PATIENT-CENTERED OUTCOMES RESEARCH (PCOR) TRAINING FOR COMMUNITY HEALTH WORKERS (CHWS)

STUDENT WORKBOOK

To be used by training participants at in-person format sessions.

Developed through a Statewide Partnership for Training Community Health Workers in PCOR EUGENE WASHINGTON PCORI ENGAGEMENT (EAIN) AWARD PROGRAM #2219: Univ. of Miami from the Patient Center Outcomes Research Institute (PCORI) 2015-2017.

Version 1.1
OVERALL DESCRIPTION OF THIS PROFESSIONAL DEVELOPMENT COURSE

This Student Workbook was developed, along with a Facilitator’s Guide and a slide deck, as part of the Patient Centered Outcomes Research (PCOR) for Community Health Workers (CHWs) Training Toolkit to educate promotores/CHWs to be stakeholder partners in patient-centered outcomes research (PCOR). The content emerged from a literature review on CHWs competencies and other essential skills for the conduct of research by lay workers. The initial content of the Training Modules received feedback from CHWs as patients, caregivers and patient advocates through focus groups, conference calls, webinars before implementation. Then, from the evaluation forms of the six initial training sessions and the feedback from members of a National CHW Supervisors and Curriculum Experts group.

Acknowledgements:

Thank you for the University of Miami-Division of Internal Medicine administration staff, the Board of Directors and Regional Coordinators of the FL Community Health Workers Coalition, the Health Council of South Florida, and all 148 initial training participants for their invaluable assistance, feedback and enthusiasm for the project.

Our profound thanks to our PCOR for CHWs Toolkit reviewers:

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Cordially,

Brendaly Rodríguez, MA
Florida Certification Board Recognized Education Provider (#5264-A)
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# TABLE OF CONTENTS

**Introduction**

**Student Workbook Objective**

**Key Terms**

**Chapter 1. What Is Research? Patient Centered Outcome Research?**

- What Are Key PCOR Concepts Relevant For CHW’s

  - Patient Centered Outcome Research
  - Basic Steps of a Research Study (Design)
  - Process of CHW Engagement in PCOR

**Chapter 2. Ethics: What Does IT Mean To Conduct Research in An Ethical Way?**

- Protecting The Rights Of Research Participants

**Chapter 3. Study Allocation And Randomization: How To Ensure All Research Participants Have Equal Chances, Without Bias?**

**Chapter 4: Different Ways To Gather Research Data**

- Qualitative Methods

**Chapter 5: What Is The Process Of Informing The Participants About Their Rights And Risks Associated With A Study?**

**Chapter 6: Following The Rules And Instructions As Part Of A Team**

- Following Study Protocol And Reporting

**Chapter 7: How To Report The Results Of A Study And To Whom?**

- Dissemination Of Study Results
Introduction

This Student Workbook is to be used by training participants at in-person format sessions of the Patient Centered Outcomes Research (PCOR) for Community Health Workers (CHWs) Training. It provides individual and group class exercises following the slides used at the training sessions guided by the Facilitator.

The content of the 7 sessions starts with a general Welcome and Introduction section, followed by modules on the seven topics on what is research, what is patient centered outcomes research, ethics, study allocation and randomization, informed consent, following research protocol and reporting, and dissemination of study results.

Student Workbook Objective

This workbook received feedback from CHWs like you, CHW instructors, researchers, patients/caregivers and other stakeholders in patient centered outcomes research (PCOR). It is designed to help you be an informed and successful CHW trainee, as part of the PCOR for CHWs Training Toolkit.

The goal of PCOR for CHWs training is to introduce already experienced promotores de salud/CHWs to the world of patient-centered outcomes research. Different states have varying certification standards/training programs on both core and elective competencies/skills, and there are many CHW core competency training resources available for in-person and online modalities.

Thus, this course will not teach how to be a promotora/CHW, but it will build on the skills of trained promotores/CHWs to better understand patient centered outcomes research and their role in it, as an elective competency.

Thank you for your interest and we wish you the best in your professional development journey!
**Key Terms**

**Community Health Worker (CHW)** - is a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served.

**Concept** - a general idea referring to a behavior or characteristic of an individual, group, or nation.

**Research** - is the collection of information (data) to obtain more knowledge or to answer a specific question about a certain topic.

**Researcher/ Investigator** - is the person who conducts research to gain new knowledge.

**Privacy** - is the control over the extent, timing, and circumstances of sharing information about a person with others.

**Beneficence** - do good and avoid harm.

**Justice** - benefits and burdens to be in balance, treat people fairly.

**Institutional Research Board (IRB)** - is that formal body within an institution (definition needs to be elaborated)

**Coercion** - the practice of persuading someone to do something by using force or threat.

**Personal Health Information (PHI)** - information in a patient’s file, chart or medical record considered confidential or personal in nature.

**Randomization** - assigning individuals to a group or treatment not using specific reason, but as a random process, like a lottery, giving everybody the same chance.

**Bias** - is the control over the extent, timing, and circumstances of sharing information about a person with others.

**Encounter** - is a contact or interaction between a CHW and another person in the community on a research study, a health or social services issue.

**Study Protocol** - is a document that describes, in detail, the plan for conducting the clinical study; explains the purpose of the study as well as how to do it.
Welcome and Introduction

*Disclaimer: This section is FL-specific, space here pages i-x, is to be available for local tailoring of the toolkit products.*

Thanks to hosts, sponsors, local regional coordinator of the FL CHW Coalition, and other collaborators!
We will go over logistics and general announcements. Then we will review together the training agenda.
In small groups, we will introduce ourselves, the organization or service group you associate with, and can exchange business cards.

**APHA Definition:**

"A Community Health Worker (CHW) is a frontline public health worker who is a trusted member of and/or has an unusually close understanding of the community served. This trusting relationship enables the CHW to serve as a liaison/link/intermediary between health/social services and the community to facilitate access to services and improve the quality and cultural competence of service delivery. A CHW also builds individual and community capacity by increasing health knowledge and self-sufficiency through a range of activities such as outreach, community education, informal counseling, social support and advocacy."


**Consensus on Strategic Value of Certification**

- **CHWs:**
  - Empowerment for building professional identity
  - Workforce development (pay, benefits, supervision, training, career pathways)

- **Providers/employers:**
  - Scope of practice in relation to other workforces
  - Training standards

- **Public & private insurers:**
  - Possible prerequisite for employment and financial support for services delivered
  - Scope of practice, training
Certification underway in multiple states

Community Health Workers (CHWs)
Training/Certification Standards

Current Status

- Legislation introduced
- Has a Training/Certification Program
- Laws/Regulations Establish CHW Certification Program Requirements
- Statute Creates a CHW Advisory Board, Taskforce, or Workgroup to Establish Program Requirements

Florida’s CHW Certification Program

- Voluntary certification program.
- Partnership between the Florida Department of Health, the Florida Certification Board and the Florida Coalition of Community Health Workers.
- Program developed and administered by the FCB, under the guidance of a standing advisory board of CHW subject matter experts.
- Under the FCB Code of Ethics.
www.flcertificationboard.org

<table>
<thead>
<tr>
<th>APPLY FOR CHW CREDENTIAL</th>
</tr>
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<tbody>
<tr>
<td>Must create an <strong>FCB online profile</strong>, first.</td>
</tr>
<tr>
<td>If you have a first degree misdemeanor or any felony, must pay a <strong>$20</strong> criminal history check fee to FCB.</td>
</tr>
<tr>
<td>Must complete an <strong>online CHW application</strong> and pay the <strong>$50</strong> non-refundable application fee.</td>
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<tr>
<td><strong>500 hours</strong> of work or volunteer experience providing CHW services</td>
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<td><strong>30 hours of specified training:</strong> 20 hours allocated across performance domains; 10 hours are electives.</td>
</tr>
<tr>
<td><strong>3 letters of recommendation:</strong> 1 supervisory; 2 of any of the following types: supervisory, professional, OR personal/character</td>
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<tr>
<th>RECEIVE APPROVAL TO TEST</th>
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<tbody>
<tr>
<td>Select test date/location/pay test fee. <strong>$65</strong> test fee to FCB.</td>
</tr>
<tr>
<td><strong>Up to $30 proctoring fee</strong> (paid to test site, directly).</td>
</tr>
<tr>
<td>CHW credential issued after earning a passing score on the CHW exam.</td>
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<tr>
<td>Credential issued for <strong>2-year period</strong>, renewing on October 31st of the renewal year.</td>
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<th>MAINTAIN CREDENTIAL</th>
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<tr>
<td>Follow the FCB Code of Ethics in daily practice, complete <strong>10 CEUs annually</strong>, pay <strong>renewal fee ($100)</strong> before expiration.</td>
</tr>
<tr>
<td>Comply with <strong>CEU Audit</strong> if randomly selected (a total of 20 CEUs are due with each renewal).</td>
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Impact of CHWs in Health

- It has been documented that as members of the care delivery team, CHWs have been critical in:
  - Securing access to health care
  - Coordinating timely access to primary care
  - Behavioral health and preventive services
  - Helping individuals manage chronic conditions

Contributions from CHWs

- CHWs bring the knowledge of their life experience of being part of a certain community, advocating for people living with a specific disease or condition or their caregivers.
- CHWs’ experience can assist and complement the researcher’s scientific knowledge in research and clinical studies.
- CHWs can expand on their skills with adequate research-related training like the one today.

Now, specifics topics for today:

1) What is research? Patient centered outcomes research?

2) What does it mean to conduct research in an ethical way, protecting the rights of research participants?

3) How to ensure all research participants have equal chances, without bias?

4) What are the different ways to collect research data; how can CHWs collect data for research studies?

5) What is the process of informing the participants about their rights and risks associated with a study?

6) How does one track data and report data collected?

7) How to report study results and to whom?
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Chapter 1. Key Patient-Centered Outcomes Research (PCOR) Concepts Relevant to CHWs

- What is Research? What is PCOR research?

Chapter Objective:
Demonstrate understanding of basic research and standards associated with patient centered outcomes research

Key Understandings:
By the end of this session, you will be able to:

- Define key research vocabulary and difference between service delivery and research
- Describe the PCOR engagement and stakeholder concepts
- Discuss Standards Associated with Patient Centeredness research
**To start the conversation:**

- Are you a **patient or a caregiver?**
- Have you been approached to participate in a **health research study?**
  - If so, did you say yes? What type of research/study was it?
- Have you **assisted/recruited for** a research study?
- Do you recall **knowing the results** of a research study?

“A general idea referring to a behavior or characteristic of an individual, group, or nation.”

- Pain
- Patient care
- Coping
- Safety
- Data
- Dignity

See if you can define these **concepts** /discussing in pairs.

