Enhancing recruitment of research participants:
The Permission to Contact strategy

Moderator:
• Cindy Trytten, Director, Research & Capacity Building, Vancouver Island Health Authority

Presenters:
• Dr. Peter Watson, Director, BCCA Tumour Tissue Repository and UBC Office of Biobank Education and Research
• Stefanie Cheah, Project Coordinator, UBC Office of Biobank Education and Research
• Rebecca Barnes, Project Manager, Research & Capacity Building, Vancouver Island Health Authority
Permission To Contact (PTC) Program

*A strategy for patient engagement*

Dr. Peter Watson, Director
BCCA Tumour Tissue Repository and
UBC Office of Biobank Education and Research
Perspectives on: Permission to Contact Program (PTC)

Problem: Low patient involvement in clinical research

Premise: ‘PTC’ is a novel solution to ‘patient research engagement’

Prototype: Developed mechanisms over >5 yrs through prototypes

Testing: Examined broad feasibility and applicability

Cost/Benefit: Identified and tracked costs and benefits

Value: Established value across all stakeholder groups
Patient involvement in clinical research

The problem:

• What is the message to patients?
• How can we translate research with this bias?
Published in final edited form as:


The Prevalence and Economic Impact of Low-Enrolling Clinical Studies at an Academic Medical Center

Darlene R. Kitterman, MBA,

“...low-enrolling studies cost the institution almost $1 million annually”
Consent Phases and Protocols:

The consent process – 3 phases

Pre-procedure/intervention

1. Referral of potential patient

2. Establishes interest and preference for format of consent interview

3. Provides opportunity for and confirms informed consent
Consent Phases and Protocols:

The consent process – 2 protocols

Pre-procedure/intervention
- Preliminary interview
- Consent interview
- Permission to contact

Post-procedure/intervention
- Preliminary interview
- Consent interview
- Permission to contact

Research Programs
- Clinical studies
- Outcomes unit
- Biobank

Pathology
Consent Phases and Protocols:

The consent process – phase 1 can be merged

Consent Phases and Protocols:

Pre-procedure/inter-vention

Diagnosis

Permission to Contact

Post-procedure/intervention

Follow-up

Clinical studies

Outcomes unit

Biobank

Consent Phases and Protocols:

The consent process – phase 1 can be merged

Consent Phases and Protocols:

Pre-procedure/inter-vention

Diagnosis

Permission to Contact

Post-procedure/intervention

Follow-up

Clinical studies

Outcomes unit

Biobank
Clinical Researchers

Research Ethics Board approval

Low risk

Waiver of consent

Permission To Contact

Patient Data + blood + tissues etc

Outcomes studies

Survey studies

Biomarker studies

Genomics studies
Clinical Researchers

Permission To Contact

Research Ethics Board approval

High risk

Informed consent

Patient Data + blood + tissues etc.

Outcomes studies
Survey studies
Biomarker studies
Genomics studies

PTC transactions
Impact on health care and clinical research

- Increases quality of clinical research
  - Reduces research bias by enabling population engagement

- Provides opportunities for clinical staff
  - Promotes culture shift and clinical staff involvement in training and research
• Increases efficiency of clinical research
  • Creates broader opportunity for patients and clinical researchers
• Creates novel training opportunities
  • Supports success in health training programs and recruitment of next generation

