All documents are not relevant for all types of projects, see also footnotes

|  |  |  |  |
| --- | --- | --- | --- |
| **Before the Project starts** | | | |
| 1.1 | Internal pre-presentation of the project. | Cf. Procedure description 2 and Appendix 2.1 Form for project planning |  |
| 1.2 | Research protocol | The final version, signed and dated |  |
| 1.3 | Template for recording data | Or electronic system |  |
| 1.4 | Information to research subjetcs 1, consent form | Version sent to REK for approval The final version, approved by REK |  |
| 1.5 | Application to REK | A copy of the complete application with attachments or reference to appendix |  |
| 1.6 | Correspondence with REK | Including any attachments 1 |  |
| 1.7 | Approval from REK |  |  |
| 1.8 | Approval from The Norwegian Biotechnology Advisory Board. | Research according to the Biotechnology Act |  |
| 1.9 | Contracts with collaborators | The final version, signed and dated |  |
| 1.10 | Contracts with subcontractors | The final version, signed and dated |  |
| 1.11 | Form for the subject identity list and a list of research participants | If relevant Cf.Procedure description 6, Appendix 6.3 Subject identity list |  |
| 1.12 | Form for the research biobank (If applicable) | Cf. Procedure description 5 and appendix 5.1 Check list for the research biobanks at UiO |  |
| 1.13 | Form for processing and storage of data | Alpha  Cf. Procedure description 6 and Appendix 6.1 Checklist for processing and storage of data in each project |  |

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **During the Project** | | | | | |  |  |  |  |
| 2.1 | Documented consent | | Dated and signed by the research subjects in the project | |  |  |  |  |  |
| 2.2 | Completed form(s) for recording data | | Or reference to the electronic system Cf. Procedure description 6 | |  |  |  |  |  |
| 2.3 | The subject identity list | | Cf. Procedure Description 6 and Appendix 6.3 Template for the Linkage Key | |  |  |  |  |  |
| 2.4 | Changes to the research protocol | | The final version, signed and dated | |  |  |  |  |  |
| 2.5 | Changed information to the research participants The amendment consent form | | Version sent REK for approval  The final version, approved by REK | |  |  |  |  |  |
| 1 research on humans  2 including any new versions of previously submitted attachments | | | | | | | | | |
| 2.6 | Amendment applications to REK | A copy of the application with attachments or reference to appendix | |  | |  |  |  |  |
| 2.7 | Correspondence with REK | Including any attachments or references to appendix 1 | |  | |  |  |  |  |
| 2.8 | Approval of amendments from REK |  | |  | |  |  |  |  |
| 2.9 | Contracts with collaborators | Updated or new | |  | |  |  |  |  |
| 2.10 | Contracts with subcontractors | Updated or new | |  | |  |  |  |  |
| 2.11 | Source documentation / raw data | Cf. Procedure description 6 | |  | |  |  |  |  |
| 2.12 | Notification of adverse medical events | Cf. Appendix 2.6 Form of notice of adverse medical events | |  | |  |  |  |  |

|  |  |  |  |
| --- | --- | --- | --- |
| **After completing the Project** | | | |
| 3.1 | Completed form (s) for recording data or reference to the electronic system | Complete set Cf. Procedure description 6 |  |
| 3.2 | Signed consent | Complete set Cf. Procedure description 6 |  |
| 3.3 | Final report to REK |  |  |
| 3.4 | Source documents / raw data | Complete set Cf. Procedure description 6 |  |
| 3.5 | Complete subject identity list | Store separately Cf. Procedure description 6 and       Procedure description 2, item 4.10 |  |
| 3.6 | Statistical calculations |  |  |
| 3.7 | Final Report |  |  |
| 3.8 | Publication |  |  |
| 3.9 | Form for research biobank (if relevant) | Fully completed Cf. Appendix 5.1 Checklist for biobank research at the University |  |
| 3.10 | Form for processing and storage of data | Fully completed Cf. Procedure description 6 and Appendix 6.1 Checklist for handling and storage of data in the individual project. |  |
| 3.11 | Notification of adverse medical events | Cf. Appendix 2.6 Form for notice of adverse medical events |  |

3 research on humans

4 including any new versions of previously submitted attachments