<table>
<thead>
<tr>
<th>What is research? research studies?</th>
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<table>
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<tr>
<th>What are health and social service programs?</th>
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<tr>
<th>What is research involving human subjects?</th>
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What is Research?

Research is an organized, planned process of collecting and analyzing information (data) to obtain more knowledge, increase our understanding or to answer a specific question about a certain topic.

- A "researcher" or "investigator" is the person who conducts research to gain new knowledge. Participation is voluntary.
- Health and healthcare research focuses on outcomes or results. Outcomes research tries to understand what happened as a result of using some type of action (also called an intervention) to improve health. It is not known if the treatment/intervention will work or be of direct benefit to participants, but rather is intended to benefit other patients, the community or the society in the future.

Health and Human Services

Direct activities, goods, screenings, samples provided to recipients who are eligible/qualify.

Are community or individual benefits that are known to work and have been tested, evaluated, or otherwise shown to be effective?

Please write examples below:
Service Programs vs Research Studies

Are they the same thing?

- True
- False
- Don't know

Explain your answer below:
Basic Steps of a Research Study (Design)

<table>
<thead>
<tr>
<th>Find a topic to study</th>
<th>What, When</th>
</tr>
</thead>
<tbody>
<tr>
<td>Create questions</td>
<td>What, Why</td>
</tr>
<tr>
<td>Define a group/population</td>
<td>Who, When</td>
</tr>
<tr>
<td>Select design &amp; measurement</td>
<td>How</td>
</tr>
<tr>
<td>Collect evidence/data</td>
<td>How</td>
</tr>
<tr>
<td>Interpret evidence/data</td>
<td>Why</td>
</tr>
<tr>
<td>Dissemination</td>
<td>Tell about what you did and found out</td>
</tr>
</tbody>
</table>

What is Research Involving Human Subjects?

When research calls for getting personal information from, or about people, then the researcher is doing research involving human subjects. Research can involve such things as asking simple questions about the foods people like, or it can involve looking at the good and bad effects of one or many drugs for treating a disease.

- Studies can also get information about people without directly speaking to them, or asking them to do things.

- A study may take personal information from medical or school records in order to answer a research question.

NOTES:
**Patient Centered Outcomes Research Institute (PCORI)**

- PCORI is an **independent nonprofit, nongovernmental organization** authorized by Congress in 2010 located in Washington, DC.
- Committed to continuously **seeking input from patients and a broad variety of stakeholders** to guide the research that PCORI funds. This patient-centered outcomes research (PCOR) focuses on answering patients and caregivers’ questions about the outcomes and issues that are of greatest interest and concern to them. PCOR is based on the belief that patients have unique perspectives that can change and improve healthcare.
- PCORI requires that patients and other stakeholders participate at **every stage of the research** it funds, from the selection of the questions to be studied to the sharing of the results.
- Compared to traditional research, PCOR often involves patients, caregivers, and other non-researcher stakeholders in **unique ways**.
- In PCOR, **patients and other stakeholders** often act as human subjects or **research participants**. They may also serve as **advisors** to study teams, **members of study teams**, or **investigators**.

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Researchers look for funding. Define the possible explanation of why and the way the study will be conducted.

Patients define what is important to answer and how that answer will impact them. They provide input on ways to get the info.

Stakeholders define how the questions and the results will play out in real world and in existing settings. They inform the process.

[www.pcori.org](http://www.pcori.org)
**Research about Diseases & Conditions**

- Patients, caregivers, and clinicians need to be equipped with the best available information for making informed decisions. They are research partners.

Please write in your workbook, the roles each one play or activities they do.

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**Patient-Centered Outcomes Research (PCOR) Defined**

<table>
<thead>
<tr>
<th>Patient-Centeredness:</th>
<th>Patient and Stakeholder Engagement:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the project aim to answer questions or examine outcomes that matter to patients/caregivers?</td>
<td>Are patients/caregivers and other stakeholders involved as partners in research, as opposed to being merely study participants?</td>
</tr>
</tbody>
</table>

**Relevant to me?**

**Done with me?**
**PCOR Engagement Principles**

- Stakeholder involvement at all stages of PCOR ensures that the work responds to relevant and important issues, that it develops products that are accessible and user-friendly, and that ultimately research reaches its intended audiences.

- To promote the capacity for CHW engagement in PCOR by developing and implementing a structured research training program for CHWs.

**CHWs: Partners/Stakeholders in PCOR**

- Patient or caregiver themselves act as advocates of their community.
- Being a CHW, you can assist in very unique ways:
  - To inform the questions to ask, the ways to gather that information/data
  - To identify people that might be interested
  - To recruit subjects/participants
  - To inform them about benefits and risks of participating in the research study
  - To collect and inform how to interpret data
  - To help tell the story and to whom

**PCORI Video(s)** Andrea Jenson, PCORI Patient Partner: 45 secs

https://www.youtube.com/watch?v=pNmw255muzk
What are the Eugene Washington PCORI Engagement Awards?

Lia Hotchkiss, who directs the award program, explains. 1:16 mins
https://vimeo.com/158661405

Patients with rare diseases can become empowered through involvement in patient-centered research, says University of Maryland researcher Eleanor Perfetto, PhD. 1:22 mins
https://vimeo.com/156000384

Eugene Washington PCORI Engagement Awardee
In summary: PCOR

- Defined research, research with human subjects as participants and patients
- Explained the reasons why PCOR gets patients involved in the “how to” of the process
- Discussed standards of PCOR
- Identified CHWs as a PCOR Stakeholder

NOTES:

Next Chapters:

1) What does it mean to conduct research in an ethical way, protecting the rights of research participants?

2) How to ensure all research participants have equal chances, without bias?

3) What are the different ways to collect research data; how can CHWs collect data for research studies?

4) What is the process of informing the participants about their rights and risks associated with a study?

5) How does one track data and report data collected?

6) How to report study results and to whom?

Sample Study Manual outline is provided on the following page.
National Institute on Aging (NIA)
Outline for Manual of Operating Procedures (MOP) for Single Site Studies

The following is an outline of sections of the Manual of Operating Procedures (MOP) which should be considered for a single-site study. However, given that each study is unique, sections could be omitted and/or added at the investigator's discretion depending on the nature and complexity of the study. For guidance on the content that should be discussed in each of these sections, please refer to the Single-Site MOP Guidelines.

1.0 Introduction
2.0 Brief Overview of the Study Protocol
3.0 Study Staff Responsibilities
4.0 Study Flow Diagram
5.0 Recruitment and Retention Plan
   5.2 Screening Log
   5.3 Eligibility Criteria
6.0 Informed Consent
   6.1 HIPAA Authorization
7.0 Study Intervention
8.0 Randomization
9.0 Blinding and Unblinding (Masking and Unmasking)
10.0 Safety Reporting
11.0 Study Compliance
12.0 Data Collection and Study Forms
   12.1 Participant Binder
   12.2 Study Forms
   12.3 General Instructions for Completing Forms
   12.4 Data Flow
   12.5 Administrative Forms
   12.6 Retention of Study Documents
13.0 Data Management
   13.1 External Data
   13.2 Quality Control Procedures
      13.2.1 Standard Operating Procedures
      13.2.2 Data and Form Checks (as appropriate)
14.0 Concomitant Medications – Drug Intervention studies only
15.0 Data and Safety Monitoring Activities
   15.1 Study Completion and Close-Out
      15.1.1 Participant Notification
      15.1.2 Confidentiality Procedures
      15.1.3 Publications
16.0 MOP Maintenance

Note: If the study involves drug intervention, either the Package Insert for an approved drug or the Investigator's Brochure for an investigational product must be included as an appendix. The following documents should also be included in the MOP appendices: Study Forms, Informed Consent and HIPAA, Standard Operating Procedures, Recruitment Flyers, Letters to Participants, etc.
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Chapter 2. Ethics: What does it mean to conduct research in an ethical way?
  o Protecting the rights of research participants

Chapter Objective:
Identify basic ethical principles and how they apply to modern human subject research

Key Understandings:
By the end of this session, you will be able to:

- Discuss the historical basis for regulating human subjects research
- Describe the role and jurisdiction of the Institutional Research Board
- Define vulnerable populations
- Understand coercion and undue influence and potential risks to subjects
- Identify privacy and confidentiality protections for subjects
- Recognize ethical/professional boundaries/challenges to be faced as a local community health worker
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Ethics

- “Traditional” concept of research: from academic centers to the world!
  - Now done at clinics, schools, community centers, even on the streets, at parks, at people’s homes...
- Why there are so many rules for doing research with participants (human subjects)?

Please answer possible reasons/discuss in pairs.

Group Activity Discussion

- Use the cards on your table with the **keywords**.
- One card per person: You will be responsible to present that keyword in your card to your small group.
- Decide within your group who will be the **spokesperson** who will bring questions/concerns/what was not understood to the class.
- We will discuss together. (10 mins)
Ethics – Brief history for current human subjects protections

The Nuremberg Code

- Concern for the protection of people as research subjects and participants took off following the Nuremberg war crime trials.
- Standards for judging doctors and scientists who conducted experiments on prisoners in concentration camps: Done without consent!
- Code: Consent is essential, freedom from coercion, no penalties for withdrawal, understanding risks and benefits.

The Declaration of Helsinki (1964)

- Established by the World Medical Association to guide medical doctors in research involving human subjects
  - Covers international research
  - Animal experiments to be done BEFORE research done on humans
  - Risks balanced by benefits
  - Reviewed by an ethics committee (IRB)

The National Research Act (1974)

- Established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research in the USA
  - The Belmont Report: 3 basic concepts as a guide
Ethical Principles Underlying Acceptable Conduct of Research Involving Humans

- **Respect for persons**: treat each person as a free individual with dignity, with special protections for those with diminished autonomy (vulnerable)
- **Beneficence**: do good and avoid harm
- **Justice**: benefits and burdens to be in balance, treat people fairly

**Vulnerable Populations**

- **Prisoners, children, and pregnant women** are all examples of special groups or populations defined as vulnerable in human subjects research.
- They need extra protection against possible abuse!
Group Activity Discussion

1. Discuss why and how governmental protections of research with subjects/humans came to be.

2. Discuss why those rules are needed now in medical research.

3. Discuss how as a CHW member of a research team you would also be responsible to follow those guidelines for ethical research.

➤ What NOT to do?
**Who protects the participant/human subject/patient?**

- Government overall and locally, the **Institutional Research Board (IRB)**
- All U.S.-funded research involving human subjects is required by U.S. law to be reviewed according to the rules set out in the U.S. Code of Federal Regulations, Title 45, Part 46, **Protection of Human Subjects**
- Each institution conducting research is required to have a formal way for review, and must comply with all of the federal regulations
- An institutional review board (IRB) is that formal body within an institution

**IRB REVIEW**

1. **Does your work involve human subjects?**
   - **YES** — Requires IRB Review

2. **Complete required training for working with human subjects**
   - **Submit protocol for IRB review**

3. **Proceed with project once you receive approval from IRB**

4. **Do you need to make any changes to approved research?**
   - **YES** — Requires IRB Review

5. **Submit Changes**
Ethics - Risks and Discomforts to Participants / Research Subjects

Harm may result directly from actual research procedures or from not protecting sensitive or confidential information.

