PC4

Engaging general practice in practice-based research: a budgeting and best practice guide

2025

Supported by the RACGP

Primary Care Collaborative Cancer Clinical Trials Group (PC4)

Suggested citation
Jones, J., Nagorcka, S., Milley, K., Rhee, J., Vuong, K., Emery, J., Green, J., Ee, C.
Engaging general practice in practice-based research: a budgeting and best practice guide 2025 (3rd Edition)

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ABOUT THIS GUIDE

This guide was developed using a combination of expert insights and evidence review and is applicable for investigator-initiated research. Much of the available evidence relates to recruitment in pre-COVID times and the landscape has been rapidly evolving. To ensure its relevance and practicality, this guide integrates both current evidence and real-world experiences. A list of relevant case studies and references can be found on the final pages.

INTRODUCTION

General practice is the first point of access to the health system for most Australians.

Over **80%** of the population visit a general practitioner each year[1]

General practice research is vital as it provides evidence to underpin innovation and improvements to clinical practice and service design to continually enhance the delivery of efficient, equitable and effective primary care health services.

The nature and financial structure of general practice creates challenges for primary care research.[2] An early understanding of these challenges, and strategies to overcome them, may assist researchers to engage and partner more successfully with general practice, general practice staff and patients.

WHO ARE WE?

PC4 is the Primary Care Collaborative Cancer Clinical Trials Group funded by Cancer Australia to support the development of high-quality cancer clinical trial research in primary care

PC4

This guide was developed with cancer research in mind, however it is also broadly relevant to other general practice research.

UNDERSTANDING THE PRIMARY CARE LANDSCAPE

There are over **7,200** accredited general practices across Australia.[3]

Practices vary in size, staffing, geographical location and research experience and capacity.[4] To work successfully within this diversity, and acknowledging the ongoing workforce capacity challenges, researchers must be creative and flexible to meet individual practice needs.

- Most general practices are small, privately funded businesses and participating in research can be burdensome, therefore it is essential for researchers to adequately support clinics and staff to engage in research development and conduct. This includes compensation for staff time, minimising disruptions to clinic workflow, and training staff in new processes.
- Research has traditionally been under-valued in general practice,[5] therefore practices may have limited research systems in place (such as infrastructure, processes and dedicated time).
- Most GPs are engaged as self-employed sole traders (contractors) within a collaborative clinic arrangement, and therefore are independent small business owners in their own right.
- Most GPs do not receive a salary or any paid non-clinical time, nor do they receive annual leave or sick leave allowances or superannuation. Therefore, time that GPs spend on research must be remunerated, as it further dilutes their income.
- Tailored supports and incentives need to be considered, which may impact your trial design, budget and timeframes.

THREE TYPES OF GENERAL PRACTICE PARTICIPATION

There are three distinct ways general practice can be involved in research, each with their own budgeting requirements. For more details on budgeting recommendations go to page 8.

TYPE 1

GENERAL PRACTICE AS A STUDY PARTICIPANT

In this type of involvement (cluster-randomised trials) the practice is enrolled in the study as a participant.

Practice-Based Research Networks (PBRNs) such as APCReN, PARTNER, VicREN and WAGPBRN are groups of primary care practitioners, academic GPs, clinics and researchers that work together to conduct primary care research. These groups may be able to work with you to develop your project design and identify practices and clinics interested in participating in your study. There may be a cost associated with this service.

TYPE 2

GENERAL PRACTICE AS A RECRUITMENT LOCATION

In this type of involvement general practices are enrolled in the study. Depending on the specific study, the participants may be patients, staff, clinicians, or a combination of these. Patients may be screened with the goal of recruiting them into the study.

Practice-Based Research Networks (PBRNs) may be able to work with you to develop your project design and identify practices and clinics interested in participating in your study. There may be a cost associated with this service.