<table>
<thead>
<tr>
<th>#</th>
<th>Research Intern</th>
<th>Year</th>
<th>Current Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Laura Galbraith</td>
<td>2007</td>
<td>not known</td>
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<tr>
<td>2</td>
<td>Shevaun Hughes</td>
<td>2008</td>
<td>UBC MSc 2011, now Project Coordinator C&amp;W</td>
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<tr>
<td>3</td>
<td>Kate Kuss</td>
<td>2008</td>
<td>UBC Med School</td>
</tr>
<tr>
<td>4</td>
<td>Stephanie Menzies</td>
<td>2009</td>
<td>UBC Nursing School</td>
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<tr>
<td>5</td>
<td>Navina Kumar</td>
<td>2009</td>
<td>SFU MSc in Public Health</td>
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<td>6</td>
<td>Gavin Wilson</td>
<td>2009</td>
<td>UBC Med School</td>
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<td>7</td>
<td>Elisabeth Mason</td>
<td>2010</td>
<td>UBC Med School</td>
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<td>8</td>
<td>Justin Gill</td>
<td>2010</td>
<td>UBC Med School</td>
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<tr>
<td>9</td>
<td>Lyndsay Sprigg</td>
<td>2010</td>
<td>UBC Med School</td>
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<tr>
<td>10</td>
<td>Aleksey Lavrenenko</td>
<td>2011</td>
<td>Applying to Dentistry School</td>
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<td>11</td>
<td>Justin Desrochers</td>
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<td>UBC Education school</td>
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<td>12</td>
<td>Matthew Grey</td>
<td>2012</td>
<td>UVic Education School</td>
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<tr>
<td>13</td>
<td>Lauren Braun</td>
<td>2012</td>
<td>current</td>
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• Expands public support for health research
  • Changes the message to Patients and engagement levels from ~5% to >50%
• Expands public support for health research
  • Changes the message to Patients and engagement levels from ~5% to >50%
Permission To Contact (PTC) Program

Building on a prototype

Stefanie Cheah, MSc
Project Coordinator,
UBC Office of Biobank Education and Research

scheah@pathology.ubc.ca
Creating the Permission to Contact Program

- Learn & Improve
- Implement
- Plan
- Develop
PREDICT: Personal Response Determinants in Cancer Therapy

• ‘Permission to Contact’ at the core of a multifaceted project

‘permission to contact’ for research

- Engages clinical staff in shared research
- Creates population biobank to support research
- Offers research opportunities to all new patients

Timeline:
- 1st REB submission: 2006
- 1st patient: 2007
- 1st Research user: 2008
- 7000th patient: 2012
PREDICT Example

Plan

Clinical and research staff
~6 months

Develop

Clinical and research staff
~6 months

Implement

Clinical and research staff
~12 months

Learn & Improve

Ongoing

Clinical-scientists
~6 months
1. Framing scope
2. Identification of resources
3. Enlistment of design team
1. **Framing scope**
   - Determined interest in PTC
   - Secured decision to proceed

2. **Identification of resources**
   - Seed funding from local granting organizations
   - Platforms expected to be self-sustainable after first year

3. **Enlistment of design team**
   - Design team composed of front line clinic staff
   - Review of Standard Operating Procedures and workflow
Development Phase

1. Framing scope
2. Identification of resources
3. Enlistment of design team
4. Protocol design
5. Agreement on governance
6. Staff engagement
7. Submission of ethics application
Development Phase

4. Protocol design
   • Provision of templates and Standard Operating Procedures
   • Review of PTC form

By signing below, I give the St. Paul’s Hospital Heart Centre Clinics’ researchers permission to contact me to ask about possible involvement in future research.

I understand that by signing this form, I am only giving permission to be contacted to learn about the research and am not committing to participate in a research study.
4. Protocol design
   - Creation of patient database
   - Review of data fields

Data fields:
- Name
- DOB
- Date of PTC
- Eligibility Status
- Approached Status
- Permission Status

Custom fields:
- Disease type
- Ethnicity
- Reasons not approached
- Health outcomes
PTC Patient Database - Demo

Permission to Contact Demo

Username: guest
Password: password

Login

Copyright 2012 BC Women's Hospital & Health Centre OBER Permission to Contact Design by Simon Dee

http://obertools.pathology.ubc.ca/ptc/
4. **Protocol design**
   - Provision of templates and Standard Operating Procedures
   - Review of PTC form, database and data fields

5. **Agreement on governance**
   - Determine oversight and access processes
   - Establishment of committees

