PRAGMATIC CLINICAL TRIALS OPEN FUNDING CALL

Competition Guidelines

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B. Key Dates

Competition materials available online	On or before December 2, 2024
Application submission deadline	January 31, 2025
Application review period	February/March 2025
Competition results communicated to researchers	March 2025
Funding start date	April 1, 2025

C. Competition Funder

Ovarian Cancer Canada (OCC) is the only national organization dedicated to overcoming ovarian cancer (OC). Our mission is to boldly and unapologetically take action against OC until the number of deaths from this disease is zero. Central to this is our commitment to investing in all stages of research from bench to bedside to drive scientific progress and improvements to patient-centered care in OC prevention, early detection, treatment and survivorship (https://ovariancanada.org/about-our-research).

D. Brief overview on pragmatic clinical trials

Pragmatic clinical trials (PCTs) are designed to assess the effectiveness of treatments or interventions in everyday healthcare settings, providing insights that are broadly applicable to diverse patient populations.

In contrast to traditional clinical trials that seek to answer the question, "Can this intervention work under ideal conditions?", pragmatic clinical trials seek to answer the question, "Can this intervention work in the real world (e.g., clinical care)?"

Examples of research questions that can be addressed with a pragmatic clinical trial include, but are not limited to:

- Do different doses of a drug impact patient-reported side effects or quality of life?
- Do patients with increased frailty (e.g., patients who are older or have more co-morbidities) experience the same level of clinical benefit from a new treatment as patients who are not frail?
- Do patients who take a specific drug in the morning experience different side effects than those who take the same drug in the evening?
- How does the use of a patient-decision aid impact treatment choice?

PCTs often leverage existing healthcare infrastructure to assess novel treatment protocols and approaches, making them easier to implement in standard healthcare settings. Furthermore, in contrast to traditional (explanatory) clinical trials, PCTs promote health equity by broadening eligibility criteria to include a wide range of participants varying in age, ethnic background, and health status, to ensure that findings reflect typical patient populations. By focusing on outcomes that matter in daily practice—such as quality of life, patient satisfaction, and functionality—PCTs are more patient-centered and produce evidence that is especially valuable for clinicians, policymakers, and patients seeking practical, effective healthcare solutions.

A non-comprehensive overview of PCT considerations and resources are included in **Annex A**.

E. Project eligibility & evaluation criteria

This competition will fund one or more pragmatic clinical trials with the greatest potential to drive advancements in OC care in Canada. Innovative and patient-centred ideas that can be integrated into the existing healthcare system are encouraged. The following criteria will be considered when evaluating applications:

Standard criteria used in all OCC competitions

- Scientific merit/research strategy
- Project fit
- Innovation/novelty
- Plan for patient engagement
- Clarity of communication
- Readiness/feasibility
- Strength of supporting/preliminary data
- Qualifications of research team/research environment
- Budget & timelines
- National scope: projects involving multiple sites across Canada are encouraged
- Canadian content: projects building on Canadian science will be prioritized
- Potential for impact

Additional criteria specific to current competition

- Level of pragmatism
- Relevance and importance to real-world clinical practice
- Risk assessment
- Measurable outcomes
- Potential for acceptability
- Strength of implementation protocol

F. Study term & budget

A total of $400,000 is available for this competition, with no set budget per application. Applicants can apply for all or part of the total funding available, over a period of 1 or 2 years. Funding will start on April 1, 2025, upon execution of the funding agreement with the Principal Applicant's host institution. All funds must be spent by recipients by March 31, 2027, with no options for extension as per Strategic Science Fund rules.

Eligible expenses

- Salary support to staff (e.g., research coordinators, assistants, associates, technicians) or trainees (e.g., graduate students and post-doctoral fellows) responsible for the work;
- Intervention delivery costs, including consumables and service costs (e.g., core facilities) required to carry out the work;
- Costs related to acquisition, processing and molecular characterization of biospecimens;
- Costs associated with data collection and analysis;
- Costs related to engaging patients in the planning and implementation of the project, including but not limited to honoraria for patient partners;
- Costs related to sharing of materials (e.g., clinical biospecimens, research models) and data to facilitate multi-institutional collaboration;
- Publication fees up to $4,000;
- Up to $2,000 per year for attending meetings, seminars or conferences (e.g., registration, travel, accommodation).

