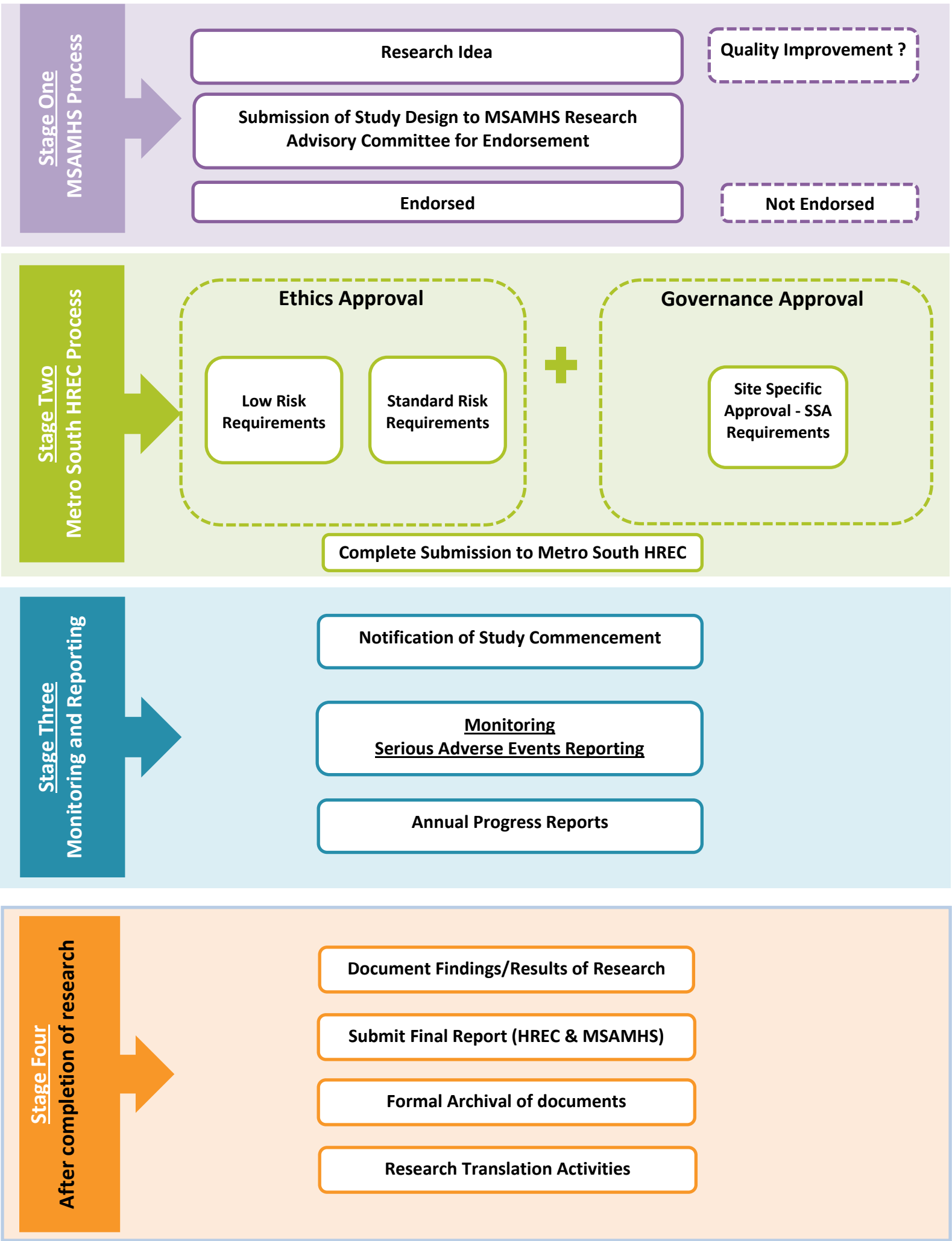
Stage One
MSAMHS Process
Research Idea
Quality Improvement ?
Submission of Study Design to MSAMHS Research Advisory Committee for Endorsement
Endorsed
Not Endorsed
Stage Two
Metro South HREC Process
Ethics Approval
Low Risk Requirements
Standard Risk Requirements
Governance Approval
Site Specific Approval - SSA Requirements
Complete Submission to Metro South HREC
Stage Three
Monitoring and Reporting
Notification of Study Commencement
Monitoring
Serious Adverse Events Reporting
Annual Progress Reports
Stage Four
After completion of research
Document Findings/Results of Research
Submit Final Report (HREC & MSAMHS)
Formal Archival of documents
Research Translation Activities

