



Government of **Western Australia**
Department of **Health**

Research Governance Service (RGS)

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Why have RGS? - 7 Major Reasons

- NMA mandatory requirement
 - Online IT system external researchers can access
 - Submit electronically, track progress of review
 - Capture mandatory annual reporting data
 - e.g. No. & type projects, clinical trials phase, type of sponsor, recruitment, funding
 - Stop clock functionality to record Ethics & Governance review 60 day KPIs
- National TTR Reporting
 - Capture WA State Gov funding for research per ABF hospital.
 - Reporting in Service Level Agreements (SLAs) required from 2016/17 on the following ABF, TTR categories:
 - Number of research directorate staff (FTE)
 - Number of peer reviewed articles published
 - Number of approved research projects – by HREC and site authorisation per ABF site

Why have RGS? (cont. 1)

- COAG Health Council Clinical Trial initiatives
 - Capture National Aggregate Statistics annually
 - e.g. No. of clinical trials, phase, type of sponsor, recruitment, funding (planned v actual), ethics/gov. review KPIs
 - Stop clock functionality to record Ethics & Governance review 60 day KPIs
 - Publish investigator speciality list - ↑ collaboration & ability for sponsors to locate potential CPI/PIs
 - Publish clinical trials - ↑ recruitment (still to be developed)
 - Standardise nationally ethics/gov. application forms, review processes and terminology (RGS glossary)
 - Implement IHPA standard costs items in budget
 - Transparency of costs V funding

Why have RGS? (cont. 2)

- NHMRC
 - Allow for incorporation of HREA
 - Implement NHMRC template PICFs and letters
 - Capture annual AHEC reporting for all registered HRECs
 - Capture annual reporting for certified NMA HRECs
- WA Health
 - Research Policy Framework – standardise processes in accordance with policy and SOPs
 - Address Corporate Governance requirements to ensure correct site authorisation occurs and is auditable in line with delegation schedules
 - Capture reporting for System Manager & HSP Boards
 - e.g. No. of project & type, costs & funding (including project specific & shared costs, overheads), funder type, recruitment, KPIs for ethics/gov. review, GCP certification and PhD projects

Why have RGS? (cont. 3)

- **Researchers**
 - SER – allow ethics application to be available to all RGO without having to submit multiple times
 - Electronic submission instead of multiple paper copies
 - ability to track review process and access submitted forms/documents & letters
 - ability for sponsors to still complete ethics forms and track progress
 - Reduce duplication of data entry between ethics and governance forms for researchers
 - One stop shop – one place for all info and submissions, including a calendar for all WA Health HREC meetings/ACD
 - Only complete personal details and upload CV once
- **Ethics/Gov. Administrators & Committee Members**
 - Reduce duplication of data entry for administrators into databases, minutes and letters. Ability to generate minutes/letters electronically
 - Ability for Committee Members to access agenda and projects without administrators having to send them multiple attachments/paper copies
 - Ability for Committee Members to have a discussion board
 - Ability to generate AHEC/NHMRC reports electronically
 - One central record management system for research which is auditable
 - Automatic stop clock to assist with reporting and reduce data entry of dates
 - Ability for RGOs to share already approved legal agreements and insurance documents within a project
 - Ability for RGOs to access ethics documents from outside their HSP

Why is RGS complex - it serves multiple masters (8)

1. Researchers

- Published Investigator Speciality list increases collaboration
- Online completion/submission of forms, documents and declarations
- Collaborative workspace – Multiple Project Members can complete forms at same time
- Upload CV and GCP evidence once
- Store active and submitted forms, documents, letters in one location, accessible by all Project Members
- View Ethics Committee Meeting Calendar – Meeting, submission closing dates
- Different roles related to who views forms/documents, ability to appoint delegate
- Audible governance processes and ability to track progress/outcomes

2. Sponsors

- Complete ethics forms, upload documents, view letters & track progress
- Not able to see Site Budget (i.e. costs of project)

3. Hospital Administrators

- Ability view all ethics/gov. forms & documents
- Auditable electronic authorisation

Why is RGS complex - it serves multiple masters (cont.1)