Ineligible expenses

- Remuneration of Principal Applicant, Co-Applicants or Collaborators (with the exception of honoraria for patient partners);
- Purchase of equipment, unless approved in advance;
- Indirect costs to institutions;
- Sabbatical or parental leave;
- Publication fees in excess of $4,000;
- Meeting, seminar or conference expenses in excess of $2,000 per year.

G. Applicant eligibility criteria

Study Principal Applicant/s must hold a research position at a Canadian academic institution and be able to hold research funds at their institution. Study co-applicants and collaborators may be affiliated with institutions outside of Canada; however, funds must be spent within Canada.

H. Multiple applications

There are no limits on the number of applications submitted, as either a principal applicant or co-applicant.

I. Application process & instructions

Ovarian Cancer Canada will administer and manage this single-stage (application only) competition. All applications must be submitted in English to facilitate peer review by international reviewers.

To be considered a complete application, the following information must be compiled into a single PDF document and emailed to atone@ovariancanada.org with the subject line **"Pragmatic Clinical Trial Competition_Application_lastname"** by **January 31, 2025 @11:59pm ET**:

1) **Application form –** includes basic project information and applicant demographics (for summary-level reporting only; EDI information will not be shared with reviewers).

2) **Written components** – description and page limits indicated below. *Formatting guidelines for each: single-spaced, minimum of ¾" (2 cm) margin all four sides, 12pt font. Please note that non-compliance to the guidelines could lead to an administrative rejection of a submitted application prior to its scientific evaluation.*

   a) **Scientific abstract (max 1 page)**
      - ❖ Describe the rationale, research aims, methodology, anticipated outcomes and their potential impact for patients.

   b) **Lay summary (max 1 page)**
      - ❖ Summary of the research project in lay terms, to be understood by those who are not in biomedical research.

   c) **Research proposal (max 5 pages)**
      - ❖ Describe the proposed research project, considering the following elements:
        - Rationale and background;
        - Proposed aim(s)/objectives and hypotheses;
        - Study design/methodology;
        - Patient engagement plan;

- How the proposed project fits eligibility/evaluation criteria (e.g., which elements of the proposed trial are pragmatic; see **Fig. 1** of Annex A)
- Significance of the proposed research and expected outcomes;
- Study timelines.

d) Research team (max 1 page)

- Describe the expertise and contributions of the applicant, co-applicant(s) and other research personnel involved in the proposed research.

e) Budget summary and justification (max 2 pages)

- All budget items, including salaries and stipends, must be justified in terms of the objectives and milestones of the project. For every item in the budget, the applicant must provide a complete breakdown of the amounts requested for the project. Where there are subprojects, clearly itemize the budgetary requirement for each one.

3) Figures & Tables (max 3 pages)

- Preliminary data and/or study schema

4) References (no page limit)

- List of references cited in the Research Proposal

5) Letters of Support (no limit)

- From lead institution, ensuring that the necessary infrastructure support is available for the project (mandatory)
- From collaborators and service providers, as applicable (optional)

6) Abbreviated CV for Principal Applicant and all co-applicants

- Academic degrees;
- Details of employment since graduation;
- 3-5 research and clinical contributions;
- List of publications (including submitted manuscripts and manuscripts in preparation) during the last 5-full time or equivalent working years;
- Grant support received in the past 5 years and relevant pending support – please note any potential overlaps with the current submission.

7) Completed Sensitive Technology Research Area Declaration form. See Section J for more information.

The submission deadlines will be strictly enforced. Only complete applications received by the submission deadline will be considered. Proposals that do not respect the guidelines will be rejected.

