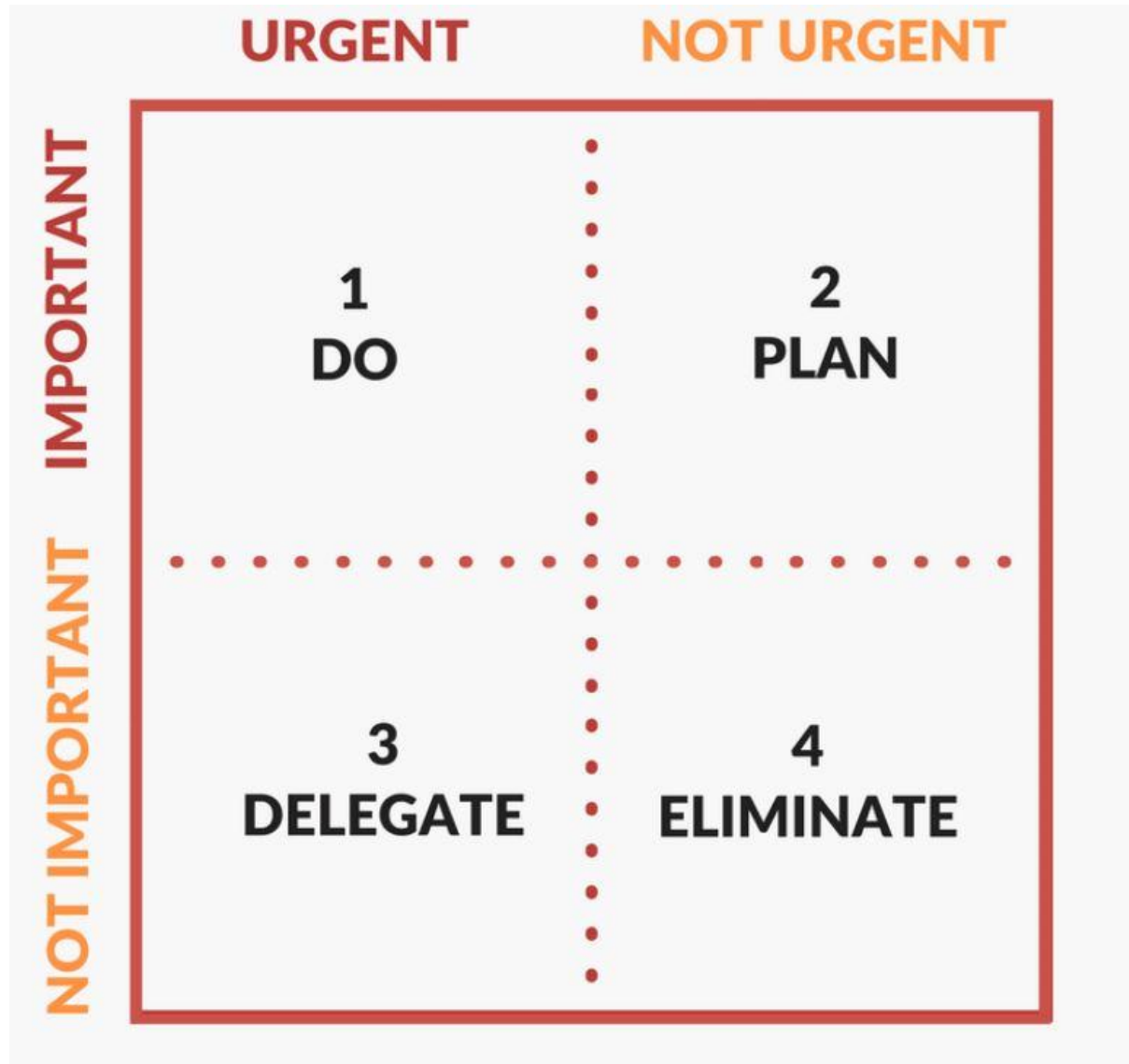


EXAMPLE: STAKEHOLDER ENGAGEMENT/COMMUNICATION PLAN

Stakeholder	Area of influence	Project Phase	Stakeholder Manager	Engagement approach	Engagement focus	Frequency
HREC	Research Governance	Planning, Execution, Control, Close	Research Manager Principal Investigator	Consultation and communication	Electronic Submission of application Email correspondence Meetings in person as required	Consult: Prior to ethics submission Communicate: as necessary Safety Reporting Annual and other reporting Amendments
Sponsor	Research Funder	All phases	Principal Investigator Research Manager Research Staff	Consultation and communication	Email correspondence Meetings in person as required TC/Video link Remote Monitoring	Site verification Site start up Site monitoring Site close out
Trial Participants	Consumers and the general public	All phases	Principal Investigator Research Manager Research Staff	Consultation and communication	Advertising Recruitment campaigns Public Forums Patient/Disease Advocacy Group meetings Social Media	At study concept planning Recruitment phase During study conduct (seek feedback on experience) Between visits Post close out



<https://www.developgoodhabits.com/eisenhower-matrix/>

Protocol ID/Name:		Principal Investigator	
Reported by:(name)	Signature of Reporter:	Date of CAPA completion:	
Description of Problem/Risk or Event: (include date event occurred)			
Was a root cause analysis (RCA) completed? No <input type="checkbox"/> Yes <input type="checkbox"/> Attach to this CAPA. Note it is best practice to complete <u>a</u> RCA for every CAPA			
Immediate action taken to manage this problem/risk/event (correction): Examples might include things like; training support, individual meeting with staff member or PI , alteration to site environment, additional human or other resources, referral to OHS/HR. You can use dot points if you like.			
Action taken to prevent the reoccurrence of this problem/risk/event in the future (prevention): Examples might include things like; amending SOPs or creating new ones, amending orientation training plans, implementation of weekly team meetings. You can use dot points if you like.			
PI Name, Signature and Date :			
Review Date: Note - this could be at the end of study, annually or more frequently if necessary. Review is an essential element of a quality management system.			
Review comments on the effectiveness of the actions taken:			
Reviewer Name/Signature :	Date of Review:	PI Name/Signature	Date:

EXAMPLE CAPA TEMPLATE - Corrective and Preventive Action Plan

EXAMPLE: RISK REGISTER

Risk		Probability	Impact	Level of Risk	Mitigation Approach	Owner	Status
1	Poor Data Quality	Moderate	Moderate	Moderate	<ul style="list-style-type: none"> Improved data management and audit process Education and Training 	Data Team	Actioned - Training program planning in process
2	Not meeting recruitment target	Moderate	High	Extreme	<ul style="list-style-type: none"> Improved pre-screening process Adequate budget planning Improved marketing skills and varied approach 	Recruitment Team Unit Manager Study Coordinator	In progress

	Risk	Probability High Moderate Low	Impact High Moderate Low	Level of Risk Extreme (Red) Moderate (Amber) Low (Green)	Mitigation Approach	Owner	Status
1							
2							
3							
4							
5							
6							

Meeting Project Objectives		Probability		
		Low	Medium	High
Impact	High / Extreme	Not receiving ethics approval	Not meeting recruitment target	Loss of funding by not meeting milestones
	Moderate	Change of team leader	Failure or malfunctions of equipment	Poor Data Quality
	Low	Withdrawal of an Associate Investigator	Change of team members	Neglecting hardcopy and electronic filing

Perform CAPA for risks identified during the planning or conduct stage of a study that are “High Impact” and “High Probability” – ie those in the red zone. CAPA does not need to be performed for all risks – only those that are likely to impact :

1. Patient Rights or Safety
2. Data Integrity
3. Compliance with regulatory requirements;
4. Trust in the clinical research enterprise

Meeting Project Objectives		Probability		
		Low	Medium	High
Impact	High / Extreme			
	Moderate			
	Low			

PROJECT TITLE:		PROJECT REF:
PROJECT MANAGER:	PROJECT SPONSOR:	AREA/DEPT:
KEY PROJECT CONTACT:		REPORT DATE:
REPORTING PERIOD:	FROM:	TO:

MILESTONES	RESPONSIBLE	PROGRESS		TARGET DATE
		% COMPLETE	✓ COMPLETE △ ON TARGET ✘ BELOW TARGET	

GENERAL UPDATE:

VARIATIONS/CHANGES:

RISKS AND ISSUES:

RECOMMENDATIONS / COMMENTS / ACTIONS REQUIRED:

ACTION	RESPONSIBLE	DUE DATE

NEXT STEPS:

PROJECT TITLE:	CHAIR:
DATE:	
ATTENDEES:	

1. WELCOME

2. GENERAL UPDATE

3. DECISIONS

DECISION DETAILS	MADE/AGREED BY:	DATE:	COMMENTS

4. KEY ACTIONS

ACTION DETAILS	RESPONSIBLE	DUE DATE:	COMMENTS

5. RISK AND ISSUES

ACTION DETAILS	RESPONSIBLE	DUE DATE:	COMMENTS

6. NEXT STEPS:

-

Books:

AXELOS. 2017. Managing Successful Projects with PRINCE2® 2017 Edition.

Project Management Institute. A Guide to the Project Management Body of Knowledge (PMBOK® Guide). 6th edition.

Wysocki, R. (2014). Effective Project Management: Traditional, Agile, Extreme. 7th edition.

Project Management Software:

The Best Project Management Software of 2018 (PC MAG AUSTRALIA) <https://au.pcmag.com/software/10283/guide/the-best-project-management-software-of-2018>

8 of the Best Project Management Tools for (Almost) Any Task <https://technologyadvice.com/blog/information-technology/5-of-the-best-project-management-tools-for-almost-any-task/>

Project Management software <https://www.capterra.com/project-management-software/>

Risk in Clinical Trials

Marsh Report: Minimising Risk in Clinical Trials. July 2017 <http://www.onenucleus.com/media/Events/2017/BioW/Report.pdf>

Quality Management Systems

CTTI: <https://www.ctti-clinicaltrials.org/projects/quality-design>

Transcelerate :

<https://journals.sagepub.com/doi/abs/10.1177/2168479016651300>

<http://www.transceleratebiopharmainc.com/initiatives/quality-management-system/>

Scope Creep

<https://www.mbopartners.com/blog/how-to-manage-scope-creep>

Templates:

Project Management Plan:

<http://www.health.nsw.gov.au/wohp/tools/Pages/pm.aspx>

https://www.aci.health.nsw.gov.au/_data/assets/word_doc/0010/279091/Implementation_PMP_template.docx

Clinical Trial Budget template (NSW Health): <https://www.medicalresearch.nsw.gov.au/clinical-trials-budget-costing-tool/>

Risk log/register: <http://www.health.nsw.gov.au/wohp/Documents/risks-issues-template.xls>

Project status report:

<https://www.aci.health.nsw.gov.au/resources/redesign/change/making-change/project-report.doc>

IHPA pricing framework: <https://www.iHPA.gov.au/what-we-do/pricing-framework>

OTHER RESOURCES:



Time Management Resources:

Smartsheet. A Detailed Guide to Time Management Skills and Techniques <https://www.smartsheet.com/time-management-techniques>

Planet of success. Effective Time Management Tips. 2010-2011. <http://www.planetofsuccess.com/effective-time-management/>

Mindtools. Managing email effectively. <https://www.mindtools.com/pages/article/managing-email.htm>

Mindtools. Managing Interruptions. https://www.mindtools.com/pages/article/newHTE_94.htm