TYPE 3

EXPERT INPUT FROM GENERAL PRACTICE STAFF

In this type of involvement individual practice staff (GPs, practice nurses or practice managers) provide early input into clinical trial development and design. They may critique the feasibility, acceptability and practicality of a study or provide ongoing input as the trial progresses. Expert input can be useful at the start of a study, continuously, or as part of a qualitative sub study.

It is recommended to include at least one general practice Investigator as part of your trial team. There is an expectation within the research field that meaningful engagement and/or co-design occurs in the development of any primary care or general practice-focused research.

PC4 has a General Practice Advisory Group comprising GPs, practice nurses and practice managers who may be able to provide expert review for members.

BARRIERS, ENABLERS AND INCENTIVES

The way in which you approach a practice can influence your success. Below is a summary of recruitment barriers and enablers from a number of practice-based research studies.[6-11]

There are also incentives to consider. Incentives are things that can be given to a practice or individual practice staff to encourage participation. Together, enabling practice participation and providing incentives to participate in research can boost your recruitment success.

RECRUITMENT BARRIERS	RECRUITMENT ENABLERS
Workload in general practice impacting participation in research	Trial team conducts most of the work, reducing pressure on practice staff
Cost of conducting research in general practice	Appropriate resourcing to reimburse for staff time
Difficulty prioritising research due to perceived demands of study or time constraints	Streamlined research process to minimise practice disruption / Flexibility to accommodate differing practice needs
Few eligible patients perceived by GP/ Lack of clarity about recruitment inclusion & exclusion criteria to identify eligible patients	Integrated screening to identify eligible patients in the clinic
Study thought not to be clinically relevant for patients/No Study GP on the research team	Engage meaningfully with a study GP, utilise GP to GP invitation
Difficulty communicating trial information to potential participants	Identifying a practice champion and providing them with resources
GP and practice staff not empowered to recruit within a group practice	Buy-in from all practice staff and a whole of practice approach

PARTICIPATION INCENTIVES

Different incentives are naturally more appealing and relevant to different practices and health professionals. The incentives fall into three broad categories:

1. **Financial incentives** (researcher funded)
2. **Financial incentives** (government/other funded)
3. **Non-financial incentives**

1 Financial incentives (researcher funded)

The following tables reflect reasonable costs for clinical trials in primary care, based on our experience, general practice consultation, and data from previously funded studies. These figures offer a guide to creating a well- funded budget for practice-based trials, depending on the study design.

- These rates apply to trials where the research team handles the majority of the work.
- Trials that involve significant practice staff input (e.g., for patient identification, consent, follow-up, or intervention delivery) should be costed differently.
- Studies that place a heavy burden on practice staff often experience lower recruitment and retention.
- Some study designs may be better suited to whole-practice payments, while others may work well with staff incentives.
- If a study has multiple components, each may require a different incentive model.
- The clinic's staffing structure (e.g., salaried staff vs. consultants) may affect payment distribution, which is important to consider as it could influence staff motivation and participation.

NB: We have used the word 'incentive' here, but when communicating with practices and health care professionals, it may be better to refer to payments as 'reimbursements' or 'tokens of appreciation', recognising that most payments will not cover the full cost associated with a clinic's involvement.

