Post-Approval Responsibilities

- How to maintain your study within approval guidelines -

Shona Van Garderen
HREC Admin Officer
19 April 2017

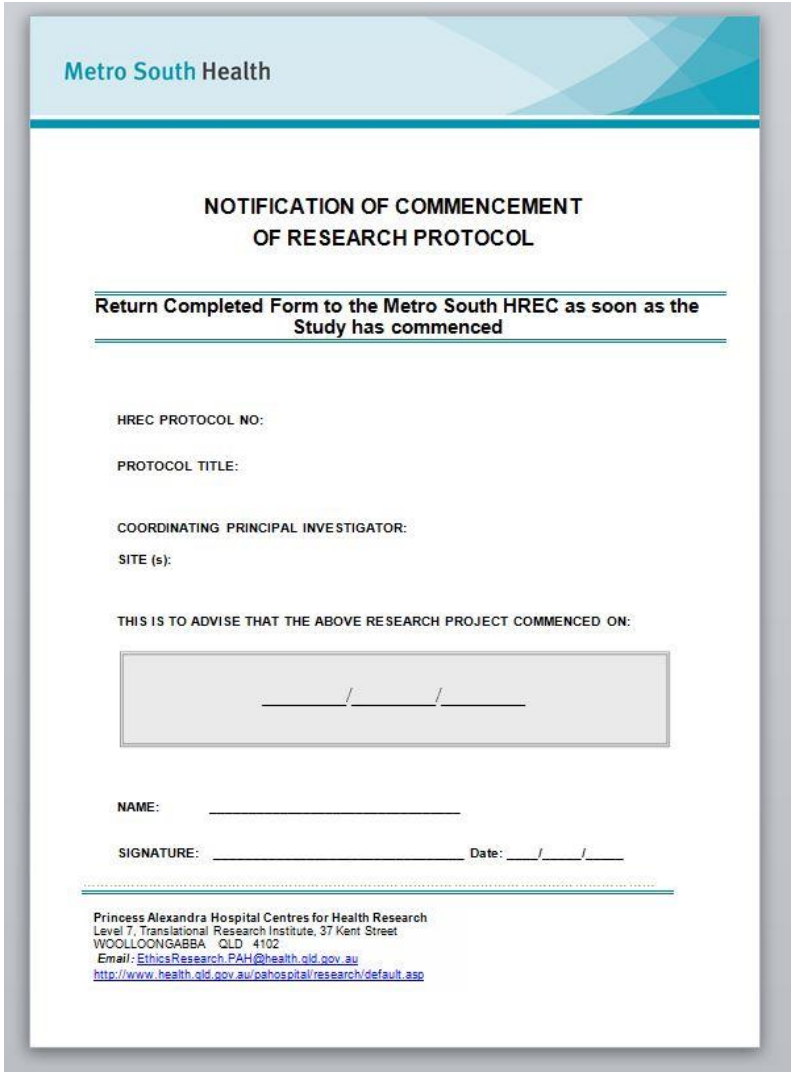
Study has been cleared by Ethics and given Governance Approval – yay!

So that's it all done now, right?

- In short – no.
- Through out the life of the study, things may happen that necessitate changes to study documentation which may need to be approved by the Human Research Ethics Committee (HREC).
- Additionally there are certain reporting requirements that must be met during the study period in order to ensure that Ethical Clearance and Governance Approval remain in place.
  - Notification of Commencement
  - Amendments
  - Annual Progress Reports
  - Safety Reporting
  - Finalisation/Closure of Study

Notification of Commencement

- When the research team “pick up a pen” and begin the study, the date this occurs must be notified to the HREC and Research Governance (external studies only).
- Complete the MSF11 Research Commencement Form and email through to the office.
- Important aspect of compliance as it informs us that the research project has begun and moves the study into “active” on our system.