Stage One - MSAMHS Process

3rd Party Research

(For Universities, Sponsored Clinical Trials, NGOs & other organisations)

MSAMHS Research

Determine whether study purpose is Research or Quality Improvement Process

Identify Research Feasibilty and appropriate MSAMHS pathway
Contact MSAMHS

Purpose is test hypothesis/ develop new knowledge = Research

Purpose is to evaluate service or program = Quality Improvement and you wish to publish or present at conference
Complete Human Research Ethic s Application (HREA) through Ethics Review Management online system (ERM)

Research Design and MSAMHS RAC Support

1 Check existing research projects — Check Research Database for duplication

2 Plan and design your research project — Use Research Protocol Template *(or If you use your own Protocol format your must complete the Research Proposal Form below)*

3 Sign off from Managers & ACU — MSAMHS Research Proposal Form *(complete if you are NOT using the MSAMHS Protocol Template – above)*
Research Contract form *Research Contracts Approval and study execution form RCASE*

4 MSAMHS Support — Sumbit Form/s to MSAMHS RAC

Supported
(Use Protocol and RAC support letter in Ethic submission – See Stage 2)

Not Supported
Consider amending protocol according to RAC feedback

Stage Two
HREC Process

Obtain Ethics Approval

Once you have received MSAMHS RAC Support, apply for Ethics approval via your preferred Hospital Human Research Ethics Committee.

The Metro South HREC Ethics process covers Low and Standard Risk applications.

Check submission deadlines(for Standard Risk Submissions only)

Enquiries:
(07) 3443 8049
MSH-Ethics@health.qld.gov.au

Note:

It is Metro South HREC preference that the Ethics and Governance applications be submitted concurrently

Obtain Governance Approval Site Specific Assessment – SSA

- You must gain Metro South Health Governance approval for all research projects conducted at any MSAMHS site.
- Follow Metro South Site Specific Assessment application requirements
- Provide the Research Contract Approval and Study Execution Form (RCASE) and a copy of the completed SSA to the MSAMHS Research Project Co-ordinator who will arrange sign off by MSAMHS Finance Manager & Executive Director. Co-ordinator will email signed copies to Researcher.

Enquiries:
(07) 3443 8050

MSH-RGO@health.qld.gov.au

To note

- Single site – research will be conducted within one site – Metro South is considered one site
- Multi-centre – research will be conducted in more than one site i.e. Metro South and Metro North
- Clinical trials – mandatory completion of Good Clinical Practice (GCP) training. Logon to Leaponline and you be taken directly to the course - Good Clinical Practice
- Annual reports - required to be submitted to respective HREC annually by 30 April through ERM
- No longer required to seek extension for projects. However, failure to submit annual reports will mean the National Statement for Ethical Conduct in Human Trials (2010) ethical requirements have not been met.

Stage Three
Monitoring and Reporting

Notification of Study Commencement

- Notify Metro South HREC/ Governance Office and MSAMHS of commencement of project Research Commencement Form

Monitor Project

The Metro South Health Human Research Ethics Committee (HREC) no longer requires reports of safety and adverse events. Metro South Health conforms to the National Health and Medical Research Council (NHMRC) Position Statement: Monitoring and Reporting of Safety for Clinical Trials.

Metro South Health Human Research Ethics Committee (HREC) will review:

- Safety reports if appropriate and necessity is provided by the researcher
- Research Protocol violations (not deviations)
- Notify of Amendment to study (if required) – Amendment process. Warning: your Ethics approval is *only* valid for the version of the documents submitted when Ethics approval was granted. *ALL* version updates must be resubmitted Ethics along with the Amendment Application Form.
- Research Project Complaint process

Progress Reporting

Annual Progress Report to HREC and MSAMHS to be submitted through ERM annually by 30 April

Stage Four
After completion of research

Research Project Completion

- Finalise documentation of research findings/results

Report Project Completion

- Submit Final Report to HREC & MSAMHS

Formal Research Document Archival Process

- Collate all research documents (electronic and hard copies)
- Provide to MSAMHS Research Project Co-ordinator for archiving as per legislative requirements

Research Translation

- Provide findings to ACU and professional groups
- Meet with Learning Development Committee for broader translation strategies
- Publish findings