Next STEPP Clinical Research Summer Camp: A How-To Toolkit

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CLINICAL AND TRANSLATIONAL SCIENCE INSTITUTE
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Introduction

The Next STEPP (STEM, Technology and Educational Pathways Program) Clinical Research Summer Camp was an initial pilot offering that was funded through in-kind donations from The Ohio State University's College of Nursing and Clinical Translational Science Institute, Nationwide Children's Hospital, and the Columbus State Foundation, with laboratory materials and activities provided by The Amgen Biotech Experience. The camp aimed to introduce high school students to clinical research through immersive, hands-on experiences and mentorship. Over four days, students engaged in activities such as developing study questions, practicing lab techniques, exploring pediatric research and presenting research posters. The camp emphasized informed consent, protocol development and career exploration, with professionals from various institutions participating in panel discussions.

This toolkit provides details on how to facilitate a clinical research summer camp for high school students. Included are lesson plans, handouts, worksheets, templates and pre- and post-survey questions.

Day 1 Toolkit Overview

Day 1 objectives:

- Form a camp community among facilitators and high school students through small groups.
- Gain a basic understanding of clinical research and importance of bioethics and good processes in conducting studies.
- Develop future study questions leading to a group-designed clinical research study.
- Demonstrate hands-on laboratory techniques for micropipetting and microbiology culture plating.

In this section of the toolkit, you will find the following:

1. Day 1 Lesson Plan
2. Handout: Icebreaker Activity
3. Handout: Group Designs a Study Question
4. Handout: Final Project Poster and Presentation
5. Handout: Learning and Skills Checklist and Journal

Not provided but part of the camp:

- Binder cover sheet
- Day 1 front sheet agenda
- Presentation:
  - Defining Clinical Research and Drug Development Process
    - Objective: Gain a basic understanding of clinical research and importance of bioethics and good processes in conducting studies

Day 1

Date:

Time:

Location:

Objectives:
- Form a camp community among facilitators and high school students through small groups.
- Gain a basic understanding of clinical research and importance of bioethics and good processes in conducting studies.
- Develop future study questions leading to a group-designed clinical research study.
- Demonstrate hands-on laboratory techniques for micropipetting and microbiology culture plating.

ACTIVITIES

Welcome and introductions | Time:

Facilitator(s):

Logistics: Where are bathrooms and water located? Lunch will be brought to this room for the Lunch and Learn activity. We will travel to the laboratory to learn some interesting science skills.

Objective:
- Form a camp community among facilitators and high school students through small groups.

Materials needed:
- Provide binders at check-in
  - Binders will be collected at the end of each day and then returned to the students at the beginning of the next day.
- **Day 1 handouts in folder:**
  - Final project instructions
  - Activity checklist
  - Icebreaker tabulations scratch pad
  - Worksheet: Developing the study question
  - Presentations
  - Final project instructions (Beginning with the End in Mind)
- Quick introductions from our facilitators today

Introduction (5 minutes):

- We are excited to have all of you attend. By the end of this camp, your groups will develop a clinical study protocol and protocol materials.
- To make this the best experience for you, the camp takes place in multiple locations.
- We aim to immerse you in clinical research so that you will have an idea of what clinical research is and about future career opportunities in clinical research.
- **Today's objectives are:**
  - Form a camp community among facilitators and high school students through small groups.
  - Gain a basic understanding of clinical research and importance of bioethics and good processes in conducting studies.
  - Develop future study questions leading to a group-designed clinical research study.
  - Demonstrate hands-on laboratory techniques for micropipetting and microbiology culture plating.
- Before we get started, we want to assess your knowledge. Please scan the QR code and take the pre-assessment quiz.
  - Bring up the QR code.

Preparation (5 minutes): (Things needed to get this going)

- Binders
- Index cards

Activity (15 minutes): (List in sequence, like instructions)

- Students will be assigned to groups of 5-6 students. Each group will decide on a name of their group. The group can also name their group after a famous researcher. E.g., "The Einstein Lab."

Debrief (1 minute):

- We want to collect the group cards after the icebreaker survey activity.

ACTIVITY: ICEBREAKER – CALCULATING ICE CREAM PREFERENCES | TIME:

Facilitators:

Objectives:

- Form a camp community among facilitators and high school students through small groups.
- Use descriptive statistics to calculate frequencies from survey results.