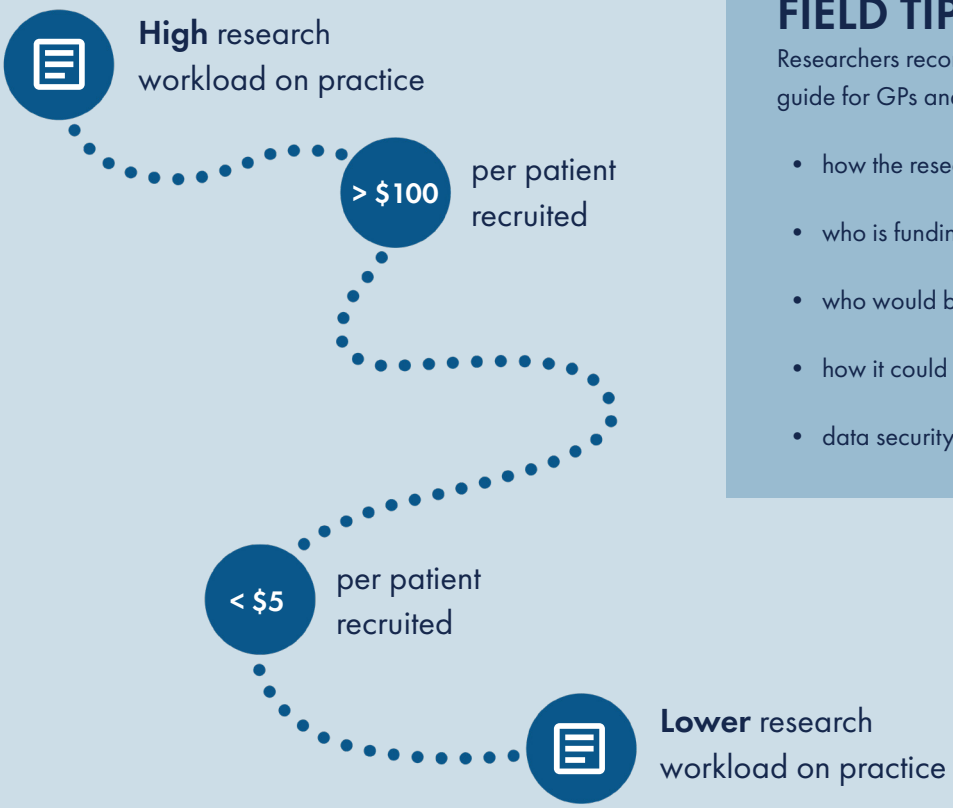
TABLE 1

SUGGESTED FINANCIAL INCENTIVES (RESEARCHER FUNDED)

TYPE 1

GENERAL PRACTICE AS A PARTICIPANT

Element	Suggested Incentive	Notes
Practice Incentives		
Practice milestone payments	**Project initiation** For example, $1000 paid to the practice on completion of all relevant paperwork and software installation	The final amount offered to the practice depends on staff/clinician time required, complexity of the project, number of participants involved, management of risks, and the existence of other incentives. Examples are offered as a general guide and should not be applied directly without consideration of your individual circumstances.
	Project completion For example, $500 paid to the practice once the study is complete and all data and trial paperwork returned.	



FIELD TIP!

Researchers recommend creating a one- page guide for GPs and practice staff, addressing:

- how the research is evidence-based
- who is funding it
- who would benefit most
- how it could help their patients
- data security and any payments

TABLE 2

SUGGESTED FINANCIAL INCENTIVES (CONTINUED)

TYPE 2

GENERAL PRACTICE AS A RECRUITMENT LOCATION

Element	Suggested Incentive	Notes
Practice Incentives		
Practice milestone payments	**Project initiation** For example, $1000 paid to the practice on completion of all relevant paperwork and software installation.	Optional: If the trial requires a private practice room, an additional $500 per day should be allocated. Dedicated space may not be viable for all practices and researchers should liaise with individual practices to discuss trial needs.
	Practice completion For example, $500 paid to the practice once the study is complete and all data and trial paperwork returned.	
Patient milestone payments	**Patient recruitment** For example, $4 paid for each patient recruited, up to $300.	
	Patient completion For example, $10 paid for each patient who completes the study, up to $500.	
Staff Incentives		
General practice nurses/primary health care nurses/ nurse practitioners	$50-200p/h	Activities are varied and may include: participating in qualitative sub-study interviews, patient recruitment and or consultations. Clinician participation increases when reimbursement matches or exceeds their hourly patient consultation rate.
GPs	$150-250 p/h	This amount is not a full compensation for lost earnings, however non-clinical time is remunerated differently by most organisations and provides a partial contribution towards lost earnings.
Administration time	$35-50 p/h	
Practice champions		This amount may be absorbed into the whole practice payment, but consider a one-off incentive

TABLE 3

SUGGESTED FINANCIAL INCENTIVES (CONTINUED)

TYPE 3

EXPERT INPUT FROM GENERAL PRACTICE STAFF

Element	Suggested Incentive	Notes
Staff Incentives		
GPs, general practice nurses and practice manager expert input into research development and/or ongoing trial input	$150-250 p/h	PC4 has established a group called the General Practice Advisory Group who may be able to provide expert input for members. You may wish to consider equal reimbursement for all staff providing expert input, regardless of role. This amount is not a full compensation for lost earnings, however non-clinical time is remunerated differently by most organisations and provides a partial contribution towards lost earnings.