Using your workbook, name examples of these types of risk:

- **Physical** (pain, drug side effects, injury)
- **Psychological** (emotional distress)
- **Social** (stigmatization)
- **Economic** (loss of job for disclosing information)

Examples of what is considered minimal risk:

- Collecting portions/samples of hair and nail clippings, urine, blood samples (<450 ml/30 Tbsp/15 ounces from non-pregnant adults)
- Taking measurements and Recording that data information in ways that are “non-invasive” (blood pressure, height, weight, etc)
- Interviews and surveys on matters that are on non-sensitive topics

Ethics: What is a CHW to do?

- Do tell/disclose what will be done about it:
  - Tell **how bad** is the risk or possible discomfort
  - Also about **burden** (time, feelings, side effects, etc.)
  - Therapy, medication or payment may be available
  - Discuss **how to balance** those risks or discomforts with participation and possible benefits
    - Explain clearly **who to contact**
Ethics: What NOT to do

- Understand coercion and undue influence and potential risks to subjects
- Informed consent (coercion/undue influence) role-play exercise

Ethics – What is privacy?

- Privacy is the control over the extent, timing, and circumstances of sharing information about a person with others.
- What participants DO NOT want researchers to have, touch or know!

- How the researcher team member (CHWs too!) accesses information from or about potential participants (e.g., like in the recruitment process).

Privacy is...

- About people
- A sense of being in control of access that others have to ourselves
- A right to be protected
- Is in the eye of the participant, not the researcher or the IRB

Privacy & Sensitive Information

Use your workbook to describe what Sensitive Information is as you define it. Cite examples.

Sensitivity of the information being collected - the greater the sensitivity, the greater the need for privacy!
Protecting Sensitive Information

- Depends on the context
  - Usually or always sensitive: illegal behavior, immigration status, sexual behavior, health status (e.g. specific disease status)

Invading of privacy: gaining information without permission!

- Individuals should not worry that they will be discriminated against because of their health information.
- Individuals should know that their sensitive health information will not be released to unauthorized entities.

Examples of Protected Health Information (PHI)

- Information in a patient’s file, chart or medical record considered confidential or personal in nature
- Billing or health care claims data
- Research or reporting data with individually identifiable health information
- Information compiled for use in a civil, criminal or administrative action or proceeding

*PHI includes: verbal info, on paper, recorded info, and electronic info (faxes, emails).

Privacy Rule List of Identifiable Patient Information

- Addresses
- Dates
- Telephone or fax #s
- SSN
- Medical Record #s
- Patient Account #s
- Insurance Plan #
- Vehicle Information
- License #s
- Medical Equipment #s
- Photographs
- Fingerprints
- Email addresses
- Internet addresses
- And of course, NAMES
What does all that mean to me?

- CHWs as employees, volunteers and service providers, we come in contact with many forms of patient information, i.e. lists, laboratory/test results, case reports, etc. We need to understand what are acceptable uses of this information.
- Follow the “need to know” rule. Ask yourself “do I need to see patient information to perform my job”. If the answer is “Yes”, you have nothing to worry about. If the answer is “no”, STOP.
- Violations of confidentiality and privacy policies can result in disciplinary action up to and getting you fired!

Practical Do’s and Don’ts

**Do…**

- Probe and clarify.
- Verify names and contact information.
- Write with black ink only.
- **Number and date all pages.**
- Shred all notes that need to be discarded.
- Close doors when discussing treatments and administering procedures.
- Avoid discussion about patients/clients in public areas.
- Secure storage and transportation of patient information.

**Don’t…**

- Throw notes away.
- Leave items blank.
- Change dates, names, etc.
- Rewrite the record.
- Leave confidential notes face up on your desk or take with you home where they can easily be viewed or accessed.
Technology Do’s…

- Use a password or other user authentication.
- Ensure a firewall and security software are installed.
- Keep up to date your security software.
- Physically secure your mobile device.
- Log off computers when away from workstation.
- Use adequate security to send or receive health information over public Wi-Fi networks.
- Delete all stored health information before discarding or reusing a mobile device.

Technology Don’ts...

- Never share your password with anyone.
- Never download mobile applications until you verify the application will perform only functions of which you approve.
- Never provide unauthorized users access to your mobile device.
- Never fax/email records/results: HIV results, alcohol abuse, mental health, substance abuse, child abuse, narcotic prescriptions.

Remember...

- Providing detailed descriptions of patients is still a violation (even if you don’t use a name).
- You never know who is listening (especially in waiting rooms, cafeterias, elevators, etc.)
- We must protect all patient information transmitted electronically.
- Dispose of patient information appropriately: NEVER dispose of patient information in any open area trash bin.

When in doubt… ASK!
How would you handle these situations as a CHW?

1. You work at a clinic/health center and could not finish work on time, so you decide to download/take with you some patient information to keep working on your computer at home.  
   *Is this OK?*

2. A man comes to your department and says he is here to work on the computer. He wants your password to log onto the computer.  
   *What should you do?*

3. Dr. Anderson is discussing a patient’s/client’s case with the social worker in the hallway next to the exit as people pass by.  
   *Is there a violation of privacy?*

4. A family member calls you or sees you at church and inquiries about the condition of a relative she knows you are assisting with.  
   *What do you do?*

Answers on next page…
Answers:

1. **No.** Documents that contain patient information may not be removed from the clinic/center unless authorized to do so by the Privacy Officer.

2. **Do not give or share your password with anyone.** You should also know the identity of anyone coming into your area. Ask questions and follow up with appropriate department to determine if the person is authorized to be in your area.

3. **Yes.** Discussing patients and disclosing protected health information in an open area where others can easily hear is a violation of patient’s privacy rights.

4. Be firm about indicating how much you care. But tell them the specific health information is confidential and cannot be shared with other individuals without consent from the patient/client.

Takeaways / Open Discussion

Recognize *ethical/professional boundaries/ challenges* to face as a local community health worker

Next Chapter:

1) How to ensure all research participants have equal chances, without bias?

2) What are the different ways to collect research data; how can CHWs collect data for research studies?

3) What is the process of informing the participants about their rights and risks associated with a study?

4) How does one track data and report data collected?

5) How to report study results and to whom?
Chapter 3. Study Allocation and Randomization:

- How to ensure all research participants have equal chances, without bias?

Chapter Objective:

Demonstrate understanding of the randomization process and how to discuss it with study participants

Key Understandings:

By the end of this session, you will be able to:

- Identify intervention vs. comparator group
- Discuss the importance of randomization
- Proficiently explain the randomization process to study participants and its implications
Engagement Guidelines

PLANNING THE STUDY: How patient and stakeholder partners like CHWs can participate in study planning and design.

- **Developing the research question and relevant outcomes to be studied**
  - To ensure that the project and its results will be useful and important to patient and stakeholder communities.

- **Defining the characteristics of study participants**
  - To minimize the risk that certain patients will be included or excluded due to criteria that are not relevant/biased.

- **Designing the study to minimize disruption to patient and stakeholder study participants**
  - To promote retention of study participants.

Medical Studies/Clinical Trials

- Research involving new drugs, devices (e.g. catheter, pacemaker), vaccines, or therapies attempting to answer specific questions.

- Who receives what or when is important, CHWs help bringing in/recruit participants when they minimize the risk that certain patients will be included or excluded due to criteria that are not relevant/biased.

Who receives What/When: Study Allocation/ Randomization

- Assigning individuals to a group or treatment not using specific reason, but as a random process, like a lottery, giving everybody the same chance!

- Identify intervention group (the one receiving the treatment, what is different in this particular study) vs. comparator (the one doing standard, the usual)
Let’s Play!

- Sampling Techniques – An Activity with candy to use as a “treatment/intervention”
- Randomization: Assignment by lottery, determined totally by chance, not predictable at all.

Randomization: Why is important?

- To give everybody the same shot, without inappropriate preferences, to be fair to all!
Example – Clinical Trial Randomization in PCORI Studies

Bias

- Inappropriate interference or factors other than the treatment or intervention that may explain/might affect the study results.

Open Discussion

How to ensure all research participants have equal chances, without bias, to be included in a research study?
Next Chapters:

1) What are the different ways to collect research data; how can CHWs collect data for research studies?

2) What is the process of informing the participants about their rights and risks associated with a study?

3) How does one track data and report data collected?

4) How to report study results and to whom?
Chapter 4. Different ways to gather research data

- How can CHWs collect data for PCOR studies?

Chapter Objective:

Identify different types of data collection methods and the CHW’s role in data collection in PCOR

Key Understandings:

By the end of this session, you will be able to:

- Describe examples of qualitative methods: observations, key informant interviews, focus groups, public forums/community consultations
- Describe examples of quantitative methods: questionnaires/surveys
- Identify mixed methods approaches
- Understand how CHWs can contribute to how data is collected
- Discuss how interviewer bias can skew the data
This page is intentionally blank.
## Ways to Collect Information/Data

<table>
<thead>
<tr>
<th>QuaNtitative</th>
<th>Qualitative</th>
<th>Mixed Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>&quot;N&quot; for Numbers</td>
<td>&quot;L&quot; isn't &quot;N&quot;... Non-numerical</td>
<td>A Mixture of Both!</td>
</tr>
<tr>
<td>- Tests</td>
<td>- Words/Texts</td>
<td></td>
</tr>
<tr>
<td>- Counting</td>
<td>- Photos/Images</td>
<td></td>
</tr>
<tr>
<td>- Measuring</td>
<td>- Observations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Conversations</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Recordings</td>
<td></td>
</tr>
</tbody>
</table>

### Notes

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Page 35
### Examples from Real World

<table>
<thead>
<tr>
<th>Quantitative Methods</th>
<th>Mixed Methods</th>
<th>Qualitative Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>- U.S. Census</td>
<td>- Both open- and closed-ended questions (Y/N)</td>
<td>- To describe pain</td>
</tr>
<tr>
<td>- Signing Sheets</td>
<td>- Multiple forms of data drawing on all possibilities</td>
<td>- TV shows/stories that demonstrate an issue in a community</td>
</tr>
<tr>
<td>- Budgets</td>
<td>- Statistical and text analyses (numbers and words)</td>
<td></td>
</tr>
<tr>
<td>- Body measurements</td>
<td>- Several sources of data/information</td>
<td></td>
</tr>
</tbody>
</table>

- Several sources of data/information
  - To describe pain
  - TV shows/stories that demonstrate an issue in a community

- To describe pain
- TV shows/stories that demonstrate an issue in a community
CHWs Collecting Qualitative and Quantitative Data for PCOR Studies

- When: At **individual health encounters** and at **group sessions**.
- **Encounter:** is a contact or interaction between a CHW and another person in the community on a research study, a health or social services issue.
- **Recording encounters** is one way to show the work that CHWs are doing as part of PCOR study. Written logs, clinic records & forms are frequently used.
- **Forms** are to be filled as instructed, filed, and safely kept. *Documentation!*

**Observations**

Qualitative research at its most simple can take the form of observation.

