## **Royal Brisbane and Women's Hospital -Renal Research - Kidney Health Service**

Location: -27.446583 - 153.027796

Local Services Offered:

Clinical trials site;Investigator Initiated Trials;Trial Patient Recruitment;Treatment of

patients;Completion of

study documentation as per ICH GCP and contract

Details: In addition to the information contained within csv generated by this website, this PDF provides additional site information

| Does your Facility perform HREC<br>(IRB/ERB/Ethics) Committee<br>submissions?   | Yes |
|---|-----|
| Does your Facility have a written<br>SOP/Policy/Procedure for Informed<br>Consent?  | Yes |
| Does your Facility have a dedicated<br>department or group to perform<br>HREC (IRB/ERB/ETHICS)<br>Committee submissions?          | Yes |
| Does your Facility have the<br>necessary equipment to treat<br>medical emergencies (for example<br>crash/code cart)?              | Yes |
| Is your Facility affiliated with a<br>government agency or part of a<br>government funded health service?                         | Yes |
| Does your Facility typically allow<br>the collection of Pharmacogenomic<br>(PGX) samples for research<br>purposes?                | Yes |
| Does your Facility have computers<br>that are dedicated to research<br>studies?   | No  |
| Does your Facility have the ability<br>to manage on-site or off-site<br>destruction of controlled substances<br>when appropriate? | Yes |
| Does the Facility have the ability to<br>handle radio-labelled Investigational<br>Products?                                       | Yes |

|  | * 7                   |
|--|-----------------------|
| Is your Facility capable of                    | Yes                   |
| administering infusions?                       |                       |
| What browser does your facility                | Microsoft Explorer 11 |
| use?   |                       |
| Does the Facility have access to               | Yes                   |
| local IT support?                              |                       |
| Does your Facility limit or prohibit           | Yes                   |
| access and use of external web-                |                       |
| based tools or sites for clinical              |                       |
| research (E.g. web portals to submit           |                       |
| documents to sponsors or CROs)?                |                       |
| documents to sponsors or cites).               |                       |
| Does your Facility have the ability            | Yes                   |
| to manage on-site or off-site                  | 105                   |
| -  |                       |
| destruction of the Investigational<br>Product? |                       |
|  | **                    |
| Does your Facility have patient                | Yes                   |
| record archiving on-site?                      |                       |
| Secure Storage Records                         | Yes                   |
| Can your Facility support in-patient           | Yes                   |
| admissions for research studies?               |                       |
|  |                       |
| Does your Facility have the ability            | Yes                   |
| to collect and store PK/PD                     |                       |
| specimens?                                     |                       |
| Facility written sop during                    | Yes                   |
| transportation to satellite site               |                       |
| Does your Facility have an SOP or              | Yes                   |
| process that ensures routine                   | 105                   |
| calibration and maintenance of                 |                       |
|  |                       |
| general equipment? Examples of                 |                       |
| general equipment include: scale,              |                       |
| pulse oximeter, stadiometer,                   |                       |
| sphygmomanometer, etc.?                        |                       |
| Does your Facility have the ability            | Yes                   |
| to collect PK/PD samples beyond                |                       |
| normal business hours?                         |                       |
| Is your Facility adequately staffed to         | Yes                   |
| support studies with both blinded              |                       |
| and unblinded Investigational                  |                       |
| Product?                                       |                       |
| Does the Facility have storage space           | Yes                   |
| for Study-Related materials (e.g.              | 105                   |
|  |                       |
| Lab Kits, Patient Materials, etc.)?            |                       |
|  |                       |