J. Sensitive Technology Research Area Declaration

OCC has developed a *Research Safeguarding Policy* (link), to ensure that all OCC research activities which receive full or partial federal research funding comply with the Government of Canada's guidelines about the integrity and security of sensitive technology research. This includes diligence in identifying sensitive technology research areas, scrutinizing researcher affiliations, and adhering to attestation and validation requirements in grant applications.

In accordance with Strategic Science Fund requirements, all Principal Applicants must review this policy and complete and submit a *Sensitive Technology Research Area Declaration Form* (link) on behalf of the study team, as part of the application process.

K. Patient engagement in research

All projects funded through this competition are **required** to meaningfully engage patient partners throughout the study period. Applicants may choose to collaborate with local patient partners within their community and/or send an inquiry to OCC's Patient Partners in Research (PPiR) program to facilitate patient-researcher partnerships. A brief overview of the PPiR program and considerations for patient engagement are included in **Annex B**.

To collaborate with members of PPiR, send an inquiry to atone@ovariancanada.org with the subject line **"PPiR Research Inquiry"** and a brief description of the research engagement as well as some general availability/timeframe for a follow-up meeting. **Please note that requests will be processed on a first-come, first-served basis. We strongly recommend contacting OCC by December 16, 2024, if you are interested in collaborating with PPiR; we can not guarantee the fulfillment of last-minute requests.** FAQs for researchers interested in collaborating with OCC's PPiR team can be found here.

L. Scientific resources available to researchers

If appropriate to the proposed study, researchers are encouraged to take advantage of the following resources:

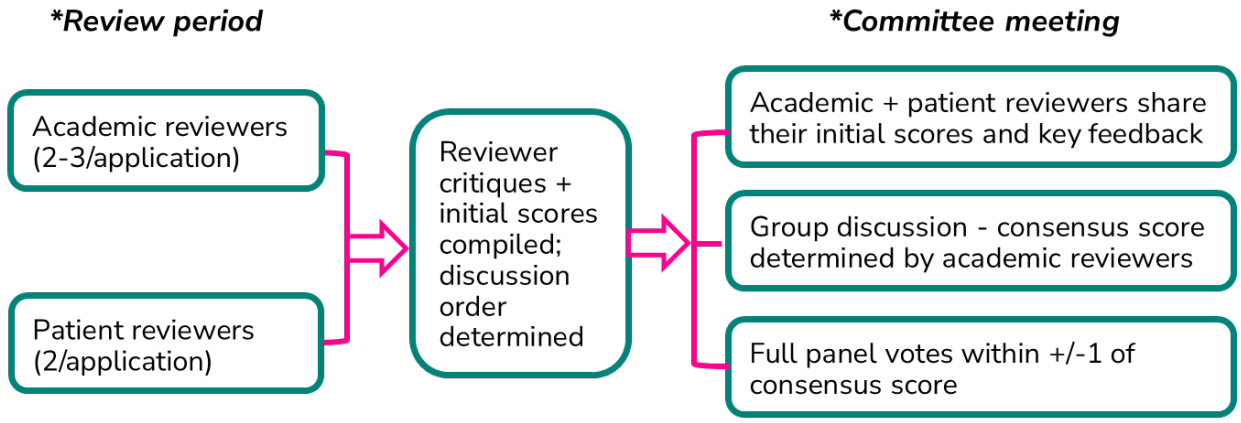
- **OCC Tissue Banking Network** (most recent report here) – a virtual network of biobanks which collect, store, and distribute biological samples (e.g., tumour tissue/cells, normal tissue/cells, blood) generously donated by individuals with ovarian cancer to enable ovarian cancer research in Canada and abroad. Scientists interested in accessing human ovarian cancer biospecimens for their research are encouraged to contact the individual biobanks for more information.
- **OvCAN Collection** (most recent report here) – a virtual collection of high-fidelity research models of ovarian cancer, whose development and/or characterization has been funded by OCC. The purpose of the OvCAN Collection is to facilitate the creation and sharing of these

gold standard models among the ovarian cancer research community, to enable and expedite high-quality research focused on improving ovarian cancer outcomes. If you are interested in incorporating one of these models into your study, please contact the individual lab for more information.