Materials needed:

- Survey worksheet for tabulating survey questions: each group will tabulate their own results and present them.
- Flip chart and marker: facilitator will tabulate results to record reports from the workgroups.

Introduction (5 minutes):

- The objectives of this activity are to take a moment to get to know each other through a mock survey exercise. A benefit of doing this exercise is that it will also introduce you to some basic (easy) statistics.
- A prospective survey is a survey of a group of participants to answer one or a series of questions. Results are typically descriptive.
- Explain the worksheet.

Preparation (5 minutes): (Things needed to get this going)
- Sticky notes given to each group (each member gets one sticky note pad)
- Pencils
- Worksheet for tabulations

Activity (15 minutes):
- Number your sticky note 1-4.
  - Would you rather have:
    - vanilla or chocolate?
    - chocolate chip or cookie dough?
    - cone or cup?
    - one scoop or two?
- Tabulate your group's results on the worksheet using descriptive statistics, e.g., percentage for each preference. The denominator is the total number in the group.

Group sharing (5 minutes):
- Present group stats to the room.

Debrief (5 minutes):
- Was it hard to tabulate the results? Any trouble with calculating results? Any ideas how you might compare results between groups? That is a higher level of statistics.
- Comments

WHAT IS CLINICAL RESEARCH AND HOW ARE DRUGS DEVELOPED FOR USE IN PATIENTS? | TIME:

Facilitators:

Objective:
- Gain a basic understanding of clinical research and importance of bioethics and good processes in conducting studies.

Materials needed:
- Laptop and projector link (both should be operational and pretested)
- Handout of slides

Instructions:
- Introduce the facilitators.
- Explain the objectives and activity to the students.

Activity (30 minutes):
- Slides: "Defining Clinical Research and the Study Question"
  - Defines Clinical Research and concept of "Cure Starters," includes sample research question; Facilitator shares their clinical research career progression and motivational challenges for students to dig deeper.
- Handouts:
  - Slide handout for note-taking
  - Top 20 medical advances
  - Wicked Problems in Health
- "The Drug Development Process"
  - Handouts:
    - Slide handout for note-taking

Debrief (5 minutes):
- Biggest take-home message from the activity?
- Comments

BREAK (20 MINUTES)
Then return to the room for Lunch and Learn activity

STATION 1: LUNCH AND LEARN: GROUPS DEVELOP PROJECT STUDY QUESTION (1 HOUR)

Facilitators: Main facilitator – presenter. Other facilitators – rotate to groups, eat lunch.

Objectives:
- Develop future study questions leading to a group-designed clinical research study while also having lunch.

Materials needed:
- Handout: Study question

Introduction (5 minutes):
- Explain the objectives and activity to the students
- The study question is the pivotal piece of designing a study. You have heard of the phrase "garbage in equals garbage out." Well, a poorly designed study that does not have a well-stated study question has no platform to build the study from. It all starts with the study question.
- Study questions include several factors:
  - **The population** (e.g., a study of insomnia in high school students) – the population is:
    - high school students
      - who have trouble getting to sleep or staying asleep
      - who agree (consent) to be in the study
  - **The intervention** (avoiding caffeine after 11 a.m.) – think about what students consume that has caffeine. Those must stop by 11 a.m. (think about how you will measure compliance – diaries?)
  - **The control** – not holding back on caffeine
  - **The outcome** – measured by a sleep diary (time went to bed, time woke up and perceived time to fall asleep)
  - **The time** – for how long? (e.g., for two weeks? three months?)

Preparation (5 minutes): (Things needed to get this going)
- Students get their lunch and get settled into their learning groups
- Provide handout: What is our study question?

Activity (30 minutes):
- While eating, students discuss together possible ideas for a study.
- They need to settle on a study topic (insomnia, sports recovery, hypertension, diabetes, eating right, exercising more, etc.), population, intervention, controls and outcomes.
- Study question:
  - Template: In (blank) (population) how well does (blank) vs. (blank) do to (blank) as measured by (blank)?
  - Example: In high school students with insomnia (defined as trouble falling asleep or staying asleep) how well does avoiding caffeine after 11 a.m. vs. no intervention do to improve hours of good sleep as measured by self-report on a checklist form?

Group sharing (5 minutes): report from each group
- The study question from our group is: In (blank) (population) how well does (blank) vs. (blank) do to (blank) as measured by (blank)?
- What is your biggest take-home message from the activity in terms of beginning to design a clinical research study?
- Student or group comments

Debrief (10 minutes):
- Clean up and move to the lab. Students may take a bathroom break on the way.