Metro South Health

NOTIFICATION OF COMMENCEMENT
OF RESEARCH PROTOCOL

Return Completed Form to the Metro South HREC as soon as the Study has commenced

HREC PROTOCOL NO:

PROTOCOL TITLE:

COORDINATING PRINCIPAL INVESTIGATOR:

SITE (s):

THIS IS TO ADVISE THAT THE ABOVE RESEARCH PROJECT COMMENCED ON:

_____/_____/_____

NAME: _____

SIGNATURE: _____ Date: ___/____/____

Princess Alexandra Hospital Centres for Health Research
Level 7, Translational Research Institute, 37 Kent Street
WOOLLOONGABBA QLD 4102
Email: EthicsResearch.PAH@health.qld.gov.au
http://www.health.qld.gov.au/pahospital/research/default.asp

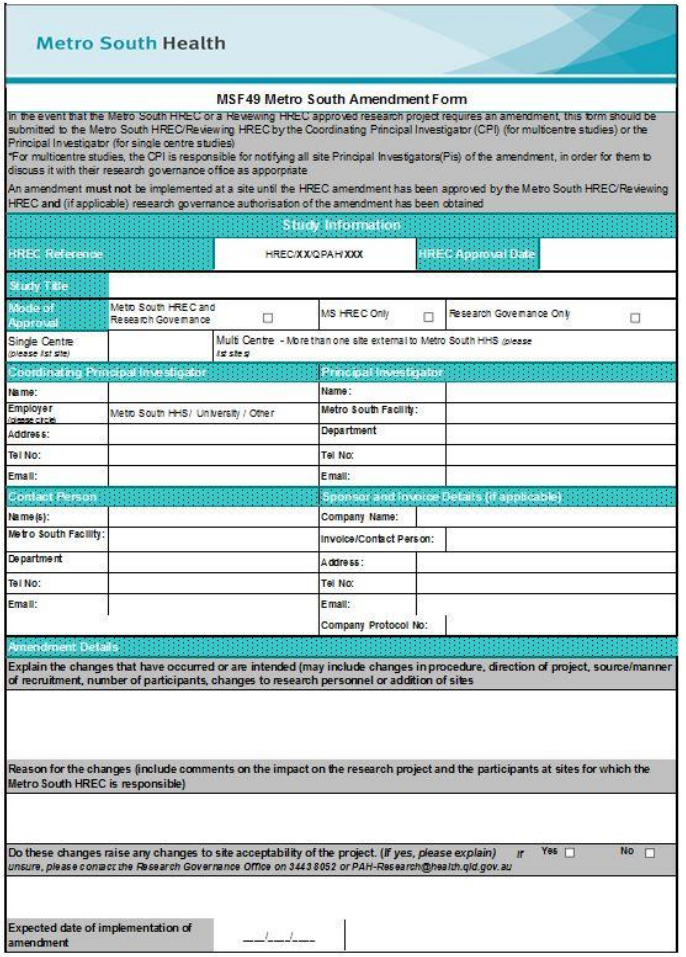
Amendments – When are they needed?

- Change to Principal/Associate Investigators or Contact Person only; do not need to be informed of research assistants or other staff.
- Addition/Removal of study sites
- Extension of Ethical Clearance: standard initial approval is only for 3 years, so if a study needs to continue beyond this time frame, need to apply for an extension. Must include justification for more time and also be accompanied by annual report.
- Updates to study documentation: Protocol, Investigator's Brochure, Participant Information and Consent Form, Advertising etc.
- HREC/Governance must always have the most up-to-date documents on file for a study for compliance purposes
- Generally do not approve "sub-studies" through amendment process, particularly if addressing new research aims/outcomes
- Amendments need to be within the risk level of the original approval eg if study was approved as Low Risk Research, then amendments should not raise the risk level. If this occurs, a new Standard Risk application may be needed.

Amendments - How to submit

- Complete the MSF49 Metro South Amendment Form and email through to the office.