- In observation, the researcher **simply observes the research matter and describes in detail the situation.** Can use diagrams, drawings and symbols to enhance the notes.
  - *Ex*) A CHW observing how a person is able to brush his teeth in his daily routine as he recovers after having a stroke
  - *Ex*) A CHW may watch a kid play and interact with other kids
- Used when the researcher wants to **examine a subject in its natural environment or study naturally occurring behaviors.**
- CHW has to be very careful to **not introduce personal bias** into his observations, but describe the facts, as neutral as possible.

**Key Individual Interviews**

- The CHW asks open-ended questions and simply records what the participant says
  - Ask What/When/How/Why Q's, allow patients to narrate their experience
- **Personal bias** and other problems to avoid:
  - The CHW may **react verbally or non-verbally** to the patient’s responses, encouraging or discouraging responses in a certain direction.
  - The CHW has to be careful that he/she **does not** influence the patient with **personal opinions.**
Facilitating a Discussion:

Focus Groups (FGs) & Group Education Sessions

- Several people are interviewed at once as a group to gain their opinions on a subject/situation/health condition.
- Be neutral; avoid influencing/sway group members.

Tips for Preparing to Conduct Focus Groups

- Clarify your goal/what you hope to learn.
- Find a note taker like minutes of a meeting.
- Decide on who should be invited.
- Decide on incentives (money, food, gift certificates, raffles, public recognition, child care, free parking, etc.)
- Decide on meeting particulars (day, place, what time, how long, signage, seating, etc.)
- Prepare your questions as a guide to the discussion.
- Conduct the session and summarize your findings.
- Share results.

Notes
Quantitative Ways to Collect Data Information: Surveys

- May focus on opinions or be based on information facts depending on its purpose.

Data Collection Methods

Using your workbook/with your partner, define these qualitative and quantitative methods used in PCOR studies:

<table>
<thead>
<tr>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surveys</td>
</tr>
<tr>
<td>Individual interviews of key informants (patients, caregivers, family members)</td>
</tr>
<tr>
<td>Focus Groups</td>
</tr>
<tr>
<td>Public Forums/ Community Consultations</td>
</tr>
</tbody>
</table>
Next Chapters:

1) What is the process of informing the participants about their rights and risks associated with a study?

2) How does a CHW track data and report data collected?

3) How to report study results and to whom?

Sample forms are provided on the following pages: Visit Checklist, Demographics, Medical History, Visit Process Flow and Study Completion.
Visit Checklist - Sample

STUDY NAME

<table>
<thead>
<tr>
<th>Site Number:</th>
<th>Visit Date:</th>
<th>Pt_ID:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>__ / ___ / __</td>
<td>__________</td>
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<tr>
<td></td>
<td>d d m m m y y y y</td>
<td></td>
</tr>
</tbody>
</table>

1. Did the participant attend this visit?  
   - Yes (if yes, continue)  
   - No

2. Please check all assessments completed at this visit:

   **Visit Name: Baseline**

   - Demographics
   - Medical History
   - Vital Signs
   - Physical Exam
   - Prior and Concomitant Medication
   - Inclusion/Exclusion Criteria
   - Randomization and Enrollment

3. Is the participant continuing in the study?  
   - Yes  
   - No

   If no, remember to complete a STUDY COMPLETION form.

   If yes, schedule next visit.

Comments:

____________________________________________________________________________________

____________________________________________________________________________________

Visit Checklist  
Version 1.0
Demographics

STUDY NAME: [Enter study name]

Site Number: [Enter site number]  Visit Date: [Enter visit date]
(DD / MMMM / YYYY)
Pt_ID: [Enter participant id]

Visit Type (check one): ☐ Screening  ☐ Baseline

1. Gender:
☐ Female  ☐ Male

2. Date of Birth: [Enter date of birth] (DD/MMM/YYYY)

3. Race ("X" those with which you identify):
☐ American Indian or Alaska Native
☐ Asian
☐ Black or African-American
☐ Native Hawaiian or Other Pacific Islander
☐ White
☐ More than one race
☐ Unknown or not reported

4. Ethnicity ("X" ONLY one with which you MOST CLOSELY identify):
☐ Hispanic or Latino
☐ Not Hispanic or Latino
☐ Unknown or not reported

Date Informed Consent Signed: [Date informed consent signed] (DD / MMMM / YYYY)

Demographics  Version 2.0
# Medical History

<table>
<thead>
<tr>
<th>Code</th>
<th>Condition/Disease</th>
<th>Start Date</th>
<th>Current / Resolved</th>
</tr>
</thead>
<tbody>
<tr>
<td>01</td>
<td>Head, Eye, Ear, Nose, Throat</td>
<td></td>
<td></td>
</tr>
<tr>
<td>02</td>
<td>Respiratory</td>
<td></td>
<td></td>
</tr>
<tr>
<td>03</td>
<td>Cardiovascular</td>
<td></td>
<td></td>
</tr>
<tr>
<td>04</td>
<td>Gastrointestinal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>05</td>
<td>Genitourinary</td>
<td></td>
<td></td>
</tr>
<tr>
<td>06</td>
<td>Musculoskeletal</td>
<td></td>
<td></td>
</tr>
<tr>
<td>07</td>
<td>Neurological</td>
<td></td>
<td></td>
</tr>
<tr>
<td>08</td>
<td>Endocrine/Metabolic</td>
<td></td>
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<tr>
<td>09</td>
<td>Blood/Lymphatic</td>
<td></td>
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<tr>
<td>10</td>
<td>Dermatologic</td>
<td></td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Psychiatric</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Allergy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>91</td>
<td>Other</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Visit Process Flow and Schedule Templates

Visit Name: Baseline

This visit process flow is designed to be used in conjunction with the Baseline visit checklist. Below is a sample process flow:

1. The subject arrives at the site and is greeted in reception
2. The study coordinator meets the subject and escorts them to an exam room
3. Vital Signs, Medical History, Demographics and Prior/Concomitant Medication information are collected
4. A Physical Exam is conducted by a nurse practitioner or study physician
5. Inclusion/Exclusion Criteria are reviewed and signed off on by the PI
6. Randomization and Enrollment are completed
7. Other assessments are completed as per protocol
8. Investigational Product is dispensed as per protocol
9. Next visit is scheduled

Sample Visit Schedule

Subject ID: [subject id]
Randomization Date: [randomization date] (dd/mm/yyyy)

<table>
<thead>
<tr>
<th>Visit</th>
<th>Window Opens</th>
<th>Target Date</th>
<th>Window Closes</th>
<th>Actual Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 2</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Visit 3</td>
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<td></td>
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<tr>
<td>Visit 4</td>
<td></td>
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<tr>
<td>Visit 5</td>
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<tr>
<td>Visit 6</td>
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<tr>
<td>Visit 7</td>
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<td></td>
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<tr>
<td>Visit 8</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Visit 9</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Visit 10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Visit Process Flow and Schedule  Version 1.0
Study Completion

<table>
<thead>
<tr>
<th>STUDY NAME</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Number:</td>
</tr>
<tr>
<td>Pt_ID:</td>
</tr>
</tbody>
</table>

1. Date of final study visit: ___/____/____
   dd  m mm  yyyy

2. Date of last known study intervention: ___/____/____
   dd  m mm  yyyy

3. Primary reason for terminating participation in the study:
   [ ] Completed study
   [ ] Participant was determined after enrollment to be ineligible (Provide Comments)
   [ ] Participant withdrew consent
   [ ] In the Investigator’s opinion it was not in the participant’s best interest to continue
     (Provide Comments)
   [ ] Adverse Event
     If checked, complete the AE form
   [ ] Death
   [ ] Lost to follow-up
   [ ] Other (specify): _______________________________
   [ ] Unknown

COMMENTS:

PI Signature: ___________________________ Date: ____________

Study Completion Form  Version 1.0
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Chapter 5. What is the process of informing the participants about their rights and risks associated with a study?

○ What is the Informed Consent Process in Recruitment

Chapter Objective:

Informed Consent Form
Demonstrate understanding of the process for legally effective informed consent

Key Understandings:
By the end of this session, trainees will be able to:

- the information that should be disclosed to subjects during List the consent process
- Describe the process for obtaining informed consent
- Discuss the voluntariness of the decision about whether or not to participate in research
This page is intentionally blank.
Several Steps in the Informed Consent Process:

Making an Informed Decision:

- Tell participants all they need to know
- Make sure they understand
- It’s their own choice; resist giving your opinion even if they ask for it!
- Tell them who you are/what organization or group you represent, especially if they have met you before at another location or in the community, even if it feels strange!
- Don’t exaggerate benefits nor minimize risks or discomforts.
- Tell people they can withdraw, even AFTER signing ICF.
Waivers

- What about **people who are not able to decide for themselves** about being a human subject/participant in a study?
  - Children because they are too young
  - Adults that are too sick, either mentally or physically to make their own decisions.
- **For children:** parents give their permission, the child has to agree and the IRB has approved it.

Notes

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**Role Play 1: Inclusion/Exclusion Criteria**

**Martha:**
- CHW responsible for obtaining informed consent

**Joseph:**
- Does not have diabetes and therefore does not meet inclusion/exclusion criteria. Still wants to participate because the research study provides $100. Lies about having diabetes in order to try to qualify. Tries to persuade Martha that she should “let you sign up because you really need the money”.

**Observer:**
- Note questions that Martha can ask to ensure that Joseph meets the study’s inclusion/exclusion criteria. Note ways that Martha can explain to Joseph why he cannot participate. Note strategies that Martha can use to tell Joseph no without being rude.

---

**Notes**

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Role Play 2: Voluntary ≠ Forced Decision

Fred:
- Responsible for enrolling participants and obtaining informed consent. Has not successfully recruited anyone today. Begs, pleads, bribes, and uses guilt – i.e., tries everything! to get Rick to sign the consent form. Tells Rick that the research is really going to help him and going to do a lot of good for the community. Tells Rick that he will lose his job if he doesn't sign up enough people. Tells Rick that if he is concerned about privacy, he doesn't have to use his real name or answer questions honestly.