M. Independent review process

All applications will be evaluated by an independent expert review committee, made up of Canadian and/or international clinical and scientific experts ("academic reviewers") and individuals with lived experience of ovarian cancer ("patient reviewers"). The selection of reviewers will be made in compliance with OCC Conflict of Interest policies (here), and all committee members will be required to sign a Confidentiality and Conflict of Interest agreement (here) prior to receipt of their assigned applications.

Each proposal will be initially reviewed and scored by at least 2 academic reviewers and a team of 2 trained patient reviewers. At the final committee meeting, the proposal will be presented, discussed and scored (see process below). Final application scores and rank order will be reviewed by OCC leadership, with funding recommendations made to the OCC Board of Directors for approval.



**academic and/or patient reviewers excluded from reviewing or discussing any application/s for which they have a conflict of interest*

N. Research ethics & institutional policies

Prior to commencing OCC-funded research activities, researchers shall ensure that the research protocol is consistent with the principles set out in the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* and is reviewed and approved by the Research Ethics Board at each participating institution. All Research Ethics Board approval letters shall be forwarded to OCC's Director, Research at atone@ovariancanada.org. It remains the responsibility

of the Principal Applicant, co-applicants and collaborators to respect the rules and policies of their institutions.

O. Reporting requirements

All award recipients will be required to provide regular updates on progress to OCC as a condition of funding. Reporting templates and deadlines will be provided to recipients upon notice of funding.

P. Contact

For questions regarding the competition, please contact Alicia Tone (Director, Research; atone@ovariancanada.org)

Annex A: Pragmatic clinical trial resources

The purpose of a pragmatic clinical trial is to demonstrate the effectiveness of a health intervention in the "real-world", not just in a highly controlled setting with a strictly selected group of similar patients. They are more "patient-centered" - multiple outcomes important to patients can be evaluated and they can help address the inequities inherent in more traditional clinical trials.

Linked below are some helpful resources for designing and conducting pragmatic clinical trials:

- **HDRN Canada Pragmatic Trials Training Program**
  https://www.schulich.uwo.ca/pragmatictrialstraining/
  Schulich Medicine and Dentistry, Western University
- **REthinking Clinical Trials (REaCT) program website**
  https://react.ohri.ca/
  The Ottawa Hospital Research Institute
- **Why are pragmatic clinical trials important for our health system?**
  https://healthresearchbc.ca/news_article/pragmatic-clinical-trials/
  Michael Smith Health Research BC, 24 June 2021
- **Readiness assessment for pragmatic clinical trials (RAPT): a model to assess the readiness of an intervention for testing in a pragmatic clinical trial**
  Baier, R.R., Jutkowitz, E., Mitchell, S.L. et al. BMC Med Res Methodol 19, 156 (2019). https://doi.org/10.1186/s12874-019-0794-9
- **Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials**
  https://rethinkingclinicaltrials.org/
  NIH Pragmatic Trials Collaboratory
- **Health Equity in Pragmatic Clinical Trials**
  https://dcricollab.dcri.duke.edu/sites/NIHKR/KR/Health-Equity-PCTs-Defined.pdf
  NIH Pragmatic Trials Collaboratory
- **Embedded Pragmatic Clinical Trial Quick Start Guides for Investigators**
  https://rethinkingclinicaltrials.org/quick-start-guide/
  NIH Pragmatic Trials Collaboratory