- Need to include other relevant documentation such as:
  - Tracked and clean copies of updated documents
  - CVs for new investigators
  - Letter of acceptance of responsibility from lead investigators at new sites
  - Annual Report when applying for extensions



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MSF49 Metro South Amendment Form

In the event that the Metro South HREC or a Reviewing HREC approved research project requires an amendment, this form should be submitted to the Metro South HREC/Reviewing HREC by the Coordinating Principal Investigator (CPI) (for multicentre studies) or the Principal Investigator (for single centre studies)
*For multicentre studies, the CPI is responsible for notifying all site Principal Investigators(PIs) of the amendment, in order for them to discuss it with their research governance office as appropriate

An amendment **must not** be implemented at a site until the HREC amendment has been approved by the Metro South HREC/Reviewing HREC and (if applicable) research governance authorisation of the amendment has been obtained

Study Information

HREC Reference	HREC/XX/QPAH/XXX	HREC Approval Date	
Study Title			
Mode of Approval	Metro South HREC and Research Governance ☐	MS HREC Only ☐	Research Governance Only ☐
Single Centre *(please list site)*		Multi Centre - More than one site external to Metro South HHS *(please list sites)*	

Coordinating Principal Investigator		Principal Investigator	
Name:		Name:	
Employer *(please circle)*	Metro South HHS / University / Other	Metro South Facility:	
Address:		Department	
Tel No:		Tel No:	
Email:		Email:	
Contact Person		**Sponsor and Invoice Details (if applicable)**	
Name(s):		Company Name:	
Metro South Facility:		Invoice/Contact Person:	
Department		Address:	
Tel No:		Tel No:	
Email:		Email:	
		Company Protocol No:	

Amendment Details

Explain the changes that have occurred or are intended (may include changes in procedure, direction of project, source/manner of recruitment, number of participants, changes to research personnel or addition of sites

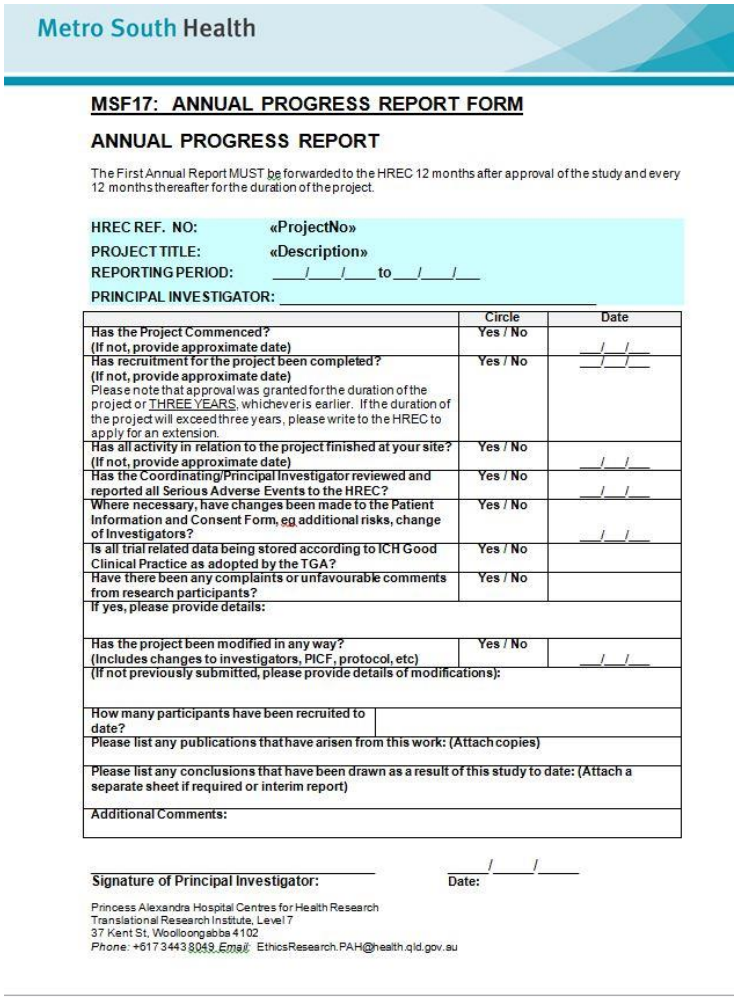
Reason for the changes (include comments on the impact on the research project and the participants at sites for which the Metro South HREC is responsible)