| Can your Facility support patient   | Yes  |
|---|--|
| visits on weekends?   |  |
| Does your facility have a written   | Yes  |
| SOP/Policy/Procedure for the  |  |
| destruction of Investigational  |  |
| Product?  |  |
| Other Meeting Frequency   | Two meetings per week in NMA   |
| Does the course content include   | Yes  |
| GCP?  |  |
| Lab Name  | Pathology Queensland- RBWH   |
| Local Lab Usage   | Yes  |
| Do you have Electronic Health   | Yes  |
| Records (EHR)/ Electronic Medical   |  |
| Records (EMR)?  |  |
| Life Sciences Queensland (LSQ)  | No   |
| Member  |  |
| Does your Facility have a written   | No   |
| SOP/Policy/Procedure for Minor  |  |
| Assent for paediatric populations?  |  |
|   | V  |
| Does your Facility have a written   | Yes  |
| SOP/Policy/Procedure for Other vulnerable populations?  |  |
|   |  |
| Please nrounde program coursels   |  |
| Please provide program course/s   | Caledonian; ARCS and Syneos online   |
| name  |  |
| name<br>IP Recipient Name   | Royal Brisbane and Women's Hospital Pharmacy   |
| name<br>IP Recipient Name<br>Does the HREC Committee require  |  |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final   | Royal Brisbane and Women's Hospital Pharmacy   |
| name<br>IP Recipient Name<br>Does the HREC Committee require  | Royal Brisbane and Women's Hospital Pharmacy   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?  | Royal Brisbane and Women's Hospital Pharmacy<br>Yes  |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to   | Royal Brisbane and Women's Hospital Pharmacy   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support  | Royal Brisbane and Women's Hospital Pharmacy<br>Yes  |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to   | Royal Brisbane and Women's Hospital Pharmacy<br>Yes  |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?  | Royal Brisbane and Women's Hospital Pharmacy<br>Yes<br>Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)   | Royal Brisbane and Women's Hospital Pharmacy<br>Yes<br>Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?  | Royal Brisbane and Women's Hospital Pharmacy<br>Yes<br>Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of  | Royal Brisbane and Women's Hospital Pharmacy<br>Yes<br>Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?  | Royal Brisbane and Women's Hospital Pharmacy         Yes         Yes         Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?<br>Retraining Research Staff   | Royal Brisbane and Women's Hospital Pharmacy         Yes         Yes         Yes         Yes         Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?<br>Retraining Research Staff<br>Training for the Staff   | Royal Brisbane and Women's Hospital Pharmacy         Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?<br>Retraining Research Staff<br>Training for the Staff<br>Training program for the research  | Royal Brisbane and Women's Hospital Pharmacy         Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?<br>Retraining Research Staff<br>Training for the Staff<br>Training program for the research<br>staff   | Royal Brisbane and Women's Hospital Pharmacy         Yes         Yes |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?<br>Retraining Research Staff<br>Training for the Staff<br>Training program for the research<br>staff<br>Storage Room Backup Power<br>Is the Investigational Product<br>Storage Room secured with | Royal Brisbane and Women's Hospital Pharmacy   Yes   Yes   Yes   Yes   Yes   Yes   Yes   Yes   |
| name<br>IP Recipient Name<br>Does the HREC Committee require<br>payment prior to the release of final<br>approval documents?<br>Does your Facility have access to<br>translators and translation support<br>for study conduct (e.g. consent,<br>study-specific instruction)?<br>Do you provide your Satellite Site(s)<br>with a dedicated inventory of<br>Investigational Product?<br>Retraining Research Staff<br>Training for the Staff<br>Training program for the research<br>staff<br>Storage Room Backup Power<br>Is the Investigational Product                              | Royal Brisbane and Women's Hospital Pharmacy         Yes         Yes |

| Storage area securely constructed   | Yes   |
|---|---|
| What type of computer operating<br>system(s) does your institution use<br>to support studies? | Windows 10  |
| Sub-Therapeutic areas   | Renal Research; Kidney Health and Nephrology;<br>renal;cancer; Acute Kidney Disease; Benign Prostatic<br>Hyperplasia; Cystitis; Endometriosis; Erectile<br>Dysfunction; Fertility; Overactive Bladder; Peyronie's<br>Disease; Renal Failure |