2 Financial incentives (government/other funded)

2.1 MBS ITEMS

Many services provided by general practices are a part of the Medicare Benefits Schedule (MBS) and will be subsidised by the Australian Government.

It is worthwhile considering if the requirements of your study match with any MBS items that can be claimed. This may impact the research-funded incentives you need to budget for, as MBS subsidisation may help cover the time and costs incurred.

Ensure that the practice you're working with is aware of any eligible MBS items that can be claimed through your study. MBS items can be searched on this website but we also recommend consulting with a practicing GP who can provide further information on the practicalities of claiming specific MBS items.

2.2 QUALITY IMPROVEMENT

Could your study be used by a practice as a quality improvement program? It is best to consult with the individual general practices about this option. Read more about the

3 Non-financial incentives

3.1 CONTINUING PROFESSIONAL DEVELOPMENT (CPD) HOURS

CPD hours can be a big motivator for clinicians and we recommend researchers familiarise themselves with the basics of CPD. We are focusing on GP CPD hours, however many of the principles also apply to nursing CPD hours, which you can read more about on APNA's website.

As an alternative or in addition to financial reimbursement, accrediting your trial as a CPD approved activity with RACGP and ACRRM can make participation more appealing to GPs.

- CPD activities often have a monetary cost to clinicians, so the chance to obtain them without financial outlay is often welcomed.
- CPD accreditation should be considered early in your project timeline, as the accreditation process can take considerable time.
- Research institutions often have an allocated person to assist with accrediting activities, so reach out to your institution to see if they can assist.
- Not all research projects and activities are suitable for CPD accreditation, however clinicians may still be able to self-log unaccredited research activities to count towards their CPD hours.
- There are three categories of CPD hours: Reviewing Performance, Measuring Outcomes and Education.
- Reviewing Performance and Measuring Outcomes CPD hours may be more appealing to clinicians as they can be harder to obtain than Education hours.
- All GPs must obtain at least 5 hours in Reviewing Performance and 5 hours in Measuring Outcomes.
- GPs should consult their CPD home for templates for recording their participation in research.

Below are two examples of activities that may be integrated into a study design to allow CPD recognition.

EXAMPLE 1
EDUCATIONAL HOURS

A one-hour education session that introduces the clinical or health services focus of the research, (delivered either face-to-face or via interactive webinar)
Participants can log their attendance at this education session as an educational activity.

EXAMPLE 2
REVIEWING PERFORMANCE / MEASURING OUTCOMES HOURS

- GPs obtain CPD hours for participating in research either as Principal Investigators, or as participants in group-based research.
- GPs record the title of the activity and the activities they were involved in. For example, reading the materials provided by the Principal Investigator, collecting data, reading or contributing to reports, attending meetings, and a self-reflection.
- The research team provides recognition of their involvement via certificate or letter.

3.2 RECOGNITION

RESEARCH PUBLICATIONS

Co-authorship or inclusion as an Associate or Chief Investigator on grant applications is an important consideration when clinicians or staff have provided ongoing expert input. Providing co-authorship recognises their time and helps encourage participatory research practices. GPs are able to claim co- authorship as part of their CPD activities under either Educational Activities or Reviewing Performance.

CONFERENCES

Financial barriers are a significant issue for general practices, who do not receive payment for non- clinical time, unlike public hospitals who have research options for health professionals. An invitation to travel to a conference under a travel or registration bursary may be appealing to some staff and clinicians who have provided ongoing expert input or contributed at the level of Associate Investigator or higher.

