*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*

***Or***

***Anne Tourault****: 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 |
| NameAddressTel/FaxEmail |                      | NameAddressTel/FaxEmail |                      |
| 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 safeguardedYes [ ]  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? | [ ] [ ]  | YesNo |
| 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 AnalysisOthers SOPs (if applicable):          Management SOPs:[ ]  Management of trial medication, dietary supplements and food[ ]  Management of life-threatening emergencies[ ]  Data management collection storage, privacy:[ ]  SAE reportingOthers 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? | [ ] [ ]  | YesNo |
| 8.2 | If yes, specificy date, type and organisation that perform the evaluation | [ ] [ ] [ ] [ ] [ ] [ ]  | registration accreditation qualification inspection auditsOther |                                |
| 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)? | [ ] [ ]  | YesNo |
| 9.2 | If yes, this is recorded on | [ ] [ ]  | Training logOther (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? | [ ] [ ] [ ]  | YesNoYes under conditions :       |
| 10.2 | If YES does your centre agree to use ECRIN SOP’s if required? | [ ] [ ]  | YESNo |
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| 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

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