6. **Staff engagement**
   - Informational meetings with staff
   - Identification of personnel required

7. **Submission of ethics application**
   - Review/approval by research ethics board
   - Inclusion of performance metrics
Implementation Phase

1. Framing scope
2. Identification of resources
3. Enlistment of design team
4. Protocol design
5. Agreement on governance
6. Staff engagement
7. Submission of ethics application
8. Launch of pilot and phased deployment
9. Monitoring
10. Research access
8. **Launch of pilot and phased deployment**
   - Pilot phase to identify and address any issues
   - Proceed to full operation roll out

9. **Monitoring**
   - Patients approached, reasons not approached
   - Patients permission status

10. **Research access**
    - Establish mechanism for access to the PTC database and patient information
Approach Rate %:
- Number of patients approached for PTC / eligible patients

Permission Rate %:
- Number of patients who agreed to PTC / approached patients

Other recorded data:
- Reasons not approached
- Performance over time
Expansion – Testing Applicability of PTC

- Expanded to 4 additional clinics/hospitals in different health areas

Vancouver Island Centre
BC Cancer Agency
CARE & RESEARCH

Cancer – PREDICT

Providence Health Care
How you want to be treated
Congenital Heart

Providence Health Care
How you want to be treated
Heart Function

Women’s BC Women’s Hospital & Health Centre
Maternal Health

Vancouver Island Health Authority
Health Authority
## Performance Results

### Data Summary

<table>
<thead>
<tr>
<th>Date Period</th>
<th>Vancouver Island Centre</th>
<th>Providence Health Care</th>
<th>Providence Health Care</th>
<th>Women's BC Women's Hospital &amp; Health Centre</th>
</tr>
</thead>
<tbody>
<tr>
<td>Duration</td>
<td>72 months</td>
<td>2 months</td>
<td>6 months</td>
<td>12 months</td>
</tr>
<tr>
<td>Total PTCs</td>
<td>6877</td>
<td>171</td>
<td>498</td>
<td>108</td>
</tr>
</tbody>
</table>

### Chart

The chart shows the approach rate and permission rate for the specified periods. The approach rate is represented by dark blue bars, and the permission rate is represented by light blue bars. The chart is segmented into four segments, each corresponding to the different time periods and institutions.
Long Term Sustainability

- Eligible Fold Change
- Approach Rate
- Permission Rate

Approach and Permission Rate %

Year

Eligible patients fold change

0 1.00 1.25 1.50
## Cost Analysis

<table>
<thead>
<tr>
<th>Personnel Type</th>
<th>Research Intern</th>
<th>Nursing Staff</th>
<th>Research Assistant</th>
<th>Research Assistant</th>
</tr>
</thead>
<tbody>
<tr>
<td>Salary</td>
<td>$36,100</td>
<td>N/A</td>
<td>$38,000</td>
<td>$42,000</td>
</tr>
<tr>
<td>Dedicated effort</td>
<td>0.75 FTE</td>
<td>N/A</td>
<td>0.8 FTE</td>
<td>0.1 FTE</td>
</tr>
<tr>
<td>Data entry costs</td>
<td>-</td>
<td>$2000</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Total costs/month</td>
<td>$2256</td>
<td>$1000</td>
<td>$2533</td>
<td>$350</td>
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<tr>
<td>PTC/month</td>
<td>123</td>
<td>86</td>
<td>83</td>
<td>9</td>
</tr>
<tr>
<td>Cost per PTC</td>
<td>$18</td>
<td>$12</td>
<td>$31</td>
<td>$39</td>
</tr>
</tbody>
</table>

- Ranged from $12-39 per PTC
- Average costs $25 per PTC
- Does not include in-kind contributions from existing staff and resources
Conclusions

• Permission to Contact platforms can be successfully established in different health areas/hospitals

• PTC has increased patient engagement (~5% to ~50% of new patients)

