |  |

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| 5 | **Personnal Data Privacy** | |
| 5.1 | The centres commit to ensure the rights of the subject to physical and mental integrity, to privacy and to the protection of the data concerning him in accordance with Directive 95/46/EC of 24 october 1995 on the protection of individuals with regards to the processing of personal data and on the free movement of such data shall be safeguarded  Yes  No | |
|  | Comments |  |

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| 6 | **Material** | |
| 6.1 | You confirm that your centre has adequate human, material and technical means to conduct biomedical research and meets the safety requirements of people suitable for that research.  Yes  No | |
| 6.2 | Comments |  |

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| 7 | **Quality management system** | | | | |
| 7.1 | Do you have SOPs for your research activity within your quality management system? | | |  | Yes No |
| 7.2 | If yes, please tick which topics are covered in your SOPs |  | Clinical SOPs:  Blood Sample collection  Samples transport  Adipose Tissue Biopsy  DEXA  Impedencemetry  Muscle Tissue Biopsy  Feacal Analysis  Clamp Analysis  Others SOPs (if applicable):      Management SOPs:  Management of trial medication, dietary supplements and food  Management of life-threatening emergencies  Data management collection storage, privacy:  SAE reporting  Others SOPs (if applicable): | | |
| 7.3 | Could you describe the process of elaboration, review and validation |  | | | |

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| 8 | **Quality management evaluation** | | | | | |
| 8.1 | Has your centre passed any qualification process (registration or others) and /or gone through an inspection and/or audit? | | | |  | Yes No |
| 8.2 | If yes, specificy date, type and organisation that perform the evaluation |  | registration  accreditation  qualification  inspection  audits  Other |  | | |
| 8.3 | Comments |  | | | | |

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| 9 | **Training** | | | | |
| 9.1 | Are the clinical staff being trained on a regular basis (GCP, on site procedures)? | | |  | Yes No |
| 9.2 | If yes, this is recorded on |  | Training log Other (please specify) | | |
| 9.3 | Comments |  | | | |

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| 10 | **Commitment of interest** | | | |
| 10.1 | Is your centre interested in participating to multi national clinical trials with the ECRIN infrastructure? |  | | Yes No Yes under conditions : |
| 10.2 | If YES does your centre agree to use ECRIN SOP’s if required? |  | YES  No | |
|  | | | | |
| Thank you for the completion of this document. If you wish to receive additional information, please contact :  **Yvonne Masson or Anne Tourault** | | | | |

I confirm that all information provided in this form is accurate

|  |  |
| --- | --- |
| Date |  |
| Name and function |  |
| Signature of CEO/Head |  |