

Lupus Clinical Trials  
Training Program

LuCTT



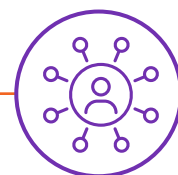
# SUMMIT PLAYBOOK



AMERICAN COLLEGE  
of RHEUMATOLOGY  
*Empowering Rheumatology Professionals*



[lupusinitiative.org/LUCTT](http://lupusinitiative.org/LUCTT)



# LuCTT

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The American College of Rheumatology developed The *Lupus Clinical Trials Training Program Summit Playbook* with support from KDH Research & Communication and subject matter experts.

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# BACKGROUND

Lupus is a chronic disease that disproportionately affects minorities, including African American and Latino women. In the United States, the reported prevalence of lupus is 1 out of 15 citizens. Lupus, an autoimmune disorder, causes inflammation that affects the skin, joints, and multiple organ systems in the body. Lupus has no cure, but early diagnosis and prompt treatment reduces lupus morbidity and mortality, allowing patients to reduce the physical, mental, and social effects of lupus; decrease possible medical complications, and decrease their risk of death.

Clinical trials systematically explore new and better treatments for lupus, but those patients most affected by lupus are the least likely to participate in such trials. In fact, African Americans represent approximately 12 percent of the population, but only 5 percent of clinical trial participants. Similarly, Latinos make up 16 percent of the US population but only 1 percent of clinical trial research participants. LuCTT exists to change these statistics.

# INTRODUCTION

Thank you for your participation in the Community Health Worker **L**upus **C**linical **T**rials **T**raining (LuCTT) program. **LuCTT** is a program that is designed to support recruitment and enrollment of minority populations affected by lupus into clinical trials. LuCTT will consist of multiple interconnected toolkits for state, local, and community organizations to host regional Community Health Worker (CHW) training summits to prepare CHWs to support and increase lupus clinical trial recruitment and participation by increasing lupus clinical trial awareness and providing clinical trial and health system navigation. Ultimately, the LuCTT toolkits will work together in the real world to increase minority participation in lupus clinical trials.

The LuCTT program is made up of four inter-connected parts. These parts are:

## The Summit Playbook.

The summit playbook will be used by lead organizations to implement LuCTT. It includes information on how to build partnerships, identify training facilitators, and host a LuCTT summit.

## Patient Education Materials.

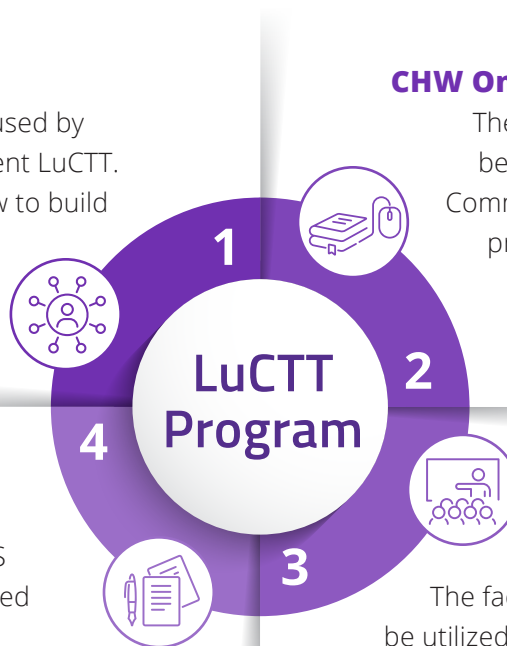
The MATERIALES EDUCATIVOS PARA PACIENTES are distributed to CHWs who attend a LuCTT summit so that they may use them with their clients. They contain information on lupus and lupus clinical trials.

## CHW Online Learning Modules.

The online learning modules will be completed independently by Community Health Workers (CHW) prior to attending an in-person summit. CHWs will learn key content about lupus and clinical trials.

## The Facilitator's Guide and In-Person Training Summit.

The facilitator's guide is designed to be utilized by a selected CHW facilitator to conduct an in-person training summit. It includes step-by-step instructions for a facilitator to lead in-person training with CHWs at the summit.





# LuCTT Program Steps



This playbook was developed to provide steps for your organization to implement the LuCTT program. You may not need to incorporate each of the steps listed in this playbook. Use this playbook as a guide based on the needs and existing capabilities of your organization.

## WHY LuCTT?

As a community-based organization (CBO), you and your CHWs are in an ideal position to help spread awareness about lupus clinical trials. You and your CHWs are trusted members of your community, interacting with clients daily. Clinical trials are a potentially life-changing health service of which many people in your community may not be aware. You can educate and empower your clients to make informed decisions about participation in a clinical trial and if clinical trials are right for them. Clinical trials have the potential to benefit individuals working to improve their health and life with chronic illnesses. Clinical trials can also create knowledge, medicine, and tools to benefit future generations of people with lupus. Clinical trials will not be for everyone, but it is everybody's right to know the possible benefits of clinical trials and to freely decide whether to participate.

The information that your CHWs will learn will benefit them in all of their outreach and support activities. The knowledge gained from this program is generalizable to all clinical trials, not just lupus clinical trials, and as such CHWs will develop an integral skillset that will help them with work in other areas. CHWs were chosen for this project because they are often members of the communities that they serve, which allows them to develop trusting one-on-one relationships with clients. CHWs can provide health systems navigation, interpretation and translation services, culturally appropriate health information and education, advocacy for patient and community health needs, and counseling and guidance on health behaviors.



## STEP ①

IDENTIFY  
AND CONTACT  
PARTNER  
ORGANIZATIONS

## STEP ②

IDENTIFY  
AND RETAIN  
A TRAINING  
FACILITATOR

## STEP ③

REACH OUT  
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## STEP ④

PREPARE  
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## STEP ⑤

DAY-OF-SUMMIT  
LOGISTICS

## STEP ⑥

INCORPORATE  
LUPUS  
OUTREACH INTO  
EXISTING CHW  
WORKLOAD

# BEFORE THE SUMMIT

## STEP ①

## IDENTIFY AND CONTACT PARTNER ORGANIZATIONS



### WHY

Partner organizations with missions related to community health, lupus, and/or clinical trials outreach can increase your training impact; reduce administrative, financial, and planning burden on your organization; and increase the areas in which CHWs conduct lupus clinical trials and support. Specifically, partner organizations may: (1) provide additional support with planning the summit, (2) contribute additional resources and funding, and (3) increase training reach to a larger and more geographically diverse pool of community health workers.



### WHEN

» **Three months out: Identify and contact potential partner organizations**

Contact potential partner organizations such as local hospitals, lupus support groups, and other community-based organizations who utilize CHWs.

» **Two months out: Cultivate partnerships**

Reach out to the interested partner organizations with a phone call, email, and/or an in-person meeting to confirm interest and outline responsibilities.

Keep partner organizations updated with summit planning progress and seek updates related to completion of their responsibilities.



## HOW

Contact potential partner organizations via phone call or email. You can use the email template below to for initial outreach to potential partner organizations.

Use existing contacts and partners to facilitate partnerships by them to forward the email template with a personal message.



## PRECAUTIONS

To ensure a smooth partnership, use a letter of agreement outlining the goals of the partnership and the role of the partner organizations. The letter of agreement should cover: the date, the time, length of service/responsibility, expectations, and compensation, as appropriate.



## SUPPORTING DOCUMENTS

### EMAIL TEMPLATE – PARTNER ORGANIZATION



To

Subject

Dear [insert their name],

My name is [insert your name] and I work for [insert your organization]. [Include a brief description of what your organization does, projects they work on, people they serve etc.]

We are looking for partners to help us host in-person training summit in [x months] focused on helping to increase minority participation in lupus clinical trials. We will do this by training community health workers (CHWs) on what lupus is, and why minority involvement in clinical trials is beneficial. The CHWs will then provide education and support to promote enrollment and recruitment in lupus clinical trials in their communities. Increasing minority participation in lupus clinical trials is critical as it benefits both the individuals participating in the trial, and the larger lupus community. I believe that with your organization's work in [x field i.e. lupus-related work, CHW work etc.] you would prove very beneficial to our project.

As partners, we would work together to plan the in-person training summit, combine resources and funding, and recruit CHWs to attend the summit. While clinical trials are a potentially life-changing health service, many people may have limited awareness about clinical trials. By working together, we can ensure that more minority lupus patients understand the options available to them.

If you have any questions about what we're doing or how you can be involved, please feel free to contact me at [insert phone number and email address]. I look forward to hearing from you soon.

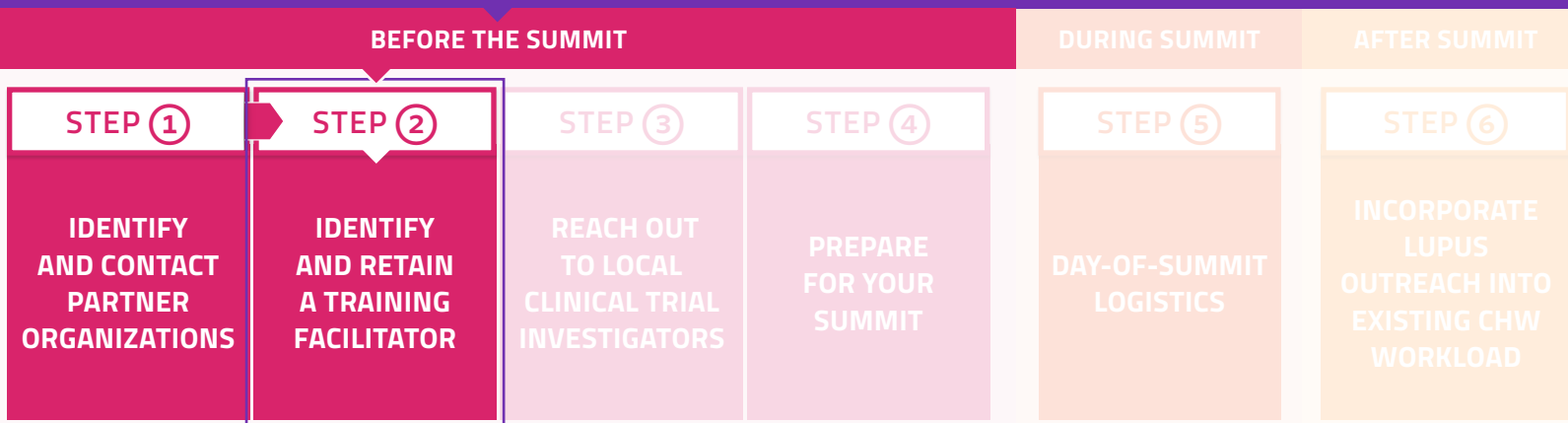
Thank you for your time,

[signature]

Send







STEP ②

# IDENTIFY AND RETAIN A TRAINING FACILITATOR



## WHY

The facilitator will drive the success of the in-person training summit. You should identify a training facilitator with (1) the right level of training as a CHW and a trainer; (2) experience as a CHW so that they understand what the CHWs are trying to accomplish and the best ways to go about conducting outreach; and (3) a positive attitude and enthusiasm about the program to engage the CHWs who attend the summit.



## WHEN

You should identify your training facilitator and give them the facilitator’s guide one to two months before holding the summit. This will give him or her ample time to learn the details of the summit and prepare ahead of time.



## HOW

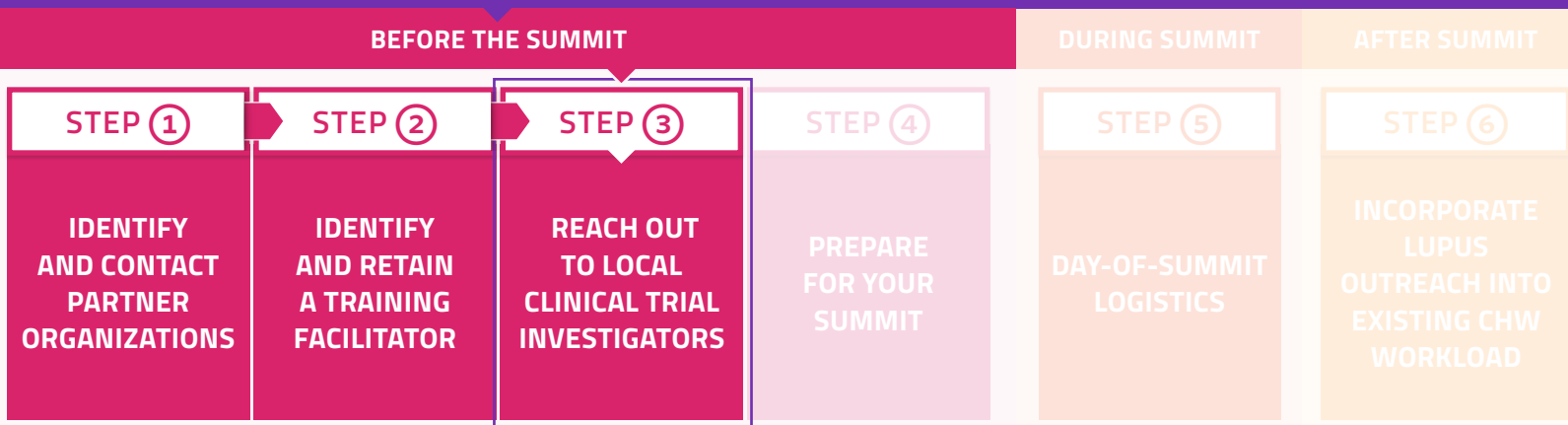
Post an announcement for the role and/or email contacts to identify potential candidates who are/were a CHW with previous experience conducting community outreach and facilitating CHW training. Screen candidates for someone who has the necessary training and skills in active listening, confidentiality, ethics, and record keeping.

If you believe you will have attendees who are more comfortable speaking Spanish, be sure to take that into consideration when selecting somebody to be the training facilitator.



## PRECAUTIONS

To ensure a smooth partnership, use a letter of agreement outlining the responsibilities and roles of the facilitator. The letter of agreement should cover: the date, the time, length of service/ responsibility, expectations, and compensation, as appropriate.



### STEP ③

## REACH OUT TO LOCAL CLINICAL TRIAL INVESTIGATORS



### WHY

While reaching out to local clinical trial investigators may seem intimidating at first, it is important to the success of LuCTT. Connecting with local clinical trial investigators/staff can: (1) yield specific information on the focus of their trials, the limits on who can enroll, and any needs they have for recruitment or supporting participants; (2) create opportunities for CHWs to learn about clinical trials in your area from clinical trial staff (e.g. during the in-person summit); (3) allow you to emphasize the value of CHWs community connections and outreach and support for lupus clinical trials to get clinical trial buy-in; and (4) develop linkages so CHWs and clinical trial staff can identify and address barriers to lupus clinical trial recruitment and enrollment.



### WHEN

You should to reach out to the clinical trial site investigators and/or staff as soon as you begin planning your summit. The investigator (the doctor who runs the trial) may have a busy schedule, so you may want to connect with a clinical trial coordinator or other clinical trial staff who oversees recruitment and enrollment.



### HOW

To find a clinical trial investigator or other clinical trial staff, first research lupus clinical trials in your geographic area. There are two useful websites with search functions where you can customize your search by geographic area. The first is [www.thelupusinitiative.org](http://www.thelupusinitiative.org) and the second is [www.clinicaltrials.gov](http://www.clinicaltrials.gov).

The [lupusinitiative.org](http://lupusinitiative.org) website is supported by the American College of Rheumatology and includes a link to information specifically for lupus clinical trials on the homepage. After you put in information such as your age, the zip code where you are looking for trials, and how far you are willing to travel, it will provide a list of nearby lupus clinical trials.

The clinicaltrials.gov website allows you to search by studies that are currently recruiting, by the condition or disease, by eligibility criteria, and by other factors. You can also search for trials within a specific distance of a zip code. Once you identify nearby lupus clinical trials, click on the specific trial to access information about the investigator and contact information for the trial.

Use the email template below to reach out to clinical trial investigators or other clinical trial staff. Be persistent. You may need to contact clinical trial staff multiple times via email or phone before you receive a response. If possible, you may also want to consider an in-person visit.



## SUPPORTING DOCUMENTS

### EMAIL TEMPLATE – CLINICAL TRIAL INVESTIGATOR/COORDINATOR

To

Subject

Dear [their name],

My name is [your name], and I work for [organization name]. [Include a brief description of what your organization does, projects they work on, people they serve etc.]

We are hosting an in-person training summit for community health workers (CHWs) to increase minority involvement in lupus clinical trials. We will do this by training community health workers (CHWs) on what lupus is, and why minority involvement in clinical trials is beneficial. The CHWs will then provide education and support to promote enrollment and recruitment in lupus clinical trials in their communities. Increasing minority participation in lupus clinical trials is critical as it benefits both the individuals participating in the trial, and the larger lupus community.

I work in a community that serves primarily minority clients. As a clinical trial [investigator or coordinator] I believe that it would be beneficial for us to remain in contact so that I can advise clients in my community who would benefit from your clinical trial. Would you be interested in connecting so that I can tell my clients about your trial and you can serve as a contact if they have any questions?

If you have any questions about what we are doing or how you would be helping, please feel free to contact me at [insert phone number and email address]. I look forward to hearing from you soon.

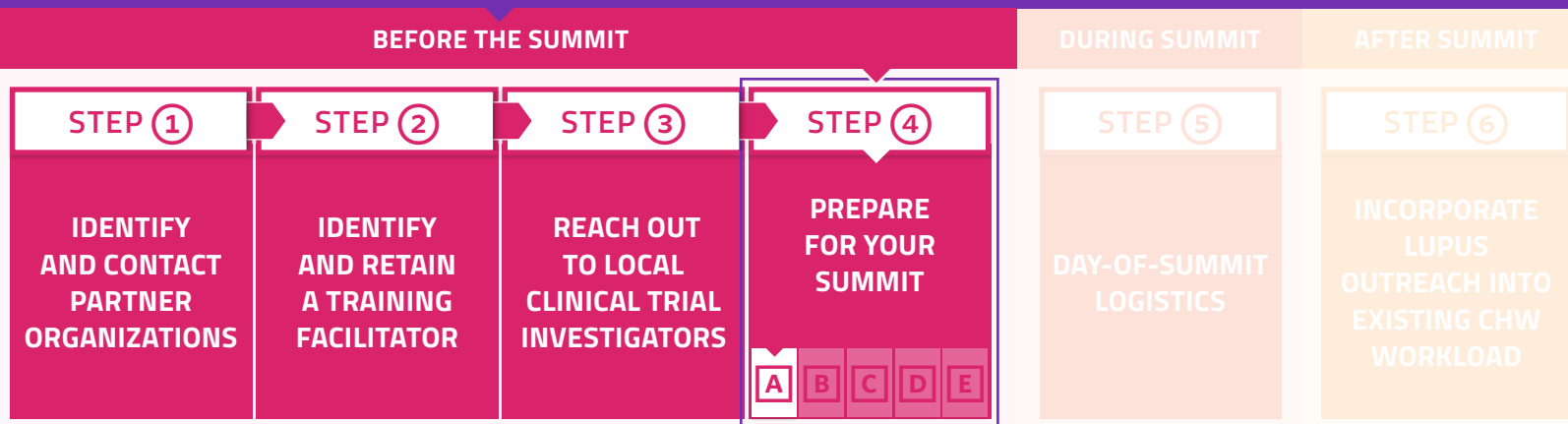
Thank you for your time,

[signature]

Send







## STEP ④

# PREPARE FOR YOUR SUMMIT

## STEP ④

### A

# SET YOUR BUDGET



## WHEN

- » Three months out: Identify funding sources, if necessary
- » Two months out: Develop budgets

We provide a budget template below. At this point in the planning process, you should be able to estimate how much you will need to spend on the space for the in-person summit, which will likely be your largest expense.



## HOW

Use the following cost categories to estimate your budget.

### Labor Costs

Labor costs include the hours spent preparing for, participating in, and following up after the LuCTT summit.

### Material Costs

Material costs include the rental space, supplies, and photocopies that you will need to implement the LuCTT summit.

Then, determine a realistic budget. What will your organization and partner organizations contribute? What are other funding sources, if necessary. Many CHW programs receive funding from a variety of sources. The options below are a few examples to help you fund the summit.

- » There are many grants available to community-based organizations (CBOs) through local, regional, state, and federal funding organizations. If your CBO already has grant funding, consider asking your project officer or contact at the funding agency for funding sources to help you meet this need. If you need help to identify funding sources, state nonprofit coalitions can give suggestions, and sometimes libraries maintain a database of available funding opportunities. It is advisable to work with an experienced grant writer to write grants. If your organization does not have someone with those skills on staff, you may need to find a volunteer with experience in this area or pay a grant writer to help you.
- » Many community foundations work with private donors who are looking for a program that meets their personal or family investment goals. Consider meeting with local foundations and give them a one-page summary about the needs and goals of LuCTT to see if they know a funding source that might be interested. Consider meeting with a local business contact and ask if the goals of LuCTT are ones that the business feels fits within its mission.
- » If your board, stakeholders, or volunteers want to support the summit, you can make a special appeal to them and ask for donations. Start a social media campaign, with a financial appeal, to garner interest and support for the program.



## SUPPORTING DOCUMENTS

We provide a sample budget table below. You may not need to purchase or use every item listed in the table, it is simply a draft that you can reference and adapt for your organization.

The table below is based on 100 CHWs attending the summit. Actual numbers may vary depending on how many CHWs will be at your summit.

Item	Number Needed	N	Other rentals (AV equipment etc).		
Venue	1		Some venues may rent hourly or by the day	\$1600	
Supplies - nametags	100		Usually 8 nametags per sheet, so 13 sheets	\$6.29	
Supplies - Pens	100		2 boxes of 60	\$12.98	
Printing – facilitator’s guide	2		Each guide is 23 pages	\$25	
Printing – MATERIALES EDUCATIVOS PARA PACIENTES	100		Each guide is 5 pages	\$75	
Printing – skills check sheet	1000			\$45	
Printing – self-assessment sheet	200			\$9	

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## STEP ⑤

DAY-OF-SUMMIT  
LOGISTICS

## STEP ⑥

INCORPORATE  
LUPUS  
OUTREACH INTO  
EXISTING CHW  
WORKLOAD

## STEP ④

B

## SELECT A LOCATION



### WHEN

#### » Three months out: Determine locations

Now that you have identified partners and set a budget, you can estimate a likely number of CHWs to attend the summit. At the very least, set a maximum number of CHWs to begin identifying different locations that can accommodate different group sizes. If you do not have a space readily available at your organization, consider meeting spaces at schools, churches, and libraries. These types of places often have halls or rooms that are available for rent. Hotel conference rooms are also a good choice and typically already have all the audio/visual equipment you would need.

#### » Two months out: Reserve a space

Once you have decided on a location, based on your budget and expected attendance, reserve the space. If you require other audio/visual equipment, for example, reserve those as well.



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## PLANNING SUMMIT LOGISTICS



### WHEN

» **Two months out: Select dates for the summit**

Based on the availability of the location to hold the summit and your partners, select a date or dates for the summit. When selecting a date, make sure that the summit doesn't conflict with any other large events that CHWs might be attending.

» **Two months out: Set maximum number of participants**

Based on size of the space that you have selected for the summit, set a maximum number of participants. If you have a very large number of anticipated participants, you might also want to consider having more than one facilitator at the summit.

» **One month out: Create a summit agenda**

As you create your agenda, consider the length of time for the summit. We recommend a 6- to 8-hour day to allow time for all five modules and the videos and role play scenarios that go along with them. Other things to keep in mind include when you want to start the summit, time for breaks, including short breaks for water or snacks and a lunch break, and remember to leave time for check-in at the beginning of the day.

» **One month out: Confirm staff and volunteers**

You will need several volunteers the day of the summit to ensure that everything runs smoothly. Volunteers can assist with things such as set-up, check-in, and logistics. The number of volunteers that you will need will vary based on how large your summit is and how many CHWs are attending. If you anticipate a large number of CHWs attending the summit, you may even want to consider having a second facilitator.

» **Three weeks out: Confirm location, finalize agenda, and touch-base with facilitator and volunteers**

One to three weeks before the summit, contact the location where you are holding the summit to confirm the date and times. Review and finalize your agenda. Reach out to the facilitator and volunteers to ensure that they are still available.

» **Three weeks out: Finalize logistics planning**

Make your final phone calls to your vendors to ensure that all your rentals are in place. Double-check plans for providing snacks, beverages, lunch, etc.

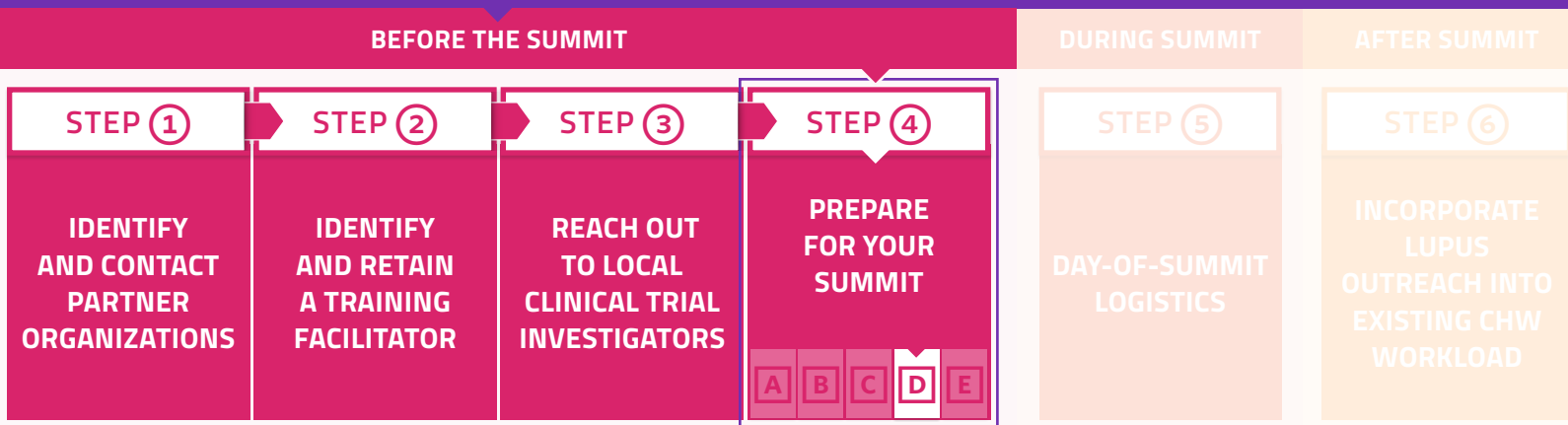
» **Two weeks out: Finalize registration/attendees**

If you can, send out a final reminder email to all potential participants to register for the summit. You need a final head count two weeks out.

» **Two weeks out: Confirm all logistics**

Make one last phone call to any vendors to finalize your logistics.





## STEP ④



# PROMOTE AND ADVERTISE THE SUMMIT



## WHEN

### » One to two months out: Announce summit dates

You will want to announce the date of the summit approximately two months before the summit, with periodic reminders as you get closer to the date. Two potential methods you can use to announce the date of the summit include using your social media accounts and through email blasts to any CHW lists, partner lists, or lists serves that you might have. Two months out: Prepare and distribute promotional materials.

Promotional materials are any materials that you might want to use to encourage interest in the summit. These can include flyers, either digital or physical, social media posts, posters, or other traditional marketing tactics. If you have a blog or other Internet presence that can reach a wide audience, this would be a good place to market the summit. You should also make announcements at other local events that you might be hosting prior to the summit. We provide a template flyer below that you can use to create your own promotional materials. Your promotional materials are very important. They will help to advertise and spread word about your summit.

### » One month out: Distribute registration form or applications and start compiling list of CHW attendees

You can choose to allow CHWs to register for the summit on a first-come, first-served basis or you may choose to use an application process. With either method, remind interested CHWs that they will have to complete the online learning modules before the summit. When CHWs sign-in at the summit, they will present a certificate of course completion as proof that they completed the online learning modules. One efficient and cost-effective way to collect registrations is through online services such as EventBrite.

### » One month out: Prepare and distribute media releases and outreach materials

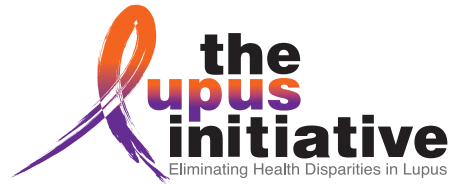
Continue sending out social media posts about the summit to encourage interest.





## SUPPORTING DOCUMENTS

AMERICAN COLLEGE  
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*Empowering Rheumatology Professionals*



YOUR ORGANIZATION  
LOGO HERE

Lupus Clinical Trials  
Training Program

LuCTT

**AT: LOCATION OF SUMMIT  
TIME**

**DATE OF SUMMIT**  
**Contact us at:**  
**(Your phone number)**

[Organization name] and the American College of Rheumatology are hosting a training summit to educate Community Health Workers (CHWs) on the benefits of participating in lupus clinical trials. Participants will take an online course to teach them about lupus and clinical trials, then attend this in-person training summit where they will learn the skills needed to conduct outreach on lupus clinical trials.

If you are interested in participating, please contact [name] at [email] or [phone number] OR visit this link: [link to LuCTT webpage]

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INCORPORATE  
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EXISTING CHW  
WORKLOAD

## STEP ④

E

## PREPARE SUMMIT MATERIALS



### WHEN

» **One month out: Order materials for participants**

These materials will include name tags, pens, or markers. You should also create a sign-in sheet to collect the CHWs names, email addresses, and organization to send follow-up information after the summit.

» **One week out: Finalize and print name tags (if using pre-made)**

Print your nametags using the finalized list of attendees. Good options for at-home name tag printing include using Avery name tags, which can be used with your personal or office printer.

» **One week out: Prepare summit materials**

As outlined below, prepare your summit materials including the facilitator's guide, the MATERIALES EDUCATIVOS PARA PACIENTES, and the skills check-sheets, and self-assessment sheets. Shop around at various stores that offer printing services for the cheapest option – such as the US Post Service, the UPS Store, FedEx Office Print and Ship Centers, and chain stores such as Staples and Office Depot.



### HOW

» You will need to print the facilitator's guide. If you have more than one facilitator, be sure to print enough copies for each facilitator.

» Each CHW attending the summit will need a full copy of the MATERIALES EDUCATIVOS PARA PACIENTES to use during outreach.

» Provide nametags (either ones you print or the blank sheets and multiple pens/

markers for participants to write their own).

» Print out copies of the skills check sheets and the self-assessment that CHWs will complete after each role play scenario. For each CHW attending, you will need 10 copies of the skills check sheet and 2 copies of the self-assessment sheets.

– We recommend creating participant packets which participants can pick up when they sign-in. The packet can

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LUPUS  
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EXISTING CHW  
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# DURING SUMMIT

## STEP ⑤

## DAY-OF-SUMMIT LOGISTICS



### WHEN

- » The day of the summit



### WHAT

These are all things that you need to keep in mind as you are conducting the summit.

- » Have a sign-in table at the entrance where your CHWs will sign-in and present their course completion certificates. We also recommend that you have CHWs pick up their participant packets here.
- » This will also be where the CHWs will pick up the name tags.
- » Schedule a 10 to 15-minute break at the end of each completed session. If you budgeted for it, provide refreshments for the participants.
- » At the end of each session, you need to collect the completed self-assessment and peer-review forms. Store all the forms in the same place so that you don't misplace any. A good place for them would be in an envelope or folder.

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LOGISTICS

## STEP ⑥

INCORPORATE  
LUPUS  
OUTREACH INTO  
EXISTING CHW  
WORKLOAD

## AFTER SUMMIT

## STEP ⑥

### INCORPORATE LUPUS OUTREACH INTO EXISTING CHW WORKLOAD



#### WHAT

One of the most important parts of the LuCTT program is the post-summit outreach that LuCTT-trained CHWs conduct to educate their clients about lupus clinical trials. CHWs should advertise their services as they normally would, whether that means it is in local stores, community centers, schools, or libraries.

Each organization that uses CHWs will have its own needs and approaches that are tailored to their communities and environments. Some different examples of ways to conduct outreach are listed below.

- » Education sessions for lupus patients during existing support meetings
- » Convening specific sessions for lupus patients
- » Participation in community health fairs



# PLAYBOOK DOCUMENTS/ MATERIALS/RESOURCES

The following documents accompany the summit playbook to help the organizations facilitate LuCTT implementation.

» **Email template for contacting partner organizations**

This is a template to email potential partner organizations for the summit.

» **Email template for communicating with clinical trial investigators**

This is a template to email the Primary Investigator (PI) or trial coordinator at lupus clinical trial sites in your area.

» **Budget outline**

This is a guide to help you set your budget.

» **Promotional Flyer**

This is a template to help you promote the program.

» **Facilitator's guide**

The facilitator's guide is for use by the summit facilitator(s). Visit [URL] to download the facilitator's guide.

» **MATERIALES EDUCATIVOS PARA PACIENTES**

These are the materials with information about lupus and clinical trials that CHWs will use during outreach. Visit [URL] to download the MATERIALES EDUCATIVOS PARA PACIENTES.

» **Summit nametags**

You can choose to make your own nametags or bring blank nametag sheets and pens for attendees to make their own. Use Avery Template 5390 for insert badges or Avery Template 5395 for adhesive badges.

» **CHW peer rating form**

You will need 10 copies of the skills check sheet for each CHW attending.

» **Self-Assessment**

CHWs will complete the self-assessment twice during the summit, once at the beginning of the day and once at the end. You will need 2 copies of the self-assessment for each CHW attending.



# EMAIL TEMPLATE FOR CONTACTING PARTNER ORGANIZATIONS

Lupus Clinical Trials  
Training Program

LuCTT

[lupusinitiative.org/LUCTT](http://lupusinitiative.org/LUCTT)

## EMAIL TEMPLATE – PARTNER ORGANIZATION



To

Subject

Dear [insert their name],

My name is [insert your name] and I work for [insert your organization]. [Include a brief description of what your organization does, projects they work on, people they serve etc.]

We are looking for partners to help us host in-person training summit in [x months] focused on helping to increase minority participation in lupus clinical trials. We will do this by training community health workers (CHWs) on what lupus is, and why minority involvement in clinical trials is beneficial. The CHWs will then provide education and support to promote enrollment and recruitment in lupus clinical trials in their communities. Increasing minority participation in lupus clinical trials is critical as it benefits both the individuals participating in the trial, and the larger lupus community. I believe that with your organization's work in [x field i.e. lupus-related work, CHW work etc.] you would prove very beneficial to our project.

As partners, we would work together to plan the in-person training summit, combine resources and funding, and recruit CHWs to attend the summit. While clinical trials are a potentially life-changing health service, many people may have limited awareness about clinical trials. By working together, we can ensure that more minority lupus patients understand the options available to them.

If you have any questions about what we're doing or how you can be involved, please feel free to contact me at [insert phone number and email address]. I look forward to hearing from you soon.

Thank you for your time,

[signature]

Send



# EMAIL TEMPLATE FOR COMMUNICATING WITH CLINICAL TRIAL INVESTIGATORS

Lupus Clinical Trials  
Training Program

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[lupusinitiative.org/LUCTT](http://lupusinitiative.org/LUCTT)

## EMAIL TEMPLATE – CLINICAL TRIAL INVESTIGATOR/COORDINATOR



To

Subject

Dear [their name],

My name is [your name], and I work for [organization name]. [Include a brief description of what your organization does, projects they work on, people they serve etc.]

We are hosting an in-person training summit for community health workers (CHWs) to increase minority involvement in lupus clinical trials. We will do this by training community health workers (CHWs) on what lupus is, and why minority involvement in clinical trials is beneficial. The CHWs will then provide education and support to promote enrollment and recruitment in lupus clinical trials in their communities. Increasing minority participation in lupus clinical trials is critical as it benefits both the individuals participating in the trial, and the larger lupus community.

I work in a community that serves primarily minority clients. As a clinical trial [investigator or coordinator] I believe that it would be beneficial for us to remain in contact so that I can advise clients in my community who would benefit from your clinical trial. Would you be interested in connecting so that I can tell my clients about your trial and you can serve as a contact if they have any questions?

If you have any questions about what we are doing or how you would be helping, please feel free to contact me at [insert phone number and email address]. I look forward to hearing from you soon.

Thank you for your time,

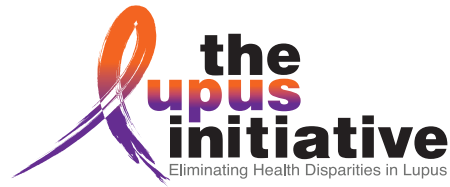
[signature]

Send



## BUDGET OUTLINE

[illegible]



YOUR ORGANIZATION  
LOGO HERE

**Lupus Clinical Trials  
Training Program**

**LuCTT**

**AT: LOCATION OF  
SUMMIT  
  
TIME**

**DATE OF SUMMIT  
  
Contact us at:  
(Your phone number)**

[Organization name] and the American College of Rheumatology are hosting a training summit to educate Community Health Workers (CHWs) on the benefits of participating in lupus clinical trials.

Participants will take an online course to teach them about lupus and clinical trials, then attend this in-person training summit where they will learn the skills needed to conduct outreach on lupus clinical trials.

If you are interested in participating, please contact [name] at [email] or [phone number] OR visit this link: [link to LuCTT webpage]







# MATERIALES EDUCATIVOS PARA PACIENTES

## PANFLETO 1

LUPUS Y GRUPOS MINORITARIOS

## PANFLETO 2

GENERALIDADES SOBRE ENSAYOS CLÍNICOS

## PANFLETO 3

RIESGOS Y BENEFICIOS DE LOS ENSAYOS CLÍNICOS  
DEL LUPUS

## PANFLETO 4

PREGUNTAS Y PREOCUPACIONES COMUNES  
ACERCA DE LOS ENSAYOS CLÍNICOS

## PANFLETO 5

CÓMO HABLO SOBRE ENSAYOS CLÍNICOS CON MI  
PROVEEDOR



# LUPUS Y GRUPOS MINORITARIOS

## Importancia del lupus entre grupos minoritarios

- ➔ Presentan síntomas más graves
- ➔ Desarrollan lupus a una edad más temprana
- ➔ El diagnóstico precoz ayuda a minorar los síntomas y prevenir problemas a largo plazo
- ➔ El diagnóstico entre afroamericanos y latinos tarda más tiempo, lo que se traduce en más problemas derivados de la enfermedad
- ➔ Experimentan más actividad derivada de la enfermedad y mayores riesgos de presentar problemas de salud mental
- ➔ Experimentan un mayor riesgo de sufrir daño a los órganos
- ➔ La tendencia del lupus a la mortalidad es más prevalente en estos dos grupos

Comparados a los blancos,  
los **latinos**   
y los **afroamericanos**  
son **2a3** veces más propensos a  
desarrollar lupus.



# GENERALIDADES SOBRE ENSAYOS CLÍNICOS

## ¿Qué es un ensayo clínico?

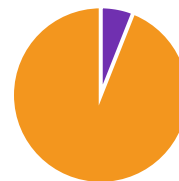
- Un ensayo clínico es un estudio de investigación que involucra a seres humanos.
- Los ensayos clínicos buscan dar respuesta a cuestiones específicas y tratan de encontrar mejores maneras de prevenir, diagnosticar o tratar una enfermedad.
- Los ensayos clínicos son el método principal como los investigadores descubren si un tratamiento nuevo es eficaz y seguro.

## ¿Qué puedo esperar al tomar parte en un ensayo clínico?

- Todos los participantes deben dar su consentimiento informado.
- El consentimiento informado es el proceso durante el cual los pacientes se enteran de los beneficios, riesgos y efectos secundarios, en potencia, de un ensayo clínico.



solamente



6%

DE MINORÍAS PARTICIPAN EN ENSAYOS CLÍNICOS

## ¿Cómo ayuda la participación en ensayos clínicos a reducir las disparidades en la salud relacionadas al lupus?

- Los ensayos clínicos buscan encontrar nuevos y mejores tratamientos para el lupus, a pesar de que los grupos minoritarios tienden a participar menos en ensayos clínicos. Es importante que todo tipo de personas con lupus participen en ensayos clínicos.
- Una población de estudio que incluya un grupo diverso de personas nos ayuda a determinar qué tratamientos son más efectivos para más personas.





# RIESGOS Y BENEFICIOS DE LOS ENSAYOS CLÍNICOS DEL LUPUS

Existen riesgos y beneficios potenciales derivados de participar en un ensayo clínico. Usted debe entender estos riesgos y beneficios antes de decidirse a participar en ellos.

## BENEFICIOS POSIBLES

### ➔ Acceso a tratamientos nuevos

- Quienes participan en ensayos clínicos reciben nuevos tratamientos que aún no están disponibles al público.

### ➔ Mejores resultados para pacientes

- Los ensayos clínicos ofrecen a los pacientes atención muy cuidadosa, incluidos cuidados de seguimiento. Esto se cumple para todos los pacientes del ensayo, incluidos aquellos en el grupo de control, los cuales no reciben el tratamiento. Muchos ensayos clínicos ofrecen cuidados que exceden los estándares de atención que usted recibe de su médico.

### ➔ Reduce las disparidades en la salud relacionadas al lupus

- Participar en ensayos clínicos ayuda a reducir la gravedad de la enfermedad y las complicaciones que experimentan las mujeres latinas y afroamericanas.

## RIESGOS POSIBLES

### ➔ Efectos secundarios

- Debido a que los ensayos clínicos son diseñados para probar la seguridad y utilidad de nuevos tratamientos, siempre cabe la posibilidad de que un tratamiento pudiera ocasionar reacciones dañinas a la gente. Se vigila muy de cerca a todos los pacientes del ensayo clínico.

### ➔ Protección para sujetos humanos

- Existen muchas medidas de protección para quienes participan en ensayos clínicos incluidas las administradas por la *Office for Human Research Protections*. <https://www.hhs.gov/ohrp/>.
- La Ley Nacional para Investigaciones Científicas de 1974 (*National Research Act of 1974*) estipula que los estudios de investigación que requieren la participación de seres humanos sean revisados por los Consejos de Revisión Institucionales (*Institutional Review Boards, IRB*). Los Consejos están conformados por elementos provenientes de hospitales, distintas disciplinas y miembros de la comunidad y se encargan de revisar un estudio detalladamente para asegurar que se realice de la manera más segura posible.



# PREGUNTAS Y PREOCUPACIONES COMUNES ACERCA DE LOS ENSAYOS CLÍNICOS

## ¿Cómo cubren los pacientes el costo de un ensayo clínico?

- ➡ La mayor parte de los ensayos clínicos son financiados por empresa privadas o el gobierno, por eso el paciente no incurre en ningún gasto.
- ➡ En ocasiones, el seguro médico del paciente podría cubrir el costo de algunos medicamentos, dispositivos o servicios proporcionados durante el ensayo clínico. Aunque, no existe ninguna garantía de que todos los costos serán cubiertos por el seguro médico del paciente. De cualquier manera, toda esta información se debe repasar con el paciente al momento de su inscripción en un ensayo clínico.

## ¿Qué efecto tiene participar en un ensayo clínico sobre mi estatus migratorio?

- ➡ Los inmigrantes legales, quienes posean estatus de residencia permanente (*green card*) o que sean ciudadanos naturalizados pueden participar en ensayos clínicos y su estatus no será afectado de ninguna forma.
- ➡ El gobierno no ha promulgado ninguna ley que afecte a inmigrantes ilegales ni contra su participación.

## ¿Con qué medidas de protección cuento?

- ➡ Los pacientes de un ensayo clínico tienen absoluto control sobre participar o no en un ensayo clínico. Los pacientes se pueden retirar en cualquier momento sin perder el acceso a cuidados.
- ➡ Desde 1970, el gobierno federal ha emitido normas que regulan y protegen tanto los derechos como la dignidad de quienes participan en ensayos clínicos.

## Cómo obtener más información sobre ensayos clínicos

- ➔ En ocasiones, se carece de información sobre ensayos clínicos en otros idiomas aparte del inglés. Sin embargo, si un individuo que no habla inglés participa en un ensayo clínico, la ley federal exige que toda la información referente al ensayo se le debe proporcionar en el idioma que entiende.

### Enlaces a más información

Informe Belmont:

<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report>

Normativas de seguridad:

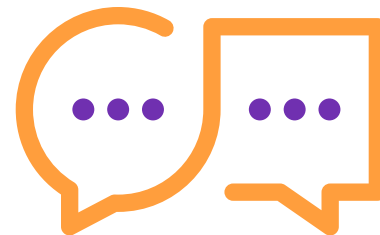
<https://www.hhs.gov/ohrp/regulations-and-policy/regulations/index.html>

Derechos de los pacientes:

[https://clinicalcenter.nih.gov/participate/patientinfo/legal/bill\\_of\\_rights.html](https://clinicalcenter.nih.gov/participate/patientinfo/legal/bill_of_rights.html)



# CÓMO HABLO SOBRE ENSAYOS CLÍNICOS CON MI PROVEEDOR



Antes de tomar la decisión de participar en un ensayo clínico, asegúrese de haber entendido completamente de qué trata el ensayo y qué se espera de usted. Una de las mejores maneras de hacerlo es obtener respuestas a las preguntas que tenga. Hable con su proveedor y con los investigadores del ensayo clínico. A continuación se proporcionan algunas preguntas para ayudar en su decisión.

- ① ¿Qué me pueden decir sobre la seguridad de mi participación en el ensayo? ¿Se vigila de cerca?

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- ② ¿Cuáles son los riesgos probables a corto y largo plazo?

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- ③ ¿Cuál es el potencial de beneficios para mí? ¿Con qué probabilidad los resultados del ensayo tendrán un efecto positivo en mi atención médica o beneficiará a los miembros de mi familia?

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- ④ ¿Cómo me inscribo en un ensayo clínico?

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- ⑤ ¿Tendrá algún costo participar en un ensayo clínico?

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⑥ ¿Qué ocurre cuando termina el ensayo clínico? Usted seguirá siendo mi médico?

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⑦ ¿Cómo se comparten mis datos del ensayo clínico con otros? ¿Cómo se mantendrá mi privacidad?

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⑧ Otras preguntas:

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También podría considerar que le acompañe un familiar o amigo como apoyo. Prepare todas sus preguntas de antemano y use el siguiente espacio en blanco para escribir preguntas adicionales.

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# CHW PEER RATING FORM

## LuCTT Study One

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[lupusinitiative.org/LUCTT](http://lupusinitiative.org/LUCTT)

This rating form is for the following CHW:

1. Please enter the first three letters of your LAST name. For example, if your last name is Perez, enter PER.
2. Please enter the FIRST, MIDDLE, AND LAST initials of your name. For example, if your name is Maritza Ana Perez, enter MAP. If you do not have a middle name, then enter the initials of your first and last name.
3. Please enter the state you live in, as an abbreviation. For example, if you live in Georgia, enter GA.

\*CHWs will fill out this form at the beginning of the summit and each time you complete a role-play, you will hand this form to the peers in your group so that they can rate you on your performance in the role-play.\*

4. Please indicate which role-play scenario you are completing:

Please respond to the following questions to evaluate the performance of your peers.

Item	Excellent	Very Good	Average	Poor	N/A
1. The CHW had ___ knowledge about lupus.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2. The CHW had ___ knowledge about lupus clinical trials.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3. The CHW had ___ knowledge about barriers to clinical trial participation.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4. The CHW was able to thoroughly explain potential clinical trial support.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5. The CHW displayed knowledge of potential clinical trial resources offered by the community.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6. The CHW accepts legitimacy of client's views and feelings; is not judgmental.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The CHW uses empathy to communicate understanding and appreciation of the client's feelings.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8. The CHW was able to clearly explain complex clinical trial information to their client.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
9. The CHW gives explanations at appropriate times; avoids giving advice, information or reassurance prematurely.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
10. The CHW uses concise, easily understood language.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

For the following questions, please place a check-mark next to each topic that the CHW covered in their elevator speech (if applicable).



1. CHW opened the conversation of clinical trials in a friendly and approachable manner
2. CHW explained the definition of a clinical trial
3. CHW explained the protocols associated with a clinical trial
4. CHW explained why clinical trials are important
5. CHW talked about the potential benefits from participating in a clinical trial

☐☐☐☐☐



## LuCTT Study One

- \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\*CHWs will fill out this form at the beginning of the summit and each time you complete a role-play, you will hand this form to the peers in your group so that they can rate you on your performance in the role-play.\*

[illegible]



**For each of the following questions, indicate to what extent you agree with each statement. (CULTURALLY AND LINGUISTICALLY APPROPRIATE SERVICES STANDARDS – FINAL POST-TRAINING SELF-ASSESSMENT ONLY)**

**To what extent did the LuCTT training prepare you to:**

**15. Explain things to your clients in a way that was easy to understand.**

(Strongly disagree) (Neutral) (Strongly agree)

0 1 2 3 4 5 6 7 8 9 10

## 16. Give your clients easy to understand instructions.

(Strongly disagree) (Neutral) (Strongly agree)

0 1 2 3 4 5 6 7 8 9 10

## 17. Show respect for what your clients have to say.

(Strongly disagree) (Neutral) (Strongly agree)

0 1 2 3 4 5 6 7 8 9 10

**18. Ask your clients what choice they think is best for them.**

(Strongly disagree) (Neutral) (Strongly agree)

0 1 2 3 4 5 6 7 8 9 10

**19. Take into account things in your client's life that worry them or cause them.**

[illegible]