• Can achieve permission rates between 80 to >90% and is sustainable at approach rates of 50%
Permission to Contact (PTC) Program

Implementation within a health authority

Rebecca Barnes, MSc
Project Manager, Research and Capacity Building
Vancouver Island Health Authority
rebecca.barnes@viha.ca
## Health Care Systems: The Past and the Future

<table>
<thead>
<tr>
<th>Antiquated health care</th>
<th>Modern health care</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inconsistent</td>
<td>Evidence-based *</td>
</tr>
<tr>
<td>Error prone</td>
<td>Safe *</td>
</tr>
<tr>
<td>Fragmented</td>
<td>Integrated *</td>
</tr>
<tr>
<td>Unaccountable</td>
<td>Accountable *</td>
</tr>
<tr>
<td>Inefficient</td>
<td>Efficient *</td>
</tr>
<tr>
<td>Physician-centered</td>
<td>Patient-centered*</td>
</tr>
<tr>
<td>Reactive</td>
<td>Proactive *</td>
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</table>

*Supported by an integrated research infrastructure*
Why Should Health Care Organizations Invest in Research?

Better Health Care

Boards of Directors
- Economic benefits including ‘gifts in kind’
- Generates public support for healthcare

Physicians/Managers
- Access to new technologies, treatments, diagnostics
- Attracts high level expertise
- Attracts health trainees
- Enhanced education/better staff

Leaders
- Appropriate oversight
- Culture of knowledge, learning and inquiry
- Improves patient engagement

Why Should Health Care Organizations Invest in Research?
The Vancouver Island Health Authority (VIHA)

- Population served: >765,000 people (17% of BC)
- Region covered: Vancouver Island, the islands of the Georgia Strait, and the mainland communities north of Powell River and south of Rivers Inlet
- Workforce: >18,000 health care professional and 1,700 physician partners
- Facilities: >150 (hospitals, clinics, health units, and residential facilities)
- Beds: >9,000
- Health services provided:
  - Acute interventional services
  - Medicine
  - Emergency
  - Diagnostics
  - Pharmacy
  - Home and community care
  - Residential services
  - Seniors health
  - Population health
  - Aboriginal health
  - Primary health care
  - Mental health
  - Addictions services
  - Child, youth and family health
  - Public health
VIHA’s Purpose Statement

- To provide superior health care through innovation, teaching and research and a commitment to quality and safety — creating healthier, stronger communities and a better quality of life for those we touch.
Vancouver Island Research Capacity Building Initiative

• The Vision: A robust, self-sustaining health research community on Vancouver Island, playing an essential role in the delivery of high quality health services, and improving health of the Island’s population.
Strategy

• Make VIHA a strong partner to support and conduct health research on Vancouver Island
• Focus on building research capacity and sustainability
• Maximize research and learning opportunities
• Create a culture of inquiry
• Identify existing internal systems and processes
• Identify needed systems and processes
• Identify “quick wins”
Research and Capacity Building

Proposed Public Engagement Framework for Research

Vancouver Island Public
- VIHA website
- Social media
- Open houses
- Press releases
- Research opportunity notifications

VIHA Patients
- Awareness campaign in VIHA facilities
- Research Participant Advisory Council
- Permission to Contact program

Research Participants
- Research results
- Recognition
- Updates

Goals
- Public as research partners
- Improved oversight and standardization of research recruitment
- Enhanced research capacity
Objectives of the PTC program

1. Research-readiness
2. Appropriate oversight, regulatory (privacy, ethics) compliance
3. Staff engagement in research
4. Novel learning opportunities for health trainees
5. Patients as partners in research
Development Phase

- Confirm buy-in from VIHA’s Board and Senior Leadership ✓ Sept 2012
- Form collaborative agreement with OBER ✓ Nov 2012
- Hire Program Manager ✓ Feb 2013
- Development of the general VIHA model (protocol, participant information form, scripts, etc.) ✓ Feb 2013
- Necessary approval submissions (Ethics; Information Stewardship, Access & Privacy) ✓ Mar 2013
- Selection and training of pilot clinics ✓ April 2013
- Communications campaign ✓ May 2013
- Commence pilot ✓ Jun 2013
Pilot Approach