Rick:
- Does not want to participate because he does not have time and is also concerned about his privacy and the confidentiality of the information he will share.

Observer:
- Note what is wrong with the ways that Fred tries to persuade Rick to sign the consent form. Note the various things that Rick does and says to demonstrate that he is not interested. Note what might be some more appropriate ways of dealing with Rick's concerns about privacy.

Notes

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Role Play 3: Participant Questions

Kim:
- Responsible for obtaining informed consent.

Janet:
- Is interested in the study, but also has a lot of concerns, questions, and ideas about research. She wants to know:
  - Why is this research being conducted in my neighborhood?
  - Who is this research going to help? What changes can she expect in her community?
  - Is she going to be used as a guinea pig? Are scientists going to experiment on her?
  - How is her information going to be kept private? Her cousin signed up for a research study, and his identity was stolen 2 weeks later.
  - Where is the money being used to provide community service?

Observer:
- Note the answers Kim provides in response to Janet’s questions. Are they accurate and persuasive? What are some other potential responses?

Notes

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Role Play 4: Understanding

George:
  - Responsible for obtaining informed consent.

Rita:
  - 60-year old woman. Has diabetes and meets other inclusion criteria. Has limited reading skills and poor eyesight. Makes excuses about why she does not want to read the form. Makes incorrect statements about the research. Asks questions that show that she does not understand what is involved in research participation.

Observer/Discussion:
  - Note different strategies that George can use to help Rita understand the study without making her feel uncomfortable.

Notes
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Next Chapters:

1) How does a CHW track data and report data collected?
2) How to report study results and to whom?

Sample forms are provided on the following pages:
Informed Consent Checklist and Informed Consent Template.
# Informed Consent Checklist

(Please refer to DHS HHS OHRP 45 CFR 46 §46.116 for details)

<table>
<thead>
<tr>
<th>Basic Elements</th>
<th>Indicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement that the study involves research</td>
<td>Yes</td>
</tr>
<tr>
<td>An explanation of the purposes of the research</td>
<td>Yes</td>
</tr>
<tr>
<td>The expected duration of the individual’s participation</td>
<td>Yes</td>
</tr>
<tr>
<td>A description of the procedures to be followed</td>
<td>Yes</td>
</tr>
<tr>
<td>Identification of any procedures which are experimental</td>
<td>Yes</td>
</tr>
<tr>
<td>A description of any reasonably foreseeable risks or discomforts to the participant</td>
<td>Yes</td>
</tr>
<tr>
<td>A description of any benefits to the participant or to others which may reasonably be expected from the research</td>
<td>Yes</td>
</tr>
<tr>
<td>A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant</td>
<td>Yes</td>
</tr>
<tr>
<td>A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained</td>
<td>Yes</td>
</tr>
<tr>
<td>For research involving more than minimal risk, an explanation as to whether any compensation, and an explanation as to whether any medical treatments are available, if injury occurs and, if so, what they consist of, or where further information may be obtained</td>
<td>Yes</td>
</tr>
<tr>
<td>An explanation of whom to contact for answers to pertinent questions about the research and participant’s rights, and whom to contact in the event of a research-related injury to the participant</td>
<td>Yes</td>
</tr>
<tr>
<td>A statement that participation is voluntary; refusal to participate will involve no penalty or loss of benefits to which the individual is otherwise entitled, and the individual may discontinue participation at any time without penalty or loss of benefits, to which he/she is otherwise entitled</td>
<td>Yes</td>
</tr>
<tr>
<td>A statement that must contain the following language: “A description of the clinical trial will be available on <a href="http://www.ClinicalTrials.gov">http://www.ClinicalTrials.gov</a>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the Web site at any time/&quot;</td>
<td>Yes</td>
</tr>
</tbody>
</table>
### Additional Elements, as appropriate

<table>
<thead>
<tr>
<th></th>
<th>Indicate</th>
</tr>
</thead>
<tbody>
<tr>
<td>A statement that the intervention may involve risks to the individual (or to the embryo or fetus, if the individual is or may become pregnant), which are currently unforeseeable</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Anticipated circumstances under which the individual’s participation may be terminated by the investigator without regard to the subject’s consent</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>Any additional costs to the individual that may result from participation in the research</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>The consequences of an individual’s decision to withdraw from the research and procedures for orderly termination of participation by the individual</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>A statement that significant new findings developed during the course of the research, which may relate to the individual’s willingness to continue participation, will be provided to the individual</td>
<td>☐ ☐</td>
</tr>
<tr>
<td>The approximate number of study participants</td>
<td>☐ ☐</td>
</tr>
</tbody>
</table>
The below template for developing an informed consent document to use in your research study is meant to provide structure and guidance to the process, not to serve as your exact informed consent document. Please remember to consult your institution and IRB for specific consent requirements, instructions and templates.

For the purposes of this document, guidelines within the template will be provided in italics. If this document is used to develop your informed consent form, please remember to delete the italicized instructions and insert your specific information.

Informed Consent Document Template and Guidelines

Informed Consent Form

(name of institution)

Title of Project: (complete title of the project as it appears on the protocol and abstract)

Principal Investigator: (only one person may be named as principal investigator)

Other Investigators:

Participant's Printed Name: [Print participant name]

The Introductory Paragraph
Example Introductory Paragraph:

We invite you to take part in a research study (title) at (location/institution), which seeks to identify a more effective means of treating (illness, condition). Taking part in this study is entirely voluntary. We urge you discuss any questions about this study with our staff members. Talk to your family and friends about it and take your time to make your decision. If you decide to participate you must sign this form to show that you want to take part.

Section 1. Purpose of the Research

This section is required in all consent forms. It focuses on explaining to the participant why they were asked to participate in the study and the purpose of the research study.

Example Section 1: Purpose of the Research

You are being offered the opportunity to take part in this research study because (state why the individual was selected, e.g., condition, age, or healthy volunteer).

This research study is being done to find out........

OR
The purpose of this research is to......

OR

The purpose of this research study is to obtain information on the safety and effectiveness of (name of drug, device, etc.).

Approximately (number) people will take part in this research (nationwide or worldwide) and about (number) people are expected to take part at (your institution).

Section 2. Procedures

This section is required in all consent forms. It outlines the procedures of the study and explains exactly what will happen to the individual should they choose to take part in the study. It should clearly identify what parts of the procedure, if any, are experimental.

Section 3. Time Duration of the Procedures and Study

This section is required in all informed consent forms. The purpose of this section is to clearly outline the time commitment a participant is committing to in choosing to take part in the study.

Example of a Time Duration Section:

If you agree to take part in this study, your involvement will last approximately (give length of time of participation). You will be asked to return to the clinic (number) times. Each clinic visit will take approximately (number) minutes.

Section 4. Discomforts and Risks

This section is required in all informed consent forms. For certain research studies, it may suffice to say that there are no know risks associated with the research. However, in most studies, this section will outline in lay terms what risks or discomforts may be associated with each procedures or drug administered. List by regimen the physical and nonphysical risks of participating in the study in percentages and numbers whenever possible. Nonphysical risks may include such things as the inability to work, potential anxiety related to the sensitive nature of the questions asked, etc. List the known human experiences related to the treatment and procedures involved, including bruising or discomfort from blood draws, as well as any relevant animal data. Highlight or otherwise identify side effects that may be irreversible, long-term or life threatening. The use of lists or a table format is recommended.

Example of a Discomforts and Risk Section for a Drug Study:

While on the study, you are at risk for the following side effects. Most of them are listed below but they will vary from person to person. Drugs will be given to make some of the side effects less serious and uncomfortable. Many side effects go away
after the drug is stopped but, in some cases, the side effects may be serious and/or lasting.

**Drug XYZ side effects.**

More likely:
- Decreased appetite
- Difficulty sleeping
- Headache, dizziness

Less likely:
- Hallucinations or delusions
- Nausea and/or vomiting

*(The following text should be added for trials with a placebo arm)*

If you are in the treatment group that receives placebo (inactive substance) your symptoms or condition may worsen or not improve.

**Other Possible Risks Associated With Participating In This Study**

**Venipuncture:** The risks of drawing blood include temporary discomfort from the needle stick, bruising, bleeding, and rarely, infection.

**Subcutaneous Injections:** Injections to the skin may be less convenient than some other forms of treatment, such as oral medications. In addition, injections may cause momentary discomfort and other local symptoms, such as bleeding, bruising, and, rarely, infection.

*(Also, if applicable, the following should be added)*

There also may be other side effects or discomforts that we cannot predict, especially to a fetus or embryo. Because the drugs in this study may affect an unborn baby, you should not become pregnant or father a baby while on this study. Your doctor will discuss this with you. You should not breast-feed a baby while on this study.

**Section 5. Potential Benefits**

This section must be in all informed consent forms. However, the way it is included may vary depending on the type of research. The purpose of this section is to describe the benefits of participating for the subject and for others. The following should be included in this section:

- This section should address two parts: 1) potential benefits to the participant; and 2) potential benefits to others. The two ideas can be integrated, but for the purposes of the example below, they have been separated into separate paragraphs.
- **NOTE:** Payment given to the subject for participation in the study is not a benefit, it is a compensation for subject’s time and any expenses that s/he could incur as a result of participation in the study, and should not be included in this section.

**Example of Possible Benefits Section:**
Possible benefits to the participant:

(for clinical research studies where direct benefit is possible) The possible benefit you may experience from the (research drug/device/procedure) described in this research includes (list any benefits that may be reasonably expected). However, there is no guarantee that you will benefit from being in this research.

(for research with no direct benefit) You will not benefit from taking part in this research study.

Possible benefits to others:

(address potential benefits to others) The results of this research may guide the future treatment of...

or

Medical science may gain further understanding of...

Section 6. Statement of Confidentiality

This section is required in all informed consent forms. This section must outline how all confidential information and or materials will be treated, stored, and maintained and for what lengths of time, as well as how materials will be disposed of at the end of the study period. Privacy and confidentiality measures must be addressed in this section.

This section must also include a statement containing the following language:

“A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search the web site at any time”.

6a. Privacy and confidentiality measures

Example Statement of Confidentiality:

Your research records that are reviewed, stored, and analyzed at (your institution) will be kept in a secured area in (list where records are stored). (Include the following if specimens are collected for research purposes) Your samples collected for research purposes will be labeled with (list all that apply: a code number, your initials, etc.) and will be stored (list where the samples will be stored and how they are secured).

(For research records/samples that are sent outside of your institution, describe methods that will be used to ensure confidentiality. If records and specimens are sent to different entities or labeled differently, describe their confidentiality measures separately). For research records (and specimens) sent to (outside entity), you will not be identified by name, social security number, address or phone number. The records (and specimens) may include (list all that apply: a code number, your initials, date of...