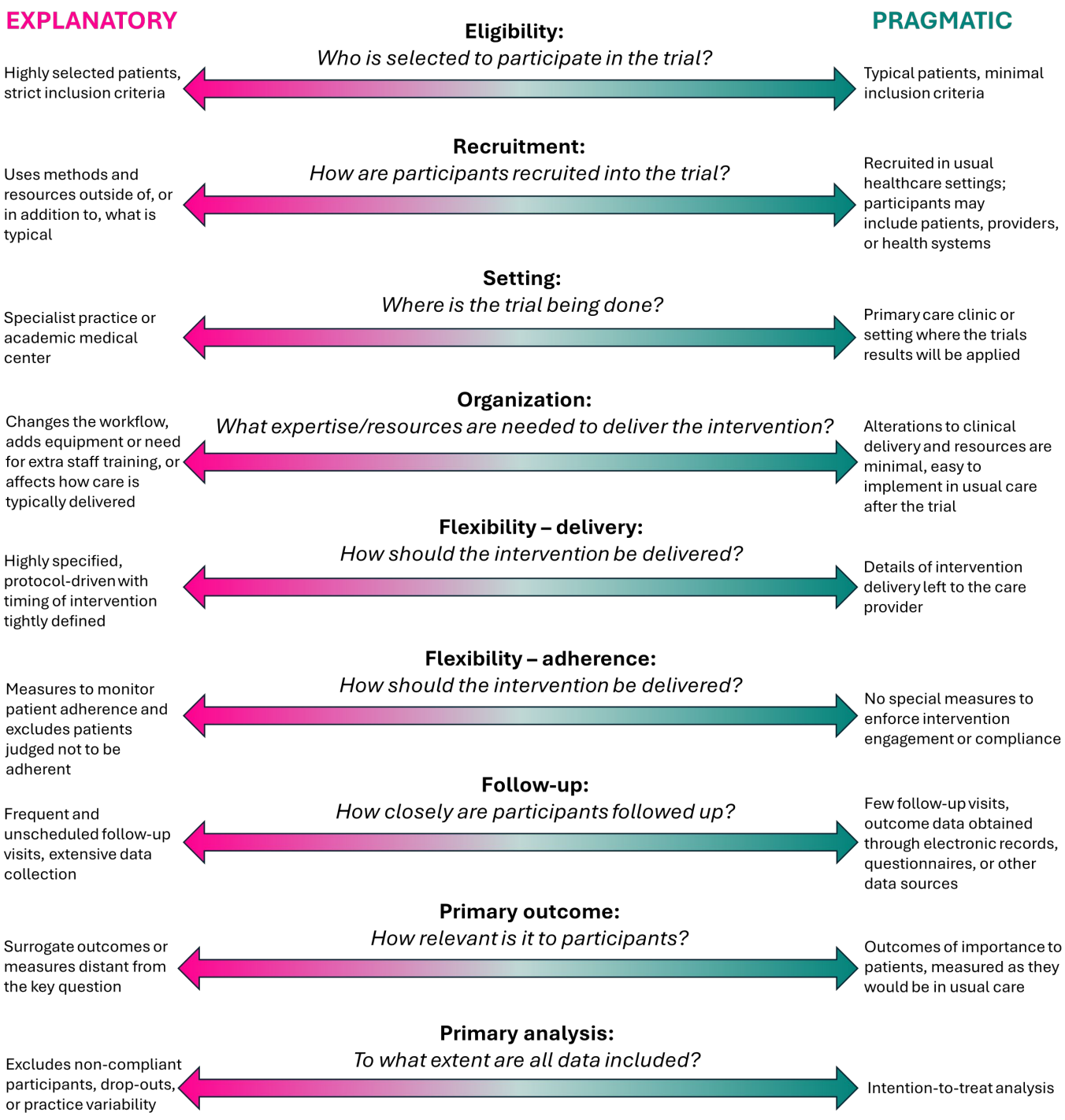


Figure 1. Elements of Pragmatic Clinical Trials. The scale from explanatory (traditional) to pragmatic clinical trials on several aspects are shown. Figure adapted from Rethinking Clinical Trials: A Living Textbook of Pragmatic Clinical Trials and The PRECIS-2 tool: designing trials that are fit for purpose.

