|  |  |
| --- | --- |
| **Short title** |  |
| **A+ / SCH Number** |  | **Date** |  |
| **Principal Investigator**  | Name, service area | **Study type** | Audit/Observational (low risk)/Observational (high risk)/Intervention *select one* |

The following list outlines the documentation that should be in place at the main site before a trial begins but will vary depending upon protocol design. (check as appropriate)

Y[ ]  N[ ]  N/A[ ]  Ethics approval letter: AHREC / HDEC (delete as appropriate); DATE: DD/MM/YYYY

Y[ ]  N[ ]  N/A[ ]  Research Review Committee approval; DATE: DD/MM/YYYY

Y[ ]  N[ ]  N/A[ ]  Details of Māori Consultation and approval; DATE: DD/MM/YYYY

Y[ ]  N[ ]  N/A[ ]  Signed CTRA, collaboration agreement, third party agreement; DATE: DD/MM/YYYY

Y[ ]  N[ ]  N/A[ ]  Agreed Sponsor budget and signed A+ Trust budget; DATE: DD/MM/YYYY

Y[ ]  N[ ]  N/A[ ]  Indemnity & compensation, insurance certificate (commercial studies); DATE: DD/MM/YYYY

Y[ ]  N[ ]  N/A[ ]  Evidence of Service Clinical Director engagement. Details:

Y[ ]  N[ ]  N/A[ ]  Final approved trial protocol signed

Y[ ]  N[ ]  N/A[ ]  Data Management Plan in accordance with HDEC and ADHB standard operating procedures

Y[ ]  N[ ]  N/A[ ]  Final ethically approved participant information sheet(s) and consent form(s) and GP letter

Y[ ]  N[ ]  N/A[ ]  Final ethically approved other written participant information e.g. diary card(s)

Y[ ]  N[ ]  N/A[ ]  Final ethically approved participant recruitment advertisement (if relevant)

Y[ ]  N[ ]  N/A[ ]  Monitoring plan

Y[ ]  N[ ]  N/A[ ]  Details of any data monitoring committee or trial steering or management group (if not in protocol)

Y[ ]  N[ ]  N/A[ ]  Sign off from a statistician (if required)

Y[ ]  N[ ]  N/A[ ]  Signed off/finalised case report forms/questionnaires (CRFs)

Y[ ]  N[ ]  N/A[ ]  Signed off/finalised clinical database (REDCap or other)

Y[ ]  N[ ]  N/A[ ]  Data transfer agreement if required

Y[ ]  N[ ]  N/A[ ]  Funding letter and conditions

Y[ ]  N[ ]  N/A[ ]  Team CVs and other evidence of relevant training (e.g. GCP/Regulation/protocol) and qualifications

Y[ ]  N[ ]  N/A[ ]  Trial start-up/initiation report or confirmation that site initiation activities have been completed

Y[ ]  N[ ]  N/A[ ]  Trial Master File to GCP standards compliant with local SoP/Investigator site files

**Signatures: Starship Research & Innovation Manager ………………………………………Laura Mackay**

**Starship Director…………………………………………………………Dr John Beca**