Version 2 – March 25, 2014
birth, etc.). The list that matches your name with the code number will be kept in a locked file in (note location, such as PI's office).

OR

For research records (and specimens) sent to (outside entity), you will be identified by (list all that apply: name, social security number, address, phone number, date of birth, any other direct personal identifier, code number). The list that matches your name with the code number will be kept in a locked file in (note location, such as PI's office). (Remember to include separate descriptions for records and specimens if they are labeled differently or stored differently or sent to separate entities.)

The following statement is considered mandatory for all research studies:

In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

The following statement is for those studies that do not include section 6b.

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people may become aware of your participation in this study. For example, the following people/groups may inspect and copy records pertaining to this research.

The Office of Human Research Protections in the U. S. Department of Health and Human Services (for drug/device studies, add the U.S. Food and Drug Administration)
- The (your institution) Institutional Review Board (a committee that reviews and approves research studies) and
- The (your institution) Human Subjects Protection Office
- The National Institutes of Health, the study sponsor

Some of these records could contain information that personally identifies you. Reasonable efforts will be made to keep the personal information in your research record private and confidential but absolute confidentiality cannot be guaranteed.

6b. The use of private health information:

- Section 6b is mandatory if the research creates, obtains, uses, and/or discloses identifiable health information about the research participants. The 18 identifiers are listed under HIPAA regulations.
- Do not include any part of Section 6b unless the research fits the above criteria.

Example Statement of Use of Private Health Information:

Health information about you will be collected if you choose to be part of this research study. Health information is protected by law as explained in the (your institution) Privacy Notice. If you have not received this notice, please request a copy from the
investigator. At *(your institution)* your information will only be used or shared as explained and authorized in this consent form or when required by law. It is possible that some of the other people/groups who receive your health information may not be required by Federal privacy laws to protect your information and may share it without your permission.

To participate in this research you must allow the study team to use your health information. If you do not want us to use your protected health information, you may not participate in this study. *(When specific therapy is only available through the research, include these sentences: The research-related therapy is investigational; therefore, it is not available unless you allow the use of your health information that is collected during this research study.)*

*(For blinded studies)* People usually have a right to access their medical records. However, while the research is in progress, you may not be allowed to see or copy certain information that is related to this research study. This is only for the period of the research. You will be allowed to see that information when the entire research project is complete.

Your permission for the use, retention, and sharing of your identifiable health information will *(Describe the date or event that will trigger the expiration of this authorization e.g., “expire upon completion of the research study” or “expire when FDA approval of the study drug is obtained” or “will continue for the period of time necessary for the preparation of a related follow-up research study” or “continue indefinitely” or “will continue until the NIA notifies the investigator that the information is no longer needed.”)*. At that time the research information not already in your medical record will be destroyed (or “will be retained until (date) in order to (reason)” or “information identifying you will be removed from such research results at (your institution)”)). Any research information in your medical record will be kept indefinitely.

If you choose to participate, you are free to withdraw your permission for the use and sharing of your health information *(if applicable, add: and your samples)* at any time. You must do this in writing. Write to Dr. *(PI)* and let *(him/her)* know that you are withdrawing from the research study. *(His/Her)* mailing address is *(address)*.

If you withdraw your permission:
- We will no longer use or share medical information about you *(if applicable, add the following: or your samples)* for this research study, except when the law allows us to do so.
- We are unable to take back anything we have already done or any information we have already shared with your permission.
- We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.
- We will keep our records of the care that we provided to you as long as the law requires.

The research team may use the following sources of health information.
(List any and all medical information collected from or about the participant in connection with this research study, e.g. blood and other tissue samples and related tests, your medical history as it relates to the research study, x-rays, MRIs, questionnaires, etc.)

Indicate the span of time from which the records are pulled, e.g., “since your diabetes was diagnosed”, “the last five years”, “only during the time span of the research study”.

Representatives of the following people/groups within (your institution) may use your health information and share it with other specific groups in connection with this research study.

- The principal investigator, (PI name)
- The (your institution) Institutional Review Board
- The (your institution) Human Subjects Protection Office
- (if using the Investigational Drug Pharmacy) The (your institution) Pharmacy
- (if applicable) The (your institution) Financial Analyst for Clinical Research
- (List every other class of persons or group affiliated with (your institution) (e.g., the research team, the study coordinators, etc.) who might need to use and/or disclose the participant’s information in connection with this study.)

The above people/groups may share your health information with the following people/groups outside (your institution) for their use in connection with this research study. These groups, while monitoring the research study, may also review and/or copy your original (your institution) records.

- The Office of Human Research Protections in the U. S. Department of Health and Human Services
- (List every other class of persons or group NOT affiliated with your institution (e.g. fellow researchers in this study at (list other institutions), outside data analysts appointed for this study, the Data Safety Monitoring Board appointed for this study, the National Institutes of Health, the Food and Drug Administration, etc., to whom the participant’s information might be disclosed)
- (if the study is international) Representatives from regulatory agencies in other countries may also review your research record, including research-related medical reports and information, along with the NIA and/or the FDA.

Section 7. Costs for Participation

7a. Costs:
- If there are costs to the participant that may result from participation in the research, include a statement describing any additional costs associated with study participation.
7b. Treatment and compensation for injury:

- Include your institution's mandatory wording for treatment for injury (see below).

**Example Cost for Participation Section:**

*(If there is no risk of physical injury to the participant, do not include this section.)* Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the event of injury resulting from this research, medical treatment is available but will be provided at the usual charge. It is the policy of this institution to provide neither financial compensation nor free medical treatment for research-related injury.

Add, as a separate paragraph, one of the following statements regarding payment for direct costs of treating research-related injuries.

*(If the institution will cover all costs of research-related injuries but did not provide consent form wording, include this statement as a separate paragraph)* If complications or injuries occur that are the result of a medication, procedure or test required for this study, the institution *(include the names)* will reimburse the standard charges for the treatment of these complications or injuries. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

*(If the (investigator institution) will cover costs of research-related injuries not covered by the participant's insurance carrier but did not provide consent form wording, include this statement as a separate paragraph)* If complications or injuries occur that are the result of a medication, procedure or test required for this study, the investigator, *(include the name of institution if appropriate)* will reimburse the standard charges for the treatment of these complications or injuries. Provided these charges have not been reimbursed by your non-governmental medical insurance or other third party. The compensation described in this section will be the only form of compensation provided to you for complications or injuries related to this study.

OR

*(If the investigator institution has not agreed to cover costs of research-related injuries, include this statement as a separate paragraph)* Costs for the treatment of research-related injuries will be charged to your insurance carrier or to you. Some insurance companies may not cover costs associated with research studies. If for any reason these costs are not covered by your insurance, they will be your responsibility. You will also be responsible for any deductible, co-insurance and/or co-pay.
Section 8. Compensation for Participation

This section is required in all research studies. It should clearly describe any monetary compensation (total amount, average total amount, amount per visit, amount per hour, etc.).

Example of Compensation for Participation Section:

You will be given $ \text{(dollar amount)} \text{ on each visit to compensate you for time and expenses for participating in this study.}

(If participants do not receive any reimbursement for participation) You will not receive any compensation for being in this research study.

Section 9. Research Funding

- Funding disclosure: Disclose what grantors, institution(s) (e.g., NIA) or companies are involved in the research through funding or grants. If none, say so.
- Conflict of Interest: Include information about any consultative or financial relationships the investigators may have with the NIA.

Example Research Funding Section:

The institution and investigators are receiving a grant from NIA (list any other grantors) to support this research.

(For funding disclosure) The institution will be reimbursed by the NIA for use of this site’s facilities and for the work the research staff does for this research.

Section 10. Voluntary Participation

Example Voluntary Participation Section:

Taking part in this research study is voluntary. If you choose to take part in this research, your major responsibilities will include (Briefly list major responsibilities. NOTE: Do not include this sentence if there are no major responsibilities for the participant). You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled.

(Optional, if appropriate) Your investigator may take you out of the research study without your permission. Some possible reasons for this are: (list possible reasons,
for example: you did not follow the study instructions, etc.). Also, the NIA may end the research study early. If your participation in the research ends early, you may be asked to visit the investigator for a final visit.

(Optional, if appropriate) (For clinical studies) If you will be participating in another clinical trial at [Institution] or elsewhere while in this research, you should discuss the procedures and/or treatments with your physician or the investigators. This precaution is intended to protect you from possible side effects from interactions of research drugs, treatments or testing.

(Optional, if appropriate) During the course of the research you will be provided with any significant new findings that may affect your willingness to continue participating in this research.

Section 11. Contact Information for Questions or Concerns

- Clarify the participant’s right to have questions answered.
- Indicate whom to contact in case of further questions about the research or to report a research-related injury.
- Indicate contact information for questions about participant rights and privacy issues.

Example Contact Information for Questions or Concerns Section:

You have the right to ask any questions you may have about this research. If you have questions, complaints or concerns or believe you may have developed an injury related to this research, contact (Principal Investigator) at (phone number). (If clinical protocol, add the next phrase) or the (study) doctor on 24-hour call at (phone number).

(All informed consent forms should include this paragraph). If you have questions regarding your rights as a research participant or you have concerns or general questions about the research (add the next phrase if using identifiable health information: or about your privacy and the use of your personal health information), contact the research subjects protection advocate in the (your institution’s) Subjects Protection Office at (phone number). You may also call this number if you cannot reach the research team or wish to talk to someone else.

For more information about participation in a research study and about the Institutional Review Board (IRB), a group of people who review the research to protect your rights, please visit the (your institution’s) IRB’s web site at (website). Included on this web site, under the heading “Participant Info”, you can access federal regulations and information about the protection of human research participants. If you do not have access to the internet, copies of these federal regulations are available by calling the (your institution) at (phone number).
Signature and Consent/Permission to be in the Research

Before making the decision regarding enrollment in this research you should have:
- Discussed this study with an investigator,
- Reviewed the information in this form, and
- Had the opportunity to ask any questions you may have.

Your signature below means that you have received this information, have asked the questions you currently have about the research and those questions have been answered. You will receive a copy of the signed and dated form to keep for future reference.

**Participant:** By signing this consent form, you indicate that you are voluntarily choosing to take part in this research.

<table>
<thead>
<tr>
<th>[Signature of participant]</th>
<th>[date]</th>
<th>[time]</th>
<th>[print name]</th>
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<tbody>
<tr>
<td>Signature of Participant</td>
<td>Date</td>
<td>Time</td>
<td>Printed Name</td>
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**Participant’s Legally Authorized Representative:** By signing below, you indicate that you give permission for the participant to take part in this research.