Domain	Assessment	Scoring Guidance		
		Low	Medium	High
1. Implementation protocol[a]	Is the protocol sufficiently detailed to be replicated?	There is no protocol.	The protocol provides some documentation, but may be difficult to replicate.	The protocol is well documented and is likely to be replicable.
2. Evidence	To what extent does the evidence base support the intervention's efficacy?	There are no efficacy studies or the efficacy studies did not use rigorous methods (e.g., a RCT).	A single study using rigorous methods demonstrated efficacy.	Multiple studies using rigorous methods have demonstrated efficacy.
3. Risk	Is it known how safe the intervention is?	The risks (harms and discomforts) are unknown or are known to be more than minimal (e.g., greater than ordinarily encountered in daily life).	The risks are unknown, but are likely minimal.	The risks are known to be minimal.
4. Feasibility	To what extent can the intervention be implemented under existing conditions?	Resources necessary for implementation (e.g., staff, infrastructure, payment) are absent or insufficient.	Minor modifications to existing resources would enable implementation.	Implementation is possible with existing resources.
5. Measurement	To what extent can the intervention's outcomes be captured?[a]	Outcomes cannot be captured without major modifications to systems (e.g., clinical assessments, documentation, or electronic health records) or increases in staff time.	Outcomes can be captured with minor modifications to systems or increases in staff time.	Outcomes are already routinely captured.
6. Cost	How likely is the intervention to be economically viable?	Cost-benefit/cost-effectiveness analysis has not been completed (formally or informally) and it is unknown whether benefits outweigh costs.	Cost-benefit/cost-effectiveness analysis has not been completed, but benefits are likely to outweigh costs.	Cost-benefit/cost-effectiveness analysis demonstrates benefits outweigh costs.
7. Acceptability	How willing are providers likely to be to adopt the intervention?	Acceptability is unknown or staff are unlikely to believe the intervention is feasible or needed.	Acceptability is unknown, but staff are likely to believe the intervention is feasible or needed.	Acceptability is known and staff believe the intervention is feasible and needed.
8. Alignment	To what extent does the intervention align with external stakeholders' priorities?	Stakeholders (policymakers, payors, advocates, and others) do not believe the intervention addresses a current or anticipated priority.	Some stakeholders believe the intervention addresses a priority.	Most or all stakeholders believe the intervention addresses a priority.
9. Impact	How useful will the intervention's results be?	Providers and stakeholders (policymakers, payors, advocates, and others) are unlikely to believe that the outcomes are useful (e.g., to inform clinical care or policy).	Some providers or stakeholders are likely to believe the outcomes are useful.	Most or all providers and stakeholders are likely to believe the outcomes are useful.

Table 1. Example rubric and assessment tool for pragmatic clinical trial domains. Table extracted from Readiness assessment for pragmatic clinical trials (RAPT): a model to assess the readiness of an intervention for testing in a pragmatic clinical trial.

Annex B: Patient engagement guidelines

The Patient Partners in Research (PPiR) program was developed in 2020 by OCC to keep the voices of those with lived experience at the forefront of research, and has since become an integral component of all research at OCC. Engaging ovarian cancer patients as partners in research reflects our philosophy that the relevance, importance and impact of scientific and clinical inquiry can be enhanced by valuing the input and viewpoints of those affected by this disease. The PPiR program is led and managed by two OCC research staff and two patient advocates. Our PPiR team includes a diverse representation of ovarian cancer types, age, sexuality, cultural backgrounds, and geography with each member bringing their unique perspective and shared experiences as ovarian cancer patients, caregivers or loved ones.