4. Committee Members – HREC, Sub Committee, Alternative Review

- View meeting agenda items, including all ethics application's forms and documents, once allocated and invited to a meeting
- Ability to review and post comments on discussion board even if not attending meeting

5. Ethics Administrators (EEO)

- Validate and review ethics forms & documents, request additional information required (AIR) before Committee meeting
- Publish Meeting & Application Closing Dates (ACD) dates on Calendar
- Create Meeting agenda and invite Members
- Develop Minutes. Populate minutes into letters and send to CPI/Delegate
- Complete Ethics Admin tab with information for auditing/reports
- Provide required reports to AHEC/NHMRC Certification

6. Governance Administrators (RGO)

- Validate and review gov. forms & documents as submitted (not as package & parallel to ethics application , request additional information required (AIR)
- Invite Chief Executive/Delegate to authorise and create letters and send to PI/Delegate
- Complete Governance Admin tab with information for auditing/reports
- Share approved documents with other project RG Offices (e.g. CTRA, insurance)
- Approve Project workspaces to ensure no duplication

Why is RGS complex - it serves multiple masters (cont.2)

7. Executive

- Produce reports for national, State, HSP reporting
- Auditable process to comply with Research Policy Framework
- Ensure security of data in accordance with Use and Disclosure Policy, Sponsor's Confidentiality Disclosure Agreements
- Record Keeping Plan compliance