Do these changes raise any changes to site acceptability of the project. (*If yes, please explain*) If unsure, please contact the Research Governance Office on 3443 8052 or PAH-Research@health.qld.gov.au Yes ☐ No ☐

Expected date of implementation of amendment __/__/____

Annual Progress Reports

- Must be submitted annually on the anniversary of HREC Ethical Clearance in order to maintain ongoing compliance.
- Enables HREC to oversee the progress of the study such as recruitment numbers, any issues that have occurred in past twelve months etc.
- Good opportunity to reflect on the state of your study and ensure that all documentation is up-to-date in case you are monitored.
- Complete MSF17 Annual Progress Report and send via email to HREC Office.



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MSF17: ANNUAL PROGRESS REPORT FORM

ANNUAL PROGRESS REPORT

The First Annual Report MUST be forwarded to the HREC 12 months after approval of the study and every 12 months thereafter for the duration of the project.

HREC REF. NO: «ProjectNo»
PROJECT TITLE: «Description»
REPORTING PERIOD: ___/___/___ to ___/___/___
PRINCIPAL INVESTIGATOR: _____

	Circle	Date
Has the Project Commenced? (If not, provide approximate date)	Yes / No	__/__/__
Has recruitment for the project been completed? (If not, provide approximate date) Please note that approval was granted for the duration of the project or THREE YEARS, whichever is earlier. If the duration of the project will exceed three years, please write to the HREC to apply for an extension.	Yes / No	__/__/__
Has all activity in relation to the project finished at your site? (If not, provide approximate date)	Yes / No	__/__/__
Has the Coordinating/Principal Investigator reviewed and reported all Serious Adverse Events to the HREC?	Yes / No	__/__/__
Where necessary, have changes been made to the Patient Information and Consent Form, eg additional risks, change of Investigators?	Yes / No	__/__/__
Is all trial related data being stored according to ICH Good Clinical Practice as adopted by the TGA?	Yes / No	
Have there been any complaints or unfavourable comments from research participants?	Yes / No	
If yes, please provide details:		
Has the project been modified in any way? (Includes changes to investigators, PICF, protocol, etc)	Yes / No	__/__/__
(If not previously submitted, please provide details of modifications):		
How many participants have been recruited to date?		
Please list any publications that have arisen from this work: (Attach copies)		
Please list any conclusions that have been drawn as a result of this study to date: (Attach a separate sheet if required or interim report)		
Additional Comments:		

_____ ____/____/____
Signature of Principal Investigator: Date:

Princess Alexandra Hospital Centres for Health Research
Translational Research Institute, Level 7
37 Kent St, Woolloongabba 4102
Phone: +617 3443 8049 *Email:* EthicsResearch.PAH@health.qld.gov.au

Safety Reporting

- In November 2016, NHMRC released an updated Guidance on Safety Reporting and Monitoring for clinical trials.
- Metro South HREC has adopted this new guidance and the changes are as follows:
  - Adverse Events (AEs), Serious Adverse Events (SAEs), Suspected Unexpected Serious Adverse Reactions (SUSARs), Unanticipated Serious Adverse Device Effects (USADEs), and Six Monthly Line Listings no longer need to be reported to the HREC. These are only reported to the Sponsor.
  - Significant Safety Issue, which results in a change to the study protocol or consent forms, must be reported to the HREC within 15 days along with the updated documentation.
  - Urgent Safety Measure, which results in change in risk level of a participant, must be reported to the HREC within 72hrs with a plan on how to manage new risk level.
  - Annual Safety Report that includes clear summary of evolving safety profile of the trial and also evidence that sponsor is conducting its ongoing safety monitoring appropriately. Executive Summary of a Development Safety Update Report (DSUR) would be acceptable.