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<tr>
<th>[Signature of participant]</th>
<th>[date]</th>
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<th>[print name]</th>
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<tbody>
<tr>
<td>Signature of Participant’s Legally Authorized Representative</td>
<td>Date</td>
<td>Time</td>
<td>Printed Name</td>
</tr>
</tbody>
</table>

(Signature of Participant’s Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative’s Authority to Act for Participant:
[Description of the authority]

**Person Explaining the Research:** Your signature below means that you have explained the research to the participant/participant representative and have answered any questions he/she has about the research.

<table>
<thead>
<tr>
<th>[Signature of participant]</th>
<th>[date]</th>
<th>[time]</th>
<th>[print name]</th>
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</thead>
<tbody>
<tr>
<td>Signature of person who explained this research</td>
<td>Date</td>
<td>Time</td>
<td>Printed Name</td>
</tr>
</tbody>
</table>

*Only approved investigators for this research may explain the research and obtain informed consent.*

A witness or witness/translator is required when the participant cannot read the consent document, and it was read or translated.
INSTRUCTIONS: The following applies to optional parts of the research only, e.g., storage of leftover tissue for future research, optional sub-studies, etc.

In addition to the main part of the research study, there is an optional part of the research. You can participate in the main part of the research without agreeing to take part in this optional part.

(For research involving optional storage of tissue for future research) Optional Tissue Storage for Future Use

As part of this study, we are obtaining (tissue and/or blood and/or cells) from you. If you agree, the (researchers) would like to store leftover sample(s) of your (tissue and/or blood and/or cells) so that your (tissue and/or blood and/or cells) can be studied in the future after this study is over. (Add the following statement if storage is optional) These future studies may provide additional information that will be helpful in understanding [disease/condition], but it is unlikely that these studies will have a direct benefit to you. The results of these tests will not have an effect on your care. Neither the investigator nor you will receive results of these future research tests, nor will the results be put in your health record. Sometimes tissue is used for genetic research about diseases that are passed on in families. Even if your sample(s) (is/are) used for this kind of research, the results will not be put in your health records. It is possible that your (tissue and/or blood and/or cells) might be used to develop products or tests that could be patented and licensed. There are no plans to provide financial compensation to you should this occur. If you have any questions, you should contact (PI name) at (phone number).

(For linked samples) Your leftover samples will be labeled with (list all that apply: “a code number”, “your initials”, etc.). These samples will be stored (describe how the samples will be secured: “Dr. (PI’s name)’s locked laboratory”) at (sample location). If you consent to the collection of samples of your (source of sample) (e.g., blood, tissue, bone marrow) for future research, the period for the use of the samples is unknown. If you agree to allow your (tissue and/or blood and/or cells) to be kept for future research, you will be free to change your mind at any time. You should contact (PI name) at (phone number) and let (him/her) know you wish to withdraw your permission for your (tissue and/or blood and/or cells) to be used for future research. Any unused (tissue and/or blood and/or cells) will be destroyed and not used for future research studies.

(For unlinked samples) Your samples will not be labeled with any of your personal information, such as your name or a code number. Once you give your permission to have your leftover samples stored, they will be available for use in future research studies indefinitely and cannot be removed due to the inability to identify them.

(Add the following tissue options or variations if storage is optional) You should initial below to indicate your preferences regarding the optional storage of your leftover (tissue and/or blood and/or cells) for future research studies.

a. Your sample(s) may be stored and used for future research studies to learn about, prevent, treat or cure (disease/condition).
☐ Yes   ☐ No

b. Your sample[s] may be stored and used for research about other health problems.
☐ Yes   ☐ No

c. Your sample(s) may be shared with other investigator/groups without any identifying information.
☐ Yes   ☐ No

Participant: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

[Signature of participant]  [date]  [time]  [print name]
Signature of Participant  Date  Time  Printed Name

Participant’s Legally Authorized Representative: By signing below, you indicate that you have read the information written above and have indicated your choices for the optional part of the research study.

[Signature of participant]  [date]  [time]  [print name]
Signature of Participant’s Legally Authorized Representative  Date  Time  Printed Name

(Signature of Participant’s Legally Authorized Representative is required for people unable to give consent for themselves.)

Description of the Legally Authorized Representative’s Authority to Act for Participant: [Description of the authority]

Person Explaining the Research: Your signature below means that you have explained the optional part of the research to the participant/participant representative and have answered any questions he/she has about the research.

[Signature of participant]  [date]  [time]  [print name]
Signature of person who explained this research  Date  Time  Printed Name
This document was created using the following resources:

CTN Best Practices
- Informed Consent Discussion Documentation
- Informed Consent Document Template and Instructions

Fuller Theological Seminary Graduate School of Psychology
- Informed Consent Template

National Cancer Institute
- Informed Consent Template for Cancer Treatment Trials (English Language)
- Learn about Clinical Trials – Informed Consent
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Chapter 6. Following the rules and instructions as part of a team
  o Following Study Protocol and Reporting

Chapter Objective:

Demonstrate understanding of the importance of study protocol adherence and documenting efforts

Key Understandings:
By the end of this session, trainees will be able to:

- Define a study protocol and identify situations that deviate from protocol
- Understand a CHW’s role in a research study protocol
- Discuss how to report and track interactions with study participants, including phone and in person
- Describe how to work with research team as a collaborative member of the team
What is a Study Protocol?

- A study protocol is a document that describes, in detail, the plan for conducting the clinical study.
- The study protocol explains the purpose of the study as well as how to do it.
- It is the blueprint for all members of the research team to follow.

Protocol Deviation

- Accidental or unintentional changes to, or not following the research protocol that
  - does not increase risk or decrease benefit or;
  - does not have a significant effect on the subject’s rights, safety or welfare; and/or on the integrity of the data.
- Deviations may result from the action of the subject/participant, researcher, or research staff, like a CHW.

Activity: Examples of a protocol deviation, and why is a problem?

- A rescheduled study visit
- Failure to collect an additional self-report questionnaire
- Subject’s refusal to complete scheduled research activities

Discuss why these are problems and how would you handle them in your team.
**CHW Role in a research study protocol**

- Help increasing participants’
  - Recruitment
  - Participation
  - Retention
- Ensure that research **procedures are culturally appropriate** for the target population
- Provide feedback **about how feasible** are the outcome assessments used for the target population

**Tracking Study Participants**

**Tracking systems** vary from simple **paper logs** of follow-up phone calls to elaborate **computer-based** systems that track every aspect of participation, from information at baseline/starting point to a final follow-up contact.
A tracking system may be used by CHWs for multiple purposes!

- Track participant’s current participation status (e.g., refuses contact; location unknown, etc.);
- Access and update contact information on the participant and his/her proxies, relatives, friends, and health care providers;
- Schedule follow-up activities, such as annual mailings or appointment reminders;
- Track responses to follow-up contacts and completion rates;
- Automatically produce letters or forms (e.g., appointment reminders);
- Generate reports that prompt follow-up activity (e.g., a list of participants needing telephone follow-up due to nonresponse to a mailed survey);
- Generate mailing labels with the most up-to-date address;
- Track results of activities to search for participants who cannot be located; and
- Provide summaries of response rates.

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**Diagram:**

```
  Total sample size (n=100)  
     /                     /   40 recruited 
    /                     /    + 
   /                     /  60 non-responders  
  First stage          
     /                   /  20 recruited 
    /                   /   + 
   /                   /  40 non-responders  
  Second stage         
     /                  /  10 recruited 
    /                  /   + 
   /                  /  30 non-responders  
  Third stage         
  Overall            
                      70 recruited (response rate: 70%)
```
Collaboration in the Research Team

- Exchange Information
- **Ongoing Communication**
- Cross Training Activities
- **Share Resources**
- Enhance Capacity of Another Team Member

Next Chapter:

1) How to report study results and to whom?

Recruitment and Retention Tips document is provided on the following pages.
National Institute on Aging

Recruitment and Retention Tips

October 2013
RECRUITMENT AND RETENTION TIPS

Getting Started....

- **Plan**
  - Develop a recruitment plan during the protocol planning stage.
  - Avoid unnecessarily restrictive inclusion and exclusion criteria; think about the widest net, not the “perfect” participant.
  - Develop a profile of prospective study participants with consideration for:
    - What would motivate individuals to join the study?
    - Sources from which the target population is likely to obtain information (e.g., radio and television stations and programs they listen to and watch).
    - Where they live, work, shop, and play.
    - Media outlets to use for recruitment advertisements.
    - Caregivers and relatives that might serve as referral sources.
    - Community organizations (e.g., senior citizen centers, local churches, etc.) that might promote the study and encourage participation if educated about the disease/problem and the need for participation in studies.
  - Review recruitment, dropout, and screening success rates from previous studies and implement strategies that build on previous successes and incorporate lessons learned.
  - Consider assessments at locations convenient for participants.
  - Consider offering participants transportation to and from the study site.
  - Choose appropriate staff members to conduct recruitment.

- **Budget**
  - Consider costs for start-up training, advertising, staff time, and other expenses.
  - Develop a compensation strategy for participants’ time and expenses.
  - Add costs for ongoing participant contact such as holiday and birthday cards.
  - Consider items that provide study identification – key chains, sweat shirts, pill boxes, and magnets.
Once the Study Starts...

- **Participants Come First**
  - Contact interested candidates as soon as possible. The longer an individual waits before hearing back from study staff, the less likely it is that he or she will enroll in the study.
  - Stress the importance of compliance during the informed consent interview and throughout the study.
  - Establish rapport with the participants.
  - Remember that retention:
    - Begins with the participant’s first visit.
    - Is an ongoing process.
    - Is everyone’s responsibility.
  - Treat participants and their caregivers with respect.
  - Assure a welcoming atmosphere where participants are seen.
  - Be considerate of the participant’s time.
  - Identify and resolve issues in a timely manner.

- **Use the Referral Sources**
  - Network with appropriate staff not working on the study.
  - Network with other local health care providers or other relevant providers.
  - Send direct mailings to select health care providers, if necessary.
  - Give presentations about the study for study staff and provide periodic updates on the study’s progress.
  - Participate in health fairs, speaking engagements, support groups, television and radio interviews, and other forums.
  - Ask for public service announcements on radio and television.

- **Track Progress**
  - Track the number of participants enrolled against expected per site.
  - Monitor recruitment and intervene quickly to change recruitment techniques that are proving unsuccessful.
  - Identify barriers to recruitment.
  - Do not stop at one strategy; incorporate all that work for the study.
**Implement Retention Strategies**

- Consider modifying the study Manual of Procedures (MOP) to streamline assessments and procedures that are excessively burdensome and time consuming.
- Use regular teleconferences with project staff at study sites to “brainstorm” on retention strategies.
- Send reminder notes to let the participant know you will be calling shortly for their next assessment. See example below for a sample postcard/letter that can also be used as a simple reminder (note: these materials may need IRB approval).
- Be persistent. Document all attempts to contact participants, and keep trying.
- Ensure that all of these efforts preserve the privacy of the participant.
- Use the contact information for a missing participant that has not withdrawn consent. The telephone numbers for friends and/or relatives in the contact log should be accessed to locate the participant. If the participant has given consent for home visits, visit the participant’s home.
- Use public information to try to locate the participant. For example, in some states, the motor vehicle administration and other government agencies will release an individual’s contact information if it is considered to be part of the public record.
## Reminder Postcard/Letter

### Front

<table>
<thead>
<tr>
<th>Ms./Mr. X</th>
</tr>
</thead>
<tbody>
<tr>
<td>Home Address</td>
</tr>
</tbody>
</table>

**Dr. X1**

234 Main Street  
Anytown, USA

### Back

<table>
<thead>
<tr>
<th>Dear Ms./Mr. X,</th>
</tr>
</thead>
<tbody>
<tr>
<td>This is a friendly reminder that your next [study] appointment is scheduled for:</td>
</tr>
<tr>
<td><strong>MM/DD/YYYY at XX:XX am/pm</strong></td>
</tr>
</tbody>
</table>
| Our offices are located at  
1234 Main Street  
Anytown, USA |
| Please call us at **123-123-1234** if you need to reschedule or if you have any questions about your appointment. |
| Remember to bring your study [medication/diary/etc.] with you. |
| Dr. X thanks you for your participation! |
Chapter 7. How to report the results of a study and to whom?

- Dissemination of Study Results

Chapter Objective:

Identify conventional and innovative methods of study results dissemination

Key Understandings:
By the end of this session, trainees will be able to:

- Discuss how to disseminate findings to study participants
- Describe the dissemination of study results through health research journals
- Describe how CHW’s can contribute to research manuscripts
- Identify dissemination methods to the population at large

Please identify and re-phrase in your own words: What are conventional and innovative ways to share study results?
**Engaged/Involved CHWs**

Describe how patient and stakeholder partners can be involved in plans to disseminate study findings to ensure that **findings are communicated in understandable, usable ways.**

- **Identifying partner organizations for dissemination**
  - To ensure meaningful and direct connections with end-users

- **Planning dissemination efforts**
  - Shaping study design and protocol from the very beginning to be focused on the final product

- **Participating in dissemination efforts (i.e. authoring manuscripts and presenting study findings)**
  - To offer the patient and stakeholder perspective and to reach new and different audiences/groups

- **Identifying opportunities to present or share information about the study, even as it is in progress**
  - To move away from traditional models of dissemination and think creatively about how to get information into the hands of those who need it

**Telling the Story**

Discuss how to disseminate findings **to study participants**

Describe the dissemination of the results of the study through **health research journals**

**What are academic research journals you have heard of, read from, know of?**

__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________

84
**Telling the Story of Study Results**

Describe **how CHWs can contribute to research manuscripts:**

- Would you need from investigators *(specific training, supervision, mentoring, time, incentives)*?

__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________

**What do CHWs contribute to research manuscripts?**

- Community-based Participatory Research (CBPR)
  - **CHWs hold unique position** as a bridge between researchers and the communities they study
  - CHWs can bring the end users' perspectives to academic investigators
  - Successful programs often integrate **feedback from communities affected** to solve challenges that arise during implementation of programs

**Identify dissemination methods to the population at large**

- On the blank lines below, write some examples of **sharing study results** with the **affected groups and with the public**. After you have finished writing your examples, share them with your partner.

__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
__________________________________________________________________
Instructions: Fill in each box with three Pros and three Cons for each setting.

**Town Hall Meeting**

**Pros**

**Cons**

**Community Advisory Board**

**Pros**

**Cons**

**Community Education Session**

**Pros**

**Cons**
Sample Agenda For Stakeholder Meeting

**Meeting Organizer**
(10 minutes)
- Welcome
- Agenda and goals of the meeting

**Community Organizer**
(10 minutes)
- Need for action
- Call to action
- Introduce facilitator

**Facilitator**
(30 minutes)
- Introduction of all present
- Mixer to acquaint people
- Goal for stakeholders
- Brief history of process
- Role of protective factors

Break (10 minutes)

**Facilitator**
(1 hour)
- Small groups – Assessment of local programs and services
- Small groups – Determination of new services and needed or if current services should be expanded
- All – share lists and consensus
- Develop a community action plan
- Next steps: assigned tasks and timelines
- Plans for next meeting
Sample Checklist for Arranging and Scheduling a Stakeholder Meeting

<table>
<thead>
<tr>
<th>2 Months prior to Date: ____________</th>
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</thead>
<tbody>
<tr>
<td>Find the names, addresses, phone numbers and email addresses of the people you want to invite.</td>
</tr>
<tr>
<td>Select a meeting date.</td>
</tr>
<tr>
<td><strong>-Tips:</strong> Consider your audience and their work and family habits. Evenings after 7:00pm during the school year or Sunday afternoons might be best for members.</td>
</tr>
<tr>
<td>Find a place to hold meeting.</td>
</tr>
<tr>
<td>Locate a community space that is comfortable and non-threatening to everyone.</td>
</tr>
<tr>
<td><strong>-Tips:</strong> Try a local community center, a church where other community-wide events take place or a local restaurant.</td>
</tr>
<tr>
<td>Make a drawing of the room set-up for the person who will set-up.</td>
</tr>
<tr>
<td>Be prepared to explain the exact amount of space you will need and how you want the room set up for the meeting. Do you want chairs or chairs and tables?</td>
</tr>
<tr>
<td>Arrange a meeting and meet with the people who will speak at the meeting. Set the agenda, confirm the responsibilities and find out what materials or equipment they need.</td>
</tr>
<tr>
<td>Order any prevention materials or community documents 4-6 weeks in advance to guarantee delivery. Decide whether materials are to be in English or Spanish or both. Arrange for any needed translation.</td>
</tr>
<tr>
<td>Recruit volunteers to assist you in the meeting.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>4 to 5 Weeks prior to Date: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Four to five weeks before the meeting, send a mailing to the people on your list. Include a letter of invitation, the agenda, a map to the meeting site and any materials you want to read. Ask people to come to the meeting or delegate someone to take their place. Ask for replies. Be sure to maintain an updated list with addresses and phone numbers.</td>
</tr>
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<tr>
<th>1 Week prior to Date: ____________</th>
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<tbody>
<tr>
<td>One week before the meeting call everyone to remind them and answer any questions they may have.</td>
</tr>
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</table>

<table>
<thead>
<tr>
<th>3 to 5 Days prior to Date: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Three days before the meeting, check your arrangements.</td>
</tr>
<tr>
<td>Day of Meeting</td>
</tr>
<tr>
<td>----------------</td>
</tr>
<tr>
<td>Arrange for someone to check on the arrangements earlier in the day or do the set up for you.</td>
</tr>
<tr>
<td>Secure any needed equipment and supplies. This may include a screen, an overhead projector or computer, a microphone, easels with newsprint and markers.</td>
</tr>
<tr>
<td><strong>Tips:</strong> You may or may not want a microphone. A microphone can be intimidating, but it is important that every word is heard.</td>
</tr>
<tr>
<td>Arrive at the meeting an hour early to check everything and greet people.</td>
</tr>
<tr>
<td>If you are going to serve refreshments include the coffeemaker, punch bowl and cookie trays.</td>
</tr>
<tr>
<td>Select a person to present the call to action. This should be a person who can motivate others. This person will give the call to action and thank everyone at the end.</td>
</tr>
<tr>
<td>Select a facilitator to explain the process and work with the small groups. This person will also summarize the meeting.</td>
</tr>
<tr>
<td>Station volunteers: someone to greet people at the door, someone at the table for sign-in and name tags and someone to help people mix and get acquainted.</td>
</tr>
<tr>
<td><strong>Tips:</strong> Each person who enters the room should feel they are important and a part of the group.</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Post Meeting</th>
<th>Date: ____________</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 5 days of the meeting send everyone a thank you, a summary of the meeting including the next steps and the date of the next meeting.</td>
<td></td>
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Community Partners in Care (CPIC): Video Summary of Rationale, Study Approach, Implementation, and Client 6-month Outcomes (CES4Health.info: Product ID #87LWR5H2”. 2014 (2:46 mins)

The video was produced with Healthy African American Families II, a health advocacy organization in South Los Angeles; Behavioral Health Services, Inc., the largest substance/alcohol abuse service provider in LA County; UCLA, and RAND Health, who contracted with filmmakers (Eileen Cabiling and Joe Mango) to support video production. The individuals in the video are key community and academic partners who have worked on CPIC. The celebratory tone of the video is consistent with a Community Partnered Participatory Research (CPPR) approach, a local variant of participatory action research, where study findings are celebrated, and dissemination efforts include approaches that are intended for general audiences, especially from low-income, low-literacy, minority communities, in addition to traditional academic products like peer-reviewed scientific manuscripts.

Community Partners in Care (CPIC): Video Summary

This CPIC video is a dissemination tool to offer a community perspective on the study results to partners in South Los Angeles and Hollywood-Metro, where the study was conducted; the general public, other scientists, policy makers, elected officials online, at community conferences / presentations and scientific presentations. Source: Original PCORI research 3-yr award in 2012 on addressing disparities entitled: Long-Term Outcomes of Community Engagement to Address Depression Outcomes Disparities. PI: Kenneth Wells, MD, MPH
Example of Patient Engagement: Cariño

- From One CHW to Another: A Community Health Worker’s Guide (CES4Health.info: Product ID#K6GJYM8G; 2014)
- Created based on the input of the patients and experiences of the Cariño team members for use by CHWs, health care providers, community members and others interested in implementing a CHW program.
- The Cariño program is part of the Miami Heart Healthy Initiative (MHHI), a study examining how CHWs can provide Hispanics/Latinos with type II diabetes with the necessary skills to make healthy lifestyle changes.
- Many of the CHW approaches are applicable to other populations. This guide provides information about the tools used to deliver the program and the CHWs’ experiences when working with patients.
- After jointly identifying the needs and challenges, CHWs created strategies that address the needs of the patients and those are presented as tips throughout the guide. For example, patients specifically requested a health insurance information session be presented during their support group. As a response to this request, CHWs sought out a health insurance representative to present during the group session.
- The guide provides a tracking mechanism, created by CHWs to assist CHWs’ efforts and patient progress.

Open discussion, including use of technology and social media in telling the story (dissemination) of study results.
Patient-Centered Outcomes Research (PCOR) Training For

COMMUNITY HEALTH WORKERs (CHWs)

Developed through a Statewide Partnership for Training Community Health Workers in PCOR EUGENE WASHINGTON PCORI ENGAGEMENT (EAIN) AWARD PROGRAM #2219:Univ. of Miami from the Patient Center Outcomes Research Institute (PCORI) 2015-2017.