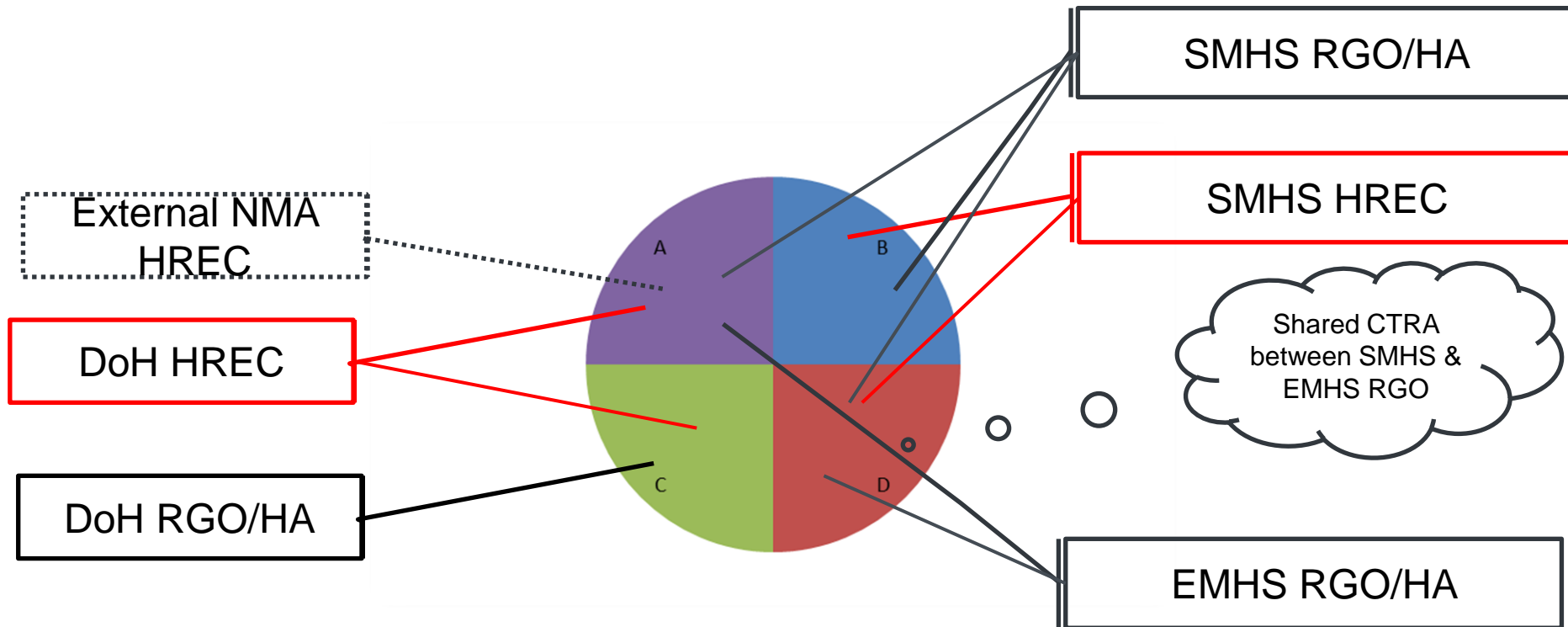
8. RGS Administrators

- Approve users to reduce likelihood of malicious users
- Update users security access
- Update Regions, Sites, Divisions, Departments to align with HSP organisational charts
- Update Funders, Ethics Committees, RG Offices, Ethics Offices
- Update Non-WA Health sites (private, universities, NMA jurisdictions PHO/HRECs)
- Maintain RGS public pages, events, notifications, Help Wiki, Newsletters

Multiple security relationships - Why have Roles, Members & Sites tab?

- **Roles** – related to security, as information held in one system must be segmented into different views (e.g. CPI versus Sponsor)
- **Sites Tab**
 - dictates who can see what for each site
 - nominates sites that Project Member aligned with
 - access to forms are aligned to sites
 - documents are associated with forms
- **Members Tab**
 - dictates who can view, edit, sign, authorise forms/documents within a project and for each site

Multiple Security Relationships – Example 1 – Multiple Projects with Multiple Administrators

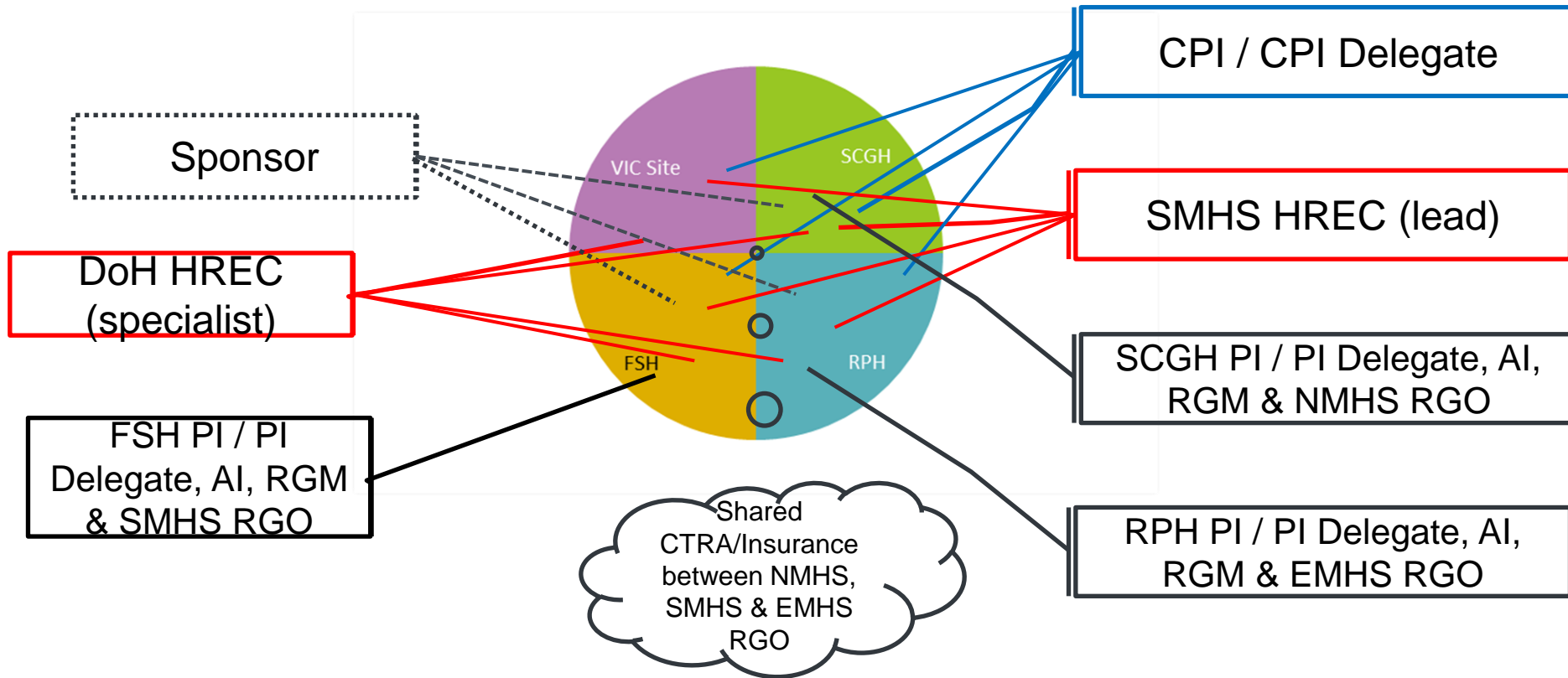


Ethics Office - EEO/Committee Members (HREC, SC, ARC) – restricted view to minutes and projects that receive an ethics submission

RG Office – RGO/CE – Sites allocated to RG Office - restricted view to projects that receive a governance submission

Hospital Administrators – in a HA pool – restricted to project sites they are invited to

Multiple Security Relationships – Example 2 – One Project with Multiple Sites & Roles



CPI / CPI Delegate – view all project ethics and governance forms/documents; edit/authorise ethics forms/documents

PI / PI Delegate / AI / RGM – view/edit all ethics forms/documents; edit site related governance forms/docs; PI/PI Delegate – authorise gov. forms/docs

Sponsor – view/edit all ethics forms/documents; edit site related governance forms/docs, except for Budget Form

How does RGS reduce data entry?

- **Users Profile**
 - Name, contact details, area of research speciality, qualifications and expertise
 - populated into tabs/forms, investigator speciality list and used for authorisation electronic signatures / audit
- **Project Details tab (Project Header, Ethics, Governance, Investigator Contact Information)**
 - Header populates into Project Search and in future will be used for public search
 - Populate into ethics & gov. forms – ethics forms not reliant on completion of Governance tab (other IT systems must complete ethics forms before gov. forms)
 - Reused for monitoring forms, ability to change and update as project progresses.
- **Pre-populated data**
 - Drop downs (e.g. NHMRC fields of research) & dates
 - Department, division, site, region names
 - HREC, RG Office, Funder names
- **Declarations - automatic confidentiality agreement for external employees**
- **Electronic signatures – click to sign (no scanning required)**


How does RGS track projects?

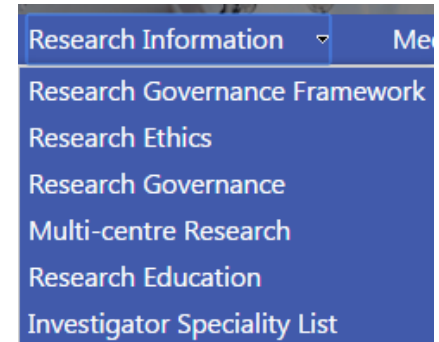
- Forms & Documents tab
 - Submission, validation, review, approval dates
 - Validation review – click on link to ‘view’ validation comments
- Summary tab
 - Summary of project, HREC approval and site authorisation dates
- Timeline tab
 - Tracks HREC and RG Office validation and review processes against 60 day KPI with clock (required for national reporting)
 - HREC start date based on Application Closing Date (ACD)
- Letters tab
 - Stores all draft and sent (EEO/RGO)/received (PM) letters
- My Projects – give a list of your project & HREC approval date

How can users communicate?

- Tasks
 - Create task – General (not project related) or Project General Task (project related)
- Comments tab – project related
 - Related to Applications/Monitoring/Ethics approval/Site authorisation
 - Number of comments highlighted on tab (for 7 days), ability to remove, flag as inappropriate, email
- Committee Discussion Board within Meeting Agenda
- Forms & Documents tab - Validation comments
- Letters tab – Review comments

How do I know how to use RGS and what ethics/gov. forms/documents required?

- Tooltips – hover mouse over to read on view or edit 
- Help Wiki – individual pages, access based on role, limited public view – extended view for RGS users
- Training Manuals – role specific
- Public Pages – information/document templates
- Research Authorisation Monitoring Form Guidelines
- Chevron – changes as progress through project with links to Help Wiki



1. Human Research Ethics Committee reviews application and grants ethics approval
2. Research Governance Officer reviews application and Chief Executive grants site authorisation
3. [Track a project through the review process](#)
4. [View the ethics and governance letters](#)

- Presentations
- Videos – to come
- RGS.Support@health.wa.gov.au – email and leave a phone number

What were the June changes to RGS?

- Introduction of External HREC approval for NMA
 - Enter HREC review information in the Project Details tab
 - Submit Ethics forms and documents to the Specialist HREC
 - Submit Ethics forms and documents to the RGO
 - Review Ethics forms and documents by the RGO
- Changes related to Budget Form
 - Amendments to Budget Form User Interface
 - Remove Project Funders that are not applicable to the Budget Form & 'Refresh' updated funders added later to Project Details
 - Invite a Supporting HoD Delegate to act on a Budget Form
 - Withdraw an invite to a HoD / Delegate on a Budget Form
 - Manage Third Party Agency – New facility to allow Budget Form to access all organisations
 - Onscreen message to add funder in Project Details (FSH)

What were the June changes to RGS? (cont.)

- Changes related to Ethics Administration
 - Revise process flows for providing review assessment to allow for monitoring – update Ethics tab with review decision & ability to close a project
 - Notify EEO if Risk Type has been changed in review assessment
 - Update the 'Project status' in the Standard Header for external HRECs
- Changes related to Governance Administration
 - Revise process flows for RGO Review – keep CE decision if form/doc has been approved but others are AIR; update Gov tab with review decision to allow for monitoring & ability to close a project
 - Revise process flows for RGO after CE/Delegate Authorisation to be notified of CE decision
 - Create a task for RGO when CE / Delegate has completed a review

What are the August changes to RGS?

- Home page UI improvements
- Login page
 - updated to prevent users clicking resend security code button by mistake; extra warning text about security code
- Sign User out of RGS after period of 4 hours inactivity
- Project Workspace (FSH)
 - Chevron with steps to make RGS more intuitive
 - Project Details - ! If unauthorised
- My Projects
 - Sort columns, add HREC approval date
- Summary tab
 - Risk type populate from HREC review decision
- Sites tab
 - Warning message to only add NMA sites
- Tasks (FSH)
 - send notification of Project Task
 - populate General Task into 'Tasks assigned to others'

What are the August changes to RGS (cont.1)?

- **Members tab**
 - CPI can be PI Delegate
- **Forms & Documents tab (FSH)**
 - View validation on 'view' not on 'date'
 - Ethics approval /Site authorisation sections are now collapsed
- **Documents (FSH) – allow special characters**
- **Forms (FSH)**
 - Tooltips & Close Button on view mode
 - Emails sent to CPI/Delegate and PI/Delegate when forms are signed
 - 'Pending signatures' status added to forms when complete but not signed
 - Coloured index added – when section of form complete, changes when you click 'Next' & 'Mark Complete' buttons
 - Change WASM questions that are not populating correctly
- **Budget Form**
 - Add a 'Total' row to section 3 – total cost, \$ funding, in-kind funding
 - Warning message if used clicks 'unlock' for research/supporting department

What are the August changes to RGS (cont.2)?

- Letters
 - Add multiple attachments to a letter & view signed letter
 - Document name has imbedded link
 - Populated validation email with forms/documents
 - New ethics submission email with populated form/documents (FSH)
- Changes to User's Personal or Contact Details
 - Require RGS Admin approval when user profile is updated
 - Impact to project workspace – changes made throughout system
 - Action task to approve request to update user's details
 - Include new 'area of research specialty' – Emergency Medicine
- Introduction of New Activity Flag for Comments Tab
 - Notify user of new / recent activity for 7 days – flag and email
- Administration
 - Update the sequence of sub-tabs within the Administration tab
 - Manage Departments – Allow RGS Admin to move departments under a different division
 - RGS Admins – revert EEO/RGO incorrect validation decision
 - Governance Admin tab - Only populate sites from WA public sites