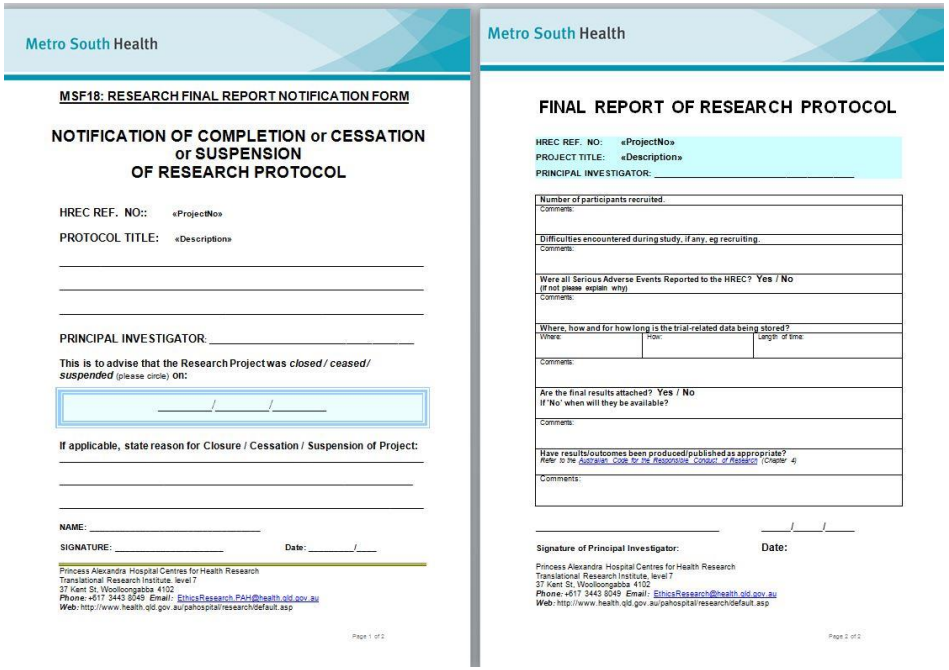
Safety Reporting Summary

- Adverse Events (AEs),
- Serious Adverse Events (SAEs),
- Suspected Unexpected Serious Adverse Reactions (SUSARs),
- Unanticipated Serious Adverse Device Effects (USADEs),
- Six Monthly Line Listings

- Significant Safety Issue – 15 Days
- Urgent Safety Measure – 72hrs
- Annual Safety Report

Study Finalisation and Closure

- When all activity on a study has been completed, “pens are down”, that is when you submit a Final Research Report to the HREC.
- Or if a study is terminated early, suspended ,or made in-active for some reason, also submit this form.
- MSF18 Research Final Report Notification Form
- Send to HREC Office via email. Must be signed and dated by Principal Investigator.
- Ensures that only ‘active’ studies are kept open on our system and you won’t receive any Annual Progress Report reminders!



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MSF18: RESEARCH FINAL REPORT NOTIFICATION FORM

NOTIFICATION OF COMPLETION or CESSATION or SUSPENSION OF RESEARCH PROTOCOL

HREC REF. NO:: «ProjectNo»

PROTOCOL TITLE: «Description»

PRINCIPAL INVESTIGATOR:

This is to advise that the Research Project was *closed / ceased / suspended* (please circle) on:

_____/_____/_____

If applicable, state reason for Closure / Cessation / Suspension of Project:

NAME:

SIGNATURE: Date: _____/___

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Metro South Health

FINAL REPORT OF RESEARCH PROTOCOL

HREC REF. NO: «ProjectNo»
PROJECT TITLE: «Description»
PRINCIPAL INVESTIGATOR:

Number of participants recruited. Comments:
Difficulties encountered during study, if any, eg recruiting. Comments:
Were all Serious Adverse Events Reported to the HREC? Yes / No (If not please explain why) Comments:
Where, how and for how long is the trial-related data being stored?

Where:	How:	Length of time:

Comments:
Are the final results attached? Yes / No If 'No' when will they be available? Comments:
Have results/outcomes been produced/published as appropriate? Refer to the Australian Code for the Responsible Conduct of Research (Chapter 4) Comments:

_____ _____/_____/_____

Signature of Principal Investigator: Date:

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Thank you

Any questions?