REGIS

NHMRC Report Dashboard and Rule

What is the NHMRC Report

For guidance on what the NHMRC report is please see
https://www.nhmrc.gov.au/research-policy/ethics/human-research-ethics-committees

What is in this report/dashboard

The dashboard has 4 main tabs:

❖ Overall – Q21-28
❖ Publicly Health Database (Commonwealth) – Q55-68
❖ Privately Held Database – Q80-94
❖ Multi-Centre – Q105-111

Each tab lists the questions and responses across the top and has a "List" table at the bottom. The List table can be filtered/ordered by selecting any of the table headings. It can be expanded for easier viewing or can be exported to a .xls table for further filtering.

To expand a list table select the maximise icon at the top right side of the table. To minimise select the restore icon.

To export a list table select the Export to icon at the top right of the screen, select the .xls icon. Export to Excel – Dashboard pop up will appear, click Export.

A temporary file will download.

Not every questions asked in the NHMRC report can or needs to be provided by REGIS. Where a response is provided in the dashboard it is reading from data available in the system. The majority of responses come from the approved HREA so it is important to understand the Rule and ensure the HREA is correct before approving.

The RO can not go back after an application has been approved to alter a HREA response for the NHMRC dashboard.

How to read/use this document

This document corresponds with the 4 tabs of the dashboard:

❖ Overall – Q21-28
❖ Publicly Health Database (Commonwealth) – Q55-68
❖ Privately Held Database – Q80-94
❖ Multi-Centre – Q105-111

It lists each section and whether or not the dashboard provides a response for the sections and/or question.

Under each question that has a dashboard response are 3 columns:

❖ Rule: this is the calculation or filtering used to provide the response.
❖ Dashboard shows response as: this is how the dashboard provides the response.
❖ Notes/guidance: This provides the user guidance on how to use the dashboard to find or validate the response. At times the user will have to take manual steps to reach the final response.
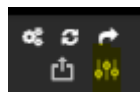
Setting Date Parameters

NHMRC Reporting runs on calendar years, you need to set the dashboard parameters

Start: 01/01/20XX
End: 31/12/20XX

Locate the dashboard parameters icon on the top right hand side of the dashboard.

Click on the calendar icon and select the dates or manually type them into the date value.

Icons

Located at the top right of the dashboard.

 Export to: used to export data from the dashboard.

 Dashboard parameters: used to set the date parameters for the report

 Multiselect tool on: used when multiple sections of data can be selected to then be filtered or exported. User must click on indicated when icon is blue.

 Multiselect tool off: used when only a single section of data is required to be selected to then be filtered or exported. Indicated when icon is grey.

 Maximise: used to maximise a section of the dashboard to full screen

 Minimise: used to minimise a section of the screen that has been maximised.

Section A (Q 1-2)

About your HREC - The first few questions are about where your HREC is based and whether it considered any research proposals in 20XX.

Not collected in REGIS, Ethics Office to respond from own database.

Section B (Q 3-7)

Composition of the HREC.

Not collected in REGIS, Ethics Office to respond from own database.

Section C (Q 8-14)

Administration & General Operation of the HREC.

Not collected in REGIS, Ethics Office to respond from own database.

Section D (Q 15-16)

Training

Not collected in REGIS, Ethics Office to respond from own database.

Section E (Q 17-34)

Review of Human Research Proposals

Q 17-20 Not collected in REGIS, Ethics Office to respond from own database.

Dashboard tab: Overall Q 21-28

Q 21 - How many new research proposals were considered by the HREC during the reporting period?

Rule:	Dashboard shows response as:	Notes/Guidance:
Migrated tag = No Has been assigned to a meeting = Yes Classification ethics pathway is Greater than low risk = Yes First Meeting closing date within date parameter = Yes	A number	The REGIS Records list (bottom table) is a list of each of the applications that meet the overall criteria for 21-28 is also shown as a list. This list can be filtered by clicking on any of the headings and exported by clicking on the Export to icon next to the dashboard parameters icon.

Q 22 - How many of these new research proposals were ultimately approved by the HREC?

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 21 Status contains Approved, Approved with Conditions	A number of applications per status.	RO will have to add the Approved and Approved with conditions numbers. If there is no Approved or Approved with Conditions appearing in the answer table this is because no study is currently in that status within the date parameters. You can click on any of the status in the answer table and this will change the information in the REGIS records list. To select more that on status (e.g. approved and approved with conditions) click the multi-select icon and select the two status, the REGIS Records list will update. REMEMBER to clear master filter before progressing.