The role of the PPiR program is to train and match patient partners to research opportunities with the goal to complement and maximize the impact of research being done by Canadian researchers. All team members are required to complete the Science of Cancer online course, in addition to task-specific training dependent on the engagement opportunity. Some examples of activities that PPiR team members have participated in include:

- Serving as patient reviewers on grant funding (pre-clinical and clinical) and trainee award review panels;
- Participating as embedded research team members on OCC-funded projects (both clinical and pre-clinical). Roles have included:
  - Review of grant applications and submission of letters of support;
  - Consultation on research study design, research questions, eligibility criteria and recruitment plans;
  - Review of lay language material (e.g., public summary, recruitment materials and informed consent forms);
  - Evaluation of patient surveys;
  - Participation in working groups led by research teams;
  - Co-development of patient decision aids and educational tools/modules;
  - Attendance at regular team meetings;
  - Review of manuscripts, meeting abstracts and other knowledge mobilization materials.
- Consulting on strategic planning, PPiR program guidelines, research partnership agreements, programmatic design and patient engagement best practices
- Participating as speakers and/or panelists at OCC events and external research conferences
- Participating on graduate student advisory committees
- Sharing their experiences and learnings with research teams and clinical trainees
- Participating in research and system advocacy alongside OCC staff and members of the research community.

The goal of PPiR is to build sustainable partnerships between patients and researchers, so that patient partners are updated regularly on the research progress and how their contribution is shaping the research project. Please consider the following when designing your patient engagement plan:

- Use the buddy system: we recommend including two patient partners for your study; this helps them feel more comfortable and also mitigates the impact of members' changing health status on the dynamics of the research team.
- For long-term partnerships, Ovarian Cancer Canada will schedule check-ins every 6 months to ensure the partnership is successful. Research teams are encouraged to have a closing meeting, where they present the results and conclusions of the research study as well as share how the input of patient partners has impacted their research project. Patient partners may also present their own reflections on their experience collaborating on the research project, to help researchers hone their patient engagement skills.

- Ask yourself these questions:
  - Why is this a good research opportunity to engage patients?
  - What will the role of the patient partner(s) be?
  - How will their input be used in the research process?
  - Are there any requirements to participate in the research opportunity? (e.g., living in a specific geographical region)
  - Does the patient partner need to have any specific experiences that they can speak to? (e.g., specific ovarian cancer type, experience with a specific treatment)
  - Will OCC need to provide task-specific training to best prepare the selected patient partners?
  - What level of participation is required from the patient partners (hours/month)?
  - What stage will the patient partner begin to participate in the research process?
  - How long will the patient partners be involved?
  - Is this a one-time engagement event or are there regular meetings?
  - Will patient partners be compensated? *Note: this is not a strict requirement; however, patient partners should be made aware from the beginning*.

- Below are some helpful resources on patient engagement in research:
  - Farrell AC, Lawson JA, Ovarian Cancer Canada's Patient Partners in Research Team, Ross A, Tone AA. Advancing Research Alongside Patient Partners: Next-Generation Best Practices for Effective Collaboration in Health Research. Current Oncology. 2024; 31(11):6956-6978. https://doi.org/10.3390/curroncol31110513
  - Richards DP, Poirier S, Mohabir V, Proulx L, Robins S, Smith J. Reflections on patient engagement by patient partners: how it can go wrong. *Res Involv Engagem.* 2023 Jun 12;9(1):41. PMID: 37308922
  - Richards DP, Cobey KD, Proulx L, Dawson S, de Wit M, Toupin-April K. Identifying potential

barriers and solutions to patient partner compensation (payment) in research. *Res Involv Engagem.* 2022 Feb 23;8(1):7. PMID: 35197113

- Liabo K, Boddy K, Bortoli S, Irvine J, Boult H, Fredlund M, Joseph N, Bjornstad G, Morris C. Public involvement in health research: what does 'good' look like in practice? *Res Involv Engagem*. 2020 Mar 31;6:11. PMID: 32266085
- Richards DP, Jordan I, Strain K, Press Z. Patients as Partners in Research: How to Talk About Compensation With Patient Partners. *J Orthop Sports Phys Ther.* 2020 Aug;50(8):413-414. PMID: 32736501
- *"A How-to Guide for Patient Engagement in Research"* (Canadian Institutes of Health Research; link)