Staff Engagement

Outpatient Clinics
- Stroke
- MS
- Diabetes
- Geriatrics

Patient/Public Awareness

- Waiting areas
- Posters
Pilot Implementation

• Communication strategy for Directors, Medical Directors and other physician/staff leaders of those areas involved in pilot
• Adaptation of general models in consultation with front-line Managers and Team Leaders
• Training for staff in pilot clinics
• General communication to entire health authority
• June 1 – July 31 all appropriate patients entering pilot clinics will be asked for permission to be contacted for future research participation
• Track metrics and feedback to inform subsequent stages and expansion
**Setting 1: Out-patient Clinics**

- **Step 1:** PTC info form is included with intake paperwork- patient reviews form and makes decision
- **Step 2:** Trained staff member oversees documentation of PTC decision – recites script
- **Step 3:** PTC info form is stamped, tracked and securely stored
Setting 2: Patient Waiting Areas

- Step 1: PTC poster is displayed in patient
- Step 2: Potential participant contacts PTC program manager
- Step 3: PTC program manager oversees documentation of PTC decision – recites script
- Step 4: PTC info form is stamped and stored
**Data Flow and Access Process**

**Patient**
- Patient enters participating clinic
- Patient decision
  - Agreed
  - PTC form is signed by participant
  - PTC form is temporarily stored within originating clinic
  - PTC forms are transferred to Research dept on a bi-weekly basis
- Research and Capacity Building (RCB)
  - Researcher submits PTC application form and required documents
  - Authorized Research personnel pre-screen matching PTC participants' health records for research study's eligibility criteria
  - Designated Research personnel identify PTC participants that match the general therapeutic area for the research study
- Researcher
  - PTC participant info forms are securely stored within the Research dept

**PTC Participant**
- PTC participant may contact researcher to begin the informed consent process for the study

**Clinic Staff**
- PTC participant info form is included with intake paperwork
- Trained clinic staff member oversees documentation of PTC participation
- Patient decision
  - Declined
  - Blank form (no identifiers) is stamped with reason declined by clinic staff member
  - Signed and blank PTC forms are temporarily stored within originating clinic

**PTC Participant**
Next Steps.....

Implementation Stages 2-3
• Extend pilot for four months, including more complex clinical settings (e.g., pediatrics, heart health, mental health)
• Target Admissions process
• **Process requests to use program by researchers**
• Assess impact on research recruitment
• Engage Professional Practice Office and consider needed change management activities
• Program a PTC field (check box) within VIHA’s Electronic Health Record system to flag charts of consenting individuals
PTC Aligns with a Health Authority’s Values

CARE will guide everything we do:

**Courage:** To do the right thing — to change, innovate and grow.

**Aspire:** To the highest degree of quality and safety.

**Respect:** To value each individual and bring trust to every relationship.

**Empathy:** To give the kind of care we would want for our loved ones.
"I was unaware of the option for clinical trials for medical conditions. I have become more aware of the impact of clinical trials on society. I am proud that I was able to contribute in some small way in helping other people that may have had the same condition I had. Thank you for the opportunity to express my opinions. I had a very positive experience with my clinical trial and have recommended to family/friends to inquire about trials as an option if they are being considered for any type of procedure."
Contacts

• Dr. Peter Watson: pwatson@bccancer.bc.ca
• Cindy Trytten: cindy.trytten@viha.ca
• Stefanie Cheah: scheah@pathology.ubc.ca
• Rebecca Barnes: rebecca.barnes@viha.ca

OBER Patient Engagement webpage: http://www.biobanking.org
VIHA Research and Capacity Building website: http://www.viha.ca/rnd/

Partners