Q 23 - How many of these new research proposals were denied ethics approval by the HREC and will not be re-considered?

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 21 Status contains Not Approved	A number of applications per status	If Not Approved is not an option appearing in the answer table this is because no study is currently in that status within the date parameters. You can click on any of the status in the answer table and this will change the information in the REGIS records list.

		REMEMBER to clear master filter before progressing

Q 24 - Of the new research proposals that the HREC considered, did any involve Aboriginal and Torres Strait Islander Peoples and relate to health research?

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 21 Participant Group contains Aboriginal and Torres Strait Islander peoples (HREA, Q1.19) was selected.	A number	The REGIS Records list can be filtered/ordered by clicking on the Participant Group column header. To further investigate, expand or export (See REGIS Records tab) the list.

Q 25-27 Not collected in REGIS, Ethics Office to respond from own database.

Q 28 - How many new clinical trial research proposals were considered in the reporting period by the HREC?

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 21 Classification Study Type = Clinical trial	A number	The REGIS Records list can be filtered/ordered by clicking on the Study type column header. To further investigate, expand or export (See REGIS Records tab) the list. If a study has an incorrect classification the Research Office can correct this in the Application AND Project Classifications. This change will not be visible in the report until the next business day. If classifications are changed in the ETH, the Research Office should notify all Sites so they can ensure their data is correct.

Q 29-34 Not collected in REGIS, Ethics Office to respond from own database.

Section F (Q 35-42)
Monitoring

Not collected in REGIS, Ethics Office to respond from own database.

Section G (Q 43-53)
Complaints Handling Process & Complaints Received

Not collected in REGIS, Ethics Office to respond from own database.

Section H (Q 54-78)
s95 Guidelines – Commonwealth Agency/ies

Q 54 Not collected in REGIS, Ethics Office to respond from own database.

Dashboard tab: Publicly Held Database (Commonwealth) Q 55-68

Q 55 - With respect to these proposals, did any require the use or disclosure of information from a Commonwealth agency?
Note: This does not include the use or disclosure of information from a state/territory agency as you are not required to report these instances to NHMRC.

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 21 Where response HREA Q3.6 (Identify the source/s of the information/data that you will be collecting and/or using in this project) Publicly held database (Commonwealth) was selected.	A number	Filter/order the Publicly held Database (Commonwealth) list can by clicking on the Information Source header. To further investigate, expand or export (See Publicly Held Database tab) the list.

Q 56 - With respect to these proposals, did any require use or disclosure of personal information?
Note: Under the Privacy Act 1988, 'personal information' means information or an opinion about an identified

individual, or an individual who is reasonably identifiable: (a) whether the information or opinion is true or not, and (b) whether the information or opinion is recorded in material form or not

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 55 Where response HREA Q3.1 (Indicate the type of information/data you will be collecting for this project.) or Q3.2 (Indicate the type of information/data you will be using in this project.) Personal information was selected. (Sensitive Information and Health Information are not being collected in this question)	A number	Filter/order the Publicly held Database (Commonwealth) list by clicking Info Type Collected and Info Type Used header. To further investigate, expand or export (See Publicly Held Database tab) the list.

Q 57 - With respect to all of these proposals, was consent obtained from all individuals to whom the information related? (e.g. If consent was not obtained from any participant, in any of these proposals, please answer 'No')

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 55 Where response HREA Q1.18 (Indicate with whom or with what the research will be conducted) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected OR Where response HREA Q1.18 (Data associated with human beings only) is selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected	No and application count where consent has not been obtained. If consent has been obtained for all it will show Yes with 0 records. = obtain consent and no consent waiver.	Filter/order the Publicly held Database (Commonwealth) list by clicking "Is consent obtained" and "consent waiver" and "obtain consent headers". Count each line once when one or more values = Yes To further investigate, expand or export (See Publicly Held Database tab) the list.

Q 58 - During the reporting period, how many medical research proposals requiring the use and/or disclosure of <u>personal information</u> from a Commonwealth agency did the HREC consider in which the information was obtained without obtaining consent from all of the individuals to whom the information pertained?
Note: This does not include the use or disclosure of information from a state/territory agency as you are not required to report these instances to NHMRC, even if you have applied the s95 guidelines to these instances.