STATION 2 AND 3:

Laboratory activities | Time:
Below is an example of the rotation. Students will be escorted to lab locations by facilitators (e.g., Groups 1-3 go to Station 2 laboratory at 12:15 p.m. for an hour, then rotates to Station 2 at 1:30 p.m. for an hour).

Group	Station 2 Biotech Micropipetting Lab	Station 3 Microbiology – Plating
1	12:15-1:15 p.m.	1:30-2:30 p.m.
2	12:15-1:15 p.m.	1:30-2:30 p.m.
3	12:15-1:15 p.m.	1:30-2:30 p.m.
4	1:30-2:30 p.m.	12:15-1:15 p.m.
5	1:30-2:30 p.m.	12:15-1:15 p.m.
6	1:30-2:30 p.m.	12:15-1:15 p.m.

STATION 2: BIOTECH – MICROPIPETTING | TIME:

Facilitators:

Objectives:
- Understand the importance of micropipettes in clinical laboratory settings.
- Develop skill in using micropipettes.

Materials needed:
- P-20 pipettes
- colored water
- laminated cards to practice pipetting skills
- microplate templates
- blotting paper
- 200µl pipette tips
- conical waste container (500ml plastic beaker)

Preparation: (Things needed to get this going will already be set up so no extra time associated with prep)
- Per group of two students
  - A set of colored water tubes, set of pipettes, set of pipette tips, two laminated cards, two to four microplate templates, four sheets of blotting paper, box of tips, one waste container

Introduction (5 minutes):
- Explain the objectives and activity to the students
- Pipetting basics overview
  - Pipette anatomy and function

Activity (40 minutes): (List in sequence, like instructions)
- Micropipette practice cards (10 minutes)
  - Pipette indicated volumes onto pipette practice cards
- Microplate art (25 minutes)
  - Students are provided with various "mystery" designs for this activity
  - Pipette indicated volumes onto laminated microplate templates (1-2 designs per person)
  - Place blotting paper onto design after finishing (a keepsake)

Group sharing (0 minutes): Not needed, as students will be discussing the activity as they go

Activity transition (5 minutes):
- Reiteration of the importance of skills learned and application to real-world scenarios

STATION 3: BIOTECH 2: MICROBIOLOGY – PLATING | TIME:

Facilitators:

Objectives:
- Describe the role of transformation in the gene cloning process.
- Understand the purpose of controls in the transformation experiment and what each control does.
- Explain how information in a gene is expressed as a trait.

Materials needed:

- **Shared equipment:**
  - centrifuges
  - gloves
  - 1L Eppendorf jar
  - ice crusher
  - heat block
  - incubator

- **Per station:**
  - laminated instruction sheet
  - benchtop absorbent pads
  - safety glasses
  - microfuge tube rack
  - 250mL microfuge tube container
  - cell spreaders (two per group)
  - extra-fine tip Sharpie
  - P20 and P200 pipettes
  - 200µl tips
  - conical waste container
  - micropipette practice cards
  - LB plates:
    - No Antibiotics (one line)
    - Amp (two lines)
    - Amp + Ara (three lines)
  - isopropyl spray bottle
  - ice bucket
    - LB – Luria Broth
    - CC – Comp Cells

Instructions:

- Found on laminated sheets provided to each student group

Intro discussion (10 minutes):

- Discuss genetic engineering of bacteria and its role in medicine.
- Discuss bacterial transformation.
  - The role of plasmids
  - The role of antibiotics
  - Inducing expression of gene of interest
- Discuss aseptic technique.

Preparation (0 minutes): (Things needed to get this going will already be set up so no extra time associated with prep; see materials list above)

Activity (75 minutes): (List in sequence, like instructions)
- We'll have lab materials available on-site. The labs themselves are copyrighted materials associated with the ABE program.
- Quick summary:
  - Students are provided with competent E. coli, a plasmid containing red fluorescent protein and all the necessary materials and equipment to transform the E. coli with rfp. The following day or later in the week, students should be allowed to look at their results and discuss for approximately 10-15 minutes. Successfully transformed cells will appear as pink colonies on the plates.

Debrief (5 minutes):
- Students will discuss their thoughts on the entire process.
  - Note: a full report of results will be given by the lab instructor on Day 4
- Comments

DAY 1 CLOSEOUT | TIME:

Facilitators:

Objectives
- Recap the day and prepare for Day 2.