3.3 INFRASTRUCTURE

Some clinical trials may require additional IT requirements and/or upgrades. This may enable clinics to improve their infrastructure at little or low cost.

Is your study an opportunity for the clinic to upgrade their record keeping process or otherwise improve their data management or meet standards/requirements that were not being met?

3.4 TRAINING & KNOWLEDGE

There are many opportunities for clinical and non-clinical staff to up-skill when recruited into a trial. This may include training in the research process, procedure and ethics, but also encompasses wider training and knowledge. Some examples include:

- Process and administrative improvements - e.g. administrative staff taught how to generate patient lists so clinician time can be diverted elsewhere.
- Software up-skilling - e.g. installation of clinical reminder software with training provided to staff.
- Software up-skilling - e.g. installation of clinical reminder software with training provided to staff.
- Industry news - e.g. a presentation on the altered age-eligibility for the National Bowel Cancer Screening Program.
- Most general practices conduct some form of weekly educational meeting that can be utilised by research staff if the practice deems it appropriate. Presentations of 5-10 minutes are ideal for this setting.

STUDY EXAMPLES

EXAMPLE 1
(GENERAL PRACTICES AS TRIAL PARTICIPANT)

Cluster randomised controlled trial with 40 practices. Intervention tested a new electronic decision support tool. Clinics were reimbursed $500 to compensate for staff time on project related tasks.

Staff were also provided training both face-to-face and via webinars. As an additional incentive, the licensing costs and technical support were provided for free for 12 months following the completion of the study. More information here

EXAMPLE 2
(GENERAL PRACTICES AS TRIAL PARTICIPANT)

A large cluster-randomised controlled trial with >50 practices recruited. Intervention about increasing use of a diagnostic test. Sliding scale payment per patient based on percentage of eligible patients' tests <20% $5, 20-40% $7 and over 40% $8 per patient. More information here

EXAMPLE 3
(GENERAL PRACTICE AS RECRUITMENT LOCATION)

A large multi-site, multi-state randomised controlled trial. This study reimbursed clinics $100 for every patient recruited by GPs (note the large per patient recruitment fee due to GPs conducting recruitment). More information here

EXAMPLE 4
(EXPERT INPUT FROM GENERAL PRACTICE STAFF)

A Chief Investigator developing their research funding application met online for 30 minutes with two representatives from general practice (one general practitioner and one practice nurse) to discuss the feasibility and practicality of the proposed research design from a general practice perspective. The GP and practice nurse each received a $150 voucher. An additional $600 was allocated in the grant proposal to accommodate ongoing input from general practice (two additional meetings with a general practitioner and a practice nurse).

CHECKLIST

GENERAL

- O Create a one-page FAQ for staff (see tip on page 9)
- O Prepare for the heterogenous nature of general practices by allowing extra time for recruitment
- O Identify opportunities for expert general practice input throughout your study (early input is recommended)
- O Assess your study design and identify places you may reduce the research workload for the practice and practice staff

BUDGETING

- O Research appropriate financial incentives for your study (whole of practice incentives, vs staff incentives – you may use both in the one study)
- O Budget for practice and staff time
- O Budget for expert general practice input into study design and implementation
- O Discuss MBS items and quality improvement with a clinician to identify potential opportunities

CPD HOURS

- O Identify the person within your institution who can assist with CPD accreditation
- O Familiarise yourself with the type of CPD hours and what research participation activities may be eligible for accreditation
- O Provide a certificate or letter that acknowledges research participation

RECOGNITION

- O Decide how contributors will be recognised in publications and grant applications e.g. Consumer Investigator or Assistant
- O Investigator Identify future conferences that may be appealing for contributors to attend

INFRASTRUCTURE

- O Identify potential infrastructure offerings your study may bring to a practice e.g. IT or data management upgrades

TRAINING AND KNOWLEDGE

- O Identify potential up-skilling and training your study may provide e.g. process and administrative improvements, software up-skilling, clinical training/education and industry news

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