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 55 Where response HREA Q3.1 (Indicate the type of information/data you will be collecting for this project.) and	A number	This question uses the above filter with the additional filters.

| Q3.2 (Indicate the type of information/data you will be using in this project.) Personal information was selected.

 AND

 Where response HREA Q1.18 (Indicate with whom or with what the research will be conducted) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected

 OR

 Where response HREA Q1.18 (Data associated with human beings only) is selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected | | Filter/order in the Publicly held Database (Commonwealth) list by doing a count of the Info Type Collected AND Info Type Using for personal information. |

Q 59-66 Not collected in REGIS, Ethics Office to respond from own database.

Q 67 - For how many proposals did the HREC determine that the public interest in the proposed medical research outweighed, to a substantial degree, the public interest in the protection of privacy (i.e. the HREC approved the proposal)?

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 55 Where response HREA Q3.1 (Indicate the type of information/data you will be collecting for this project.) and Q3.2 (Indicate the type of information/data you will be using in this project.) Personal information was selected. AND Where response HREA Q1.18 (Indicate with whom or with what the research will be conducted) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected OR	Number and a status list	Value will only appear if 57 has a count that was approved. In 67&68 table user may have to manually add Approved and Approved with Conditions. **Note:** current report will only count the studies in the status of Approved or Approved with Conditions. If there has been a project status change e.g. halted, terminated it will not be captured here. Next variation of report will not have this issue.

Where response HREA Q1.18 (Data associated with human beings only) is selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected Where status contains: Approved or Approve with Conditions.		

Q 68 - For how many proposals did the HREC determine that the public interest in the proposed medical research did not outweigh, to a substantial degree, the public interest in the protection of privacy (i.e. the HREC did not approve the proposal)?

Rule:	Dashboard shows response as:	Notes/Guidance:
Of those included in 55 Where response HREA Q3.1 (Indicate the type of information/data you will be collecting for this project.) and Q3.2 (Indicate the type of information/data you will be using in this project.) Personal information was selected. AND Where response HREA Q1.18 (Indicate with whom or with what the research will be conducted) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected OR Where response HREA Q1.18 (Data associated with human beings only) is selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected Where status contains: Not approved	Number and a status list	If Not Approved does not appear in the Question 67 &68 – Personal Information Consent table the response is 0. Value only appears if there is a value at 57 that wasn't approved.

Q 69-78 Not collected in REGIS, Ethics Office to respond from own database.

Section I (Q 79-104) ***s95 Guidelines – Private Sector***

Q 79 Not collected in REGIS, Ethics Office to respond from own database.

Dashboard tab: Privately Held Database Q 80-94

Q80 - With respect to these proposals, did any involve collection, use or disclosure of personal information from a private sector organsiation? Note: This does not include the use or disclosure of personal information from a state/territory agency as you are not required to report these instances to NHMRC.		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 21 Where response HREA Q3.6 (Identify the source/s of the information/data that you will be collecting and/or using in this project) <u>Privately held database</u> was selected. AND Where response HREA Q3.1 (Indicate the type of information/data you will be <u>collecting</u> for this project.) OR Q3.2 (Indicate the type of information/data you will be <u>using</u> in this project.) Personal information was selected.	A number	The Privately Held Database list can be filtered/ordered by clicking on the Info Source header and exported by clicking on the Export to icon next to the dashboard parameters icon. To further validate the dashboard response column Info Source = Privately Held AND Info Type <u>Using</u> and/or <u>Collecting</u> has personal information.

Q 81 Not collected in REGIS. The answer should be "yes", as a HREC should not approve disclosure / use of data if it is not necessary.		
Q 82 With respect to these proposals, was it impracticable for consent to be obtained from the individuals to whom the health information related?		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 80 Where response HREA Q1.18 (Indicate with whom or with what the research will be conducted) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected OR Where response HREA Q1.18 (Data associated with human beings only) is selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected	"No"	The Privately Held Database list can be filtered/ordered by clicking Is consent obtained and Opt out headers.

Q 83 For any of these proposals, was identifiable data required (i.e. the purpose of the proposed activity could not be achieved using de-identified information)?		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 80 Where response HREA 3.3 (Indicate the degree of identifiability of information/data you will be collecting for this project) or 3.4 (Indicate the degree of identifiability of information/data you will be using in this project) Individually identifiable information is selected.	Number	The Privately Held Database list can be filtered/ordered by clicking Info Type Collected and Info Type Using

Q 84 For each of the following, how many proposals that involved the <u>collection, use or disclosure</u> of <u>identifiable health information</u> from a private sector entity did the HREC consider, in which the information was obtained <u>without obtaining consent</u> from all of the individuals to whom the information pertained:		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 83 Where response HREA 3.3 (Indicate the degree of identifiability of information/data you will be collecting for this project) or 3.4 (Indicate the degree of identifiability of information/data you will be using in this project) Individually identifiable information is selected.	Yes/No but the Research Office will need to use the link in the Privately Held Database list to view HREA to identify if 1, 2 or 3 1 Research relevant to public health or safety 2 The compilation or analysis of statistics relevant to public health or safety 3 The management, funding or monitoring of a health service	Research Office will need to manually determine of the items that appear in the Privately Held Database list which category they sit.

Q 85-92 Not collected in REGIS, Ethics Office to respond from own database.		

Q 93 For how many proposals did the HREC determine that the public interest in the proposed activity did substantially outweigh the public interest in the protection of privacy (i.e. the HREC approved the proposal)?		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 82 Where response HREA Q1.18 (Indicate with whom or with what the research will be conducted) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected OR Where response HREA Q1.18 (Data associated with human beings only) is	Number and a status list. Research Office would count Approved and Approved with Conditions	

selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected		

Q 94 For how many proposals did the HREC determine that the public interest in the proposed activity did not substantially outweigh the public interest in the protection of privacy (i.e. the HREC did not approve the proposal)?		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 82 Where response HREA Q1.18 (Indicate with whom or with what the research will be **conducted**) and Human beings (via active participation) or Human biospecimens only is selected AND HREA Q 2.2.7 (Data associated with human beings only) yes is selected or HREA Q 2.2.8 (Are you requesting a waiver of the requirement for consent with respect to some or all participants?) yes is selected OR Where response HREA Q1.18 (Data associated with human beings only) is selected AND HREA Q2.2.5 (Has consent been obtained from participants for the use of their data in the proposed research?) no is selected	Number and a status list. Research Office would count Not Approved	Response is 0 if status Not Approved does not appear.

Q 95-104 Not collected in REGIS, Ethics Office to respond from own database.		
Section J (Q 105-114) *Certified Institutions additional reporting* *Note: There is currently no clear way to identify a study as Multi-Centre in REGIS. The collection tool used may not accurately identify Multi-Centre studies.* *A new classification to have the RO manually record will be added for 2021 collection.*		

Dashboard tab: Multi-Centre Q 105-111		
Q 105 How many new multi-centre research proposals were reviewed during the reporting period?		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Checks Project Registration and Related Applications if more than 1 LHD is listed for SITE applications - so Yes if > 1 STE application	A number	The Multi List shows a list of applications and a filter for multi-centre

Q 106-107 Not collected in REGIS, Ethics Office to respond from own database.		
Q 108 Please specify the number of multi-centre research proposals reviewed for each relevant certified research category:		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 105 Where response HREA Q1.19 (From the list below, select all the research methods	A list of the Research Categories and an application count.	The Multi List shows each application and category of research. Research Office can identify individual studies and categories here.

that will be used in the research project.) is selected		
Q 109 Did your HREC review multi-centre research proposals that involved Children and Young People / Paediatrics?		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 105 Where response HREA Q1.17 (Will your research involve participation of any of the following?) and Children and young people is selected.	A number	The Multi List can be filtered/ordered by clicking on the Participant Group header
Q 110 Of all the new multi-centre research proposals reviewed, how many were completed within 60-calendar days? Note: The 60-calendar days' timeframe is to be determined by using the 'stop-clock' method. This 60-day timeframe is a Key Performance Indicator of the National Certification Scheme and further information can be found in Section 4.2 of the Certification Handbook, November 2012		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 105 Show metric 3 calculation	A number	The Multi List can be filtered/ordered by clicking on the EthicsMetrics3 header.
Q 111 Of all the new multi-centre research proposals reviewed, how many were intended for conduct:		
Rule:	**Dashboard shows response as:**	**Notes/Guidance:**
Of those included in 105 Where response HREA Q4.6 (Will this application be reviewed under the National Mutual Acceptance scheme?) response is Yes = in two or more Australian state or territories, where response is No = Within one Australian state or territory only	A number and a list	
Q 112-114 Not collected in REGIS, Ethics Office to respond from own database.		