Materials needed: N/A

Introduction (5 minutes):
- Recap Day 1
  - A lot was unpacked today. You formed your group community of practice and started your group project by forming your study question that will lead to development of your study protocol (tomorrow). You learned about the history of clinical research and drug development. Then had an amazing activity on pipetting and genetic engineering and bacterial transformation using microbiology techniques. Where do we go from here?

Preparation (5 minutes): (Things needed to get this going)
- Collect binders from participants.

Debrief (5 minutes):
- Describe what will happen on Day 2.
  - Tomorrow we will be at _____. You will start phase 2 of your group project and learn more about clinical trials and create your group's study protocol. You will learn how a study goes from initial idea to recruiting study participants. How do you recruit those participants? All of this and more will be discussed. You will also learn about the informed consent process and practice this in the research department.
  - **Groups challenge:** Think about your study question because we are going to teach you how to develop a study in this camp and you will be presenting on the study plan on Day 4. Do a little research on the topic your group chose. Possibly exchange contact information.
  - **Individual challenge**: Review the checklist terms for today's activities, consider Googling some terms to learn more.
  - Allow for questions from students.

BREAK AND WALK TO CONFERENCE ROOM FOR DISMISSAL | TIME:

HANDOUT: ICEBREAKER ACTIVITY

Group name: _____

Ice Cream Preferences Survey Instructions
This is a fast-paced activity, using sticky notes and the data collection form below, each team member numbers a sticky note 1-4 and jots down their preference. The group together tabulates the overall results for their group and calls out your preferences.

This or That?	Options	Total Number	Total Group Participants	%
Example	*Fruit topping*	2	6	33%
	Sprinkles	4	6	67%
1	Vanilla			
	Chocolate			
2	Chocolate Chip			
	Cookie Dough			
3	Cone			
	Cup			
4	One Scoop			
	Two Scoops			

Report out example:
- Group Einstein shows that 67% prefer sprinkles over fruit (33%).

Report out:
Group _____ shows the following preferences for ice cream:
1.
2.
3.
4.

What did we learn? How to work in a team. How to design, collect and analyze survey data while having fun in our groups. A lot about ice cream preferences of group members. Put activities from this on your skills checklist!

HANDOUT: GROUP DESIGNS A STUDY QUESTION

The population: Children, teens, adults, older adults (e.g., high school students)

A condition of interest: (e.g., insomnia)

An intervention to help with the condition (prevent or improve) (e.g., avoiding caffeine after 11 a.m.)

Length: (time) (e.g., after 7 days, after 14 days)

Outcome: a measure to indicate a safety or efficacy (how well it worked) outcome (e.g., data from)

Example study question:

- In high school students with insomnia (defined as trouble following asleep or staying asleep) how well does avoiding caffeine after 11 a.m. vs. no intervention over 14 days due to improve hours of good sleep as measured by self-report on a checklist form?

Group study question:
In _____(population) how well does _____vs. _____ (intervention) for _____(time), do to _____(outcome) as measured _____ (data outcome).

NOTE: This study question will be used to develop your study protocol tomorrow.

HANDOUT: FINAL PROJECT POSTER AND PRESENTATION

Title: Poster Presentations

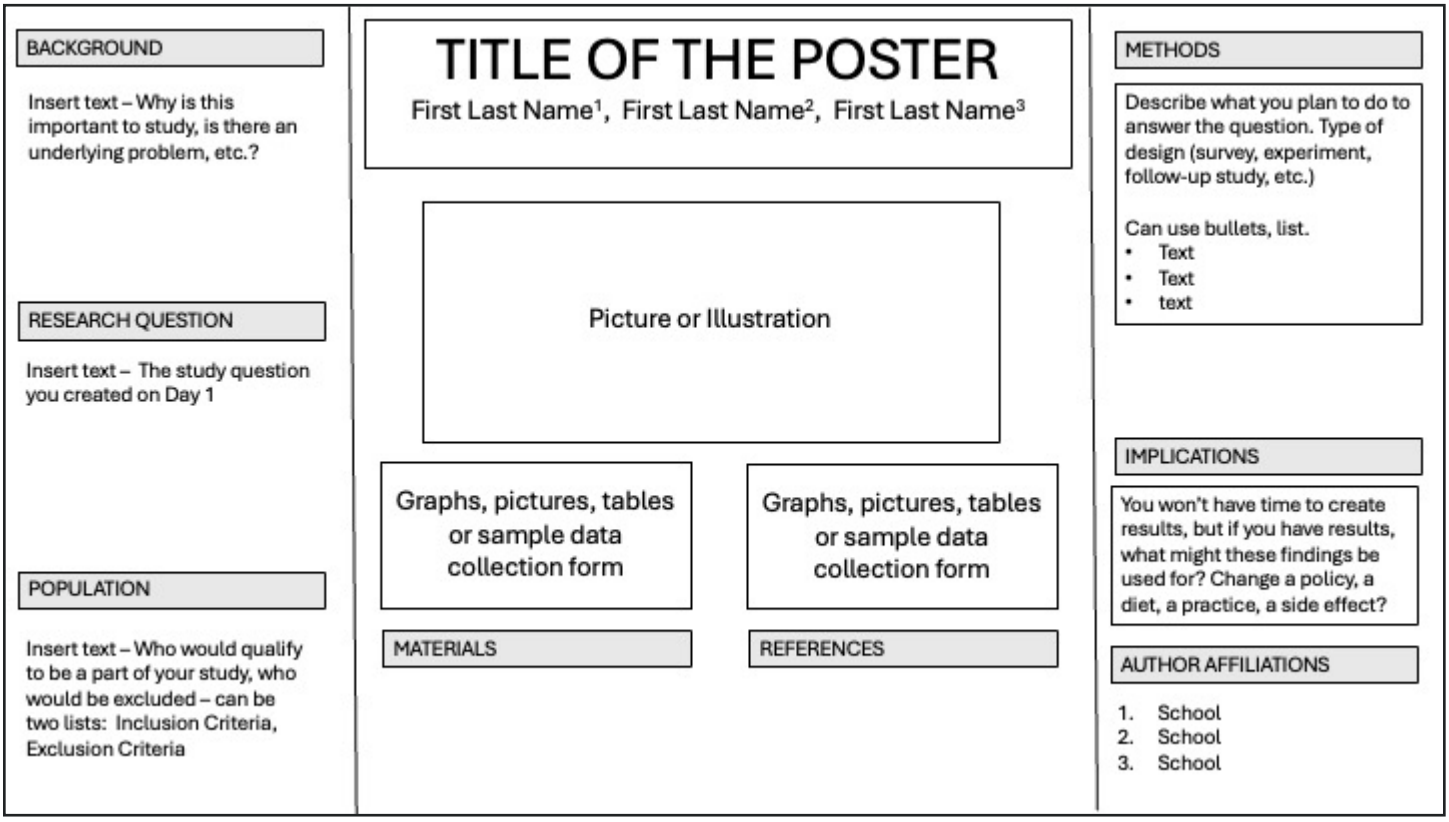
Learning objectives:
- **Illustrate/present** your group study using a provided tri-fold poster.
- **Collaborate** with group members to accomplish a common goal effectively, using leadership and equitable sharing.
- **Creatively** employ innovative methods to convey the message of your poster.

Schedule:
- **Day 1-2:** Begin working on your study and how it will be put onto a poster (worksheets below for planning).
- **Day 2-3:** Work on the poster during lunch and learns and set aside time.
- **Day 4:** Finalize poster, assemble and present your poster.

Materials needed:
- Review the sample tri-fold poster layout below
- Consider creative examples of tri-fold posters (from internet)
- Poster board
- Sharpies, colored markers, glue sticks, scissors, colored paper (IMPORTANT)
- Students may bring in illustrations or other printed materials for their posters
- Email for printing help:

Group work activity: The activity may take place during the Lunch and Learn on Days 1-4. Final touches may be made on Day 4 before presentations. The following information should be included:
- title
- authors
- background
- research question
- population
- methods or procedures
- study flow gram
- data collection form example
- implications
- references
- author affiliations (and decide who is doing what)

Final Poster Instructions



- Use worksheets below to plan your poster.
- Use Google to search creative ideas for tri-fold posters.

Debrief (5 minutes):

- What was the most important take-home message from the activity?
- Comments

LEFT PANEL WORKSHEET

Background: *Why is this important to study? What do we know? Underlying problem for the population?*

Research question:

Population:

Possible illustrations:

Sign up for roles: Who is working on what?

RIGHT PANEL WORKSHEET

Methods and procedures: What is the design? How are you going to do it? List?

Workflow: Create a workflow for the study with arrows, etc.

Title:

Reference list: Begin to create your bibliography.

Assembly:
How will you create text? Printed text should be at least 16-point font if you are pasting it on paper, or you may handwrite segments. What supplies and materials will you need for the study?

Supplies and materials needed for the poster:

Pictures to be used:

HANDOUT: LEARNING AND SKILLS CHECKLIST AND JOURNAL

Instructions: Keep track of your learning and skills in the checklist below by putting an "X" in the space next to each skill and the day you acquired that learning or skill. Terminology for each skill is /between two slashes/. You may want to learn more by doing a Google search for each of these terms.

NAME:

KNOWLEDGE AND SKILLS LEARNED	Date	Date	Date	Date
Develop a short /survey/ using sticky notes.				
Analyze /survey results/ using /descriptive statistics/ (number, mean, %).				
Form a cohesive study /team/ (small groups).				
Incorporate personal /leadership/ in team interactions.				
Develop a /study question/ with a team that will lead to a research protocol.				
Develop /micropipetting/ skills in the lab.				
Discuss concepts related to /aseptic techniques, genetic engineering, bacterial transformation, plasmid antibiotics and gene expression/.				
Develop skill of transferring a sample onto a /microbiology agar plate/ for /incubation/.				
Discuss the /importance and impact of clinical research/.				
Describe the sections of the /research protocol/.				
Discuss the /drug development process/.				
Discuss the /process of clinical research/ from concept to launch.				
Describe /Good Clinical Practice (GCP)/.				
Discuss the process of /planning recruitment of study participants/ into a study.				

KNOWLEDGE AND SKILLS LEARNED	Date	Date	Date	Date
Define the elements of /informed consent/.	☐	☐	☐	☐
Practice /informed consenting/.	☐	☐	☐	☐
Design a /study protocol/ and /data collection/ process with your team.	☐	☐	☐	☐
Explore healthcare and research /innovations/, including practicing /virtual reality/.	☐	☐	☐	☐
Consider how /pediatric patients/ are involved in clinical trials.	☐	☐	☐	☐
Discuss /medical devices/ researched and used in healthcare.	☐	☐	☐	☐
Discuss the use of a /simulation center/ for training.	☐	☐	☐	☐
Explore varied /careers in clinical research/.	☐	☐	☐	☐
Discuss /career options/ with a panel of clinical research professionals.	☐	☐	☐	☐
Create a /scientific poster/ describing the group's protocol.	☐	☐	☐	☐
Present a /scientific poster/ on a designed study.	☐	☐	☐	☐
Utilize /team science/ to create a final product.	☐	☐	☐	☐

DAILY REFLECTION:

Make notes about what you learned, something that intrigued you, things you want to learn more about and other personal reflections in the space below.

Day 1	**Day 2**
Day 3	**Day 4**

JOURNALING

Day 1:
What was your favorite activity today?

How was your team experience?

What questions do you have about what you learned today?

Notes:

Day 2:
What was your favorite activity today?

How was your team experience?

What questions do you have about what you learned today?

Notes:

Day 3:
What was your favorite activity today?

How was your team experience?

What questions do you have about what you learned today?

Notes:

Day 4:
What was your favorite activity today?

How was your team experience?

What questions do you have about what you learned today?

Notes:

Day 2 Toolkit Overview

Day 2 objectives:

- Observe examples of the importance and impact of clinical research.
- Discuss the requirements for a study protocol from concept to launch.
- Review participant recruitment and elements of informed consent.
- Expand group study question to develop a full protocol that each group collaboratively designs.
- Explore virtual reality and other innovations in healthcare through hands-on experiences and observations.

In this section of the toolkit, you will find the following:

1. Day 2 lesson plan
2. AI generated informed consent form
3. Creating a clinical research protocol – template

Not provided but part of the camp:

- Day 2 front sheet agenda
- Presentations:
  - **Why is Clinical Research So Important?**
    - Objectives:
      - Explore why clinical research is so important – examples of impact.
      - Review elements of the study protocol template for the camp protocol activity.
      - Illustrate a non-clinical study design.
  - **Concept to Launch of a Clinical Trial**
    - Objectives:
      - Discuss the requirements for a study protocol from concept to launch.
      - Review participant recruitment and elements of informed consent.
      - Discuss how data is collected and later analyzed for a study.

Day 2

Date:

Time:

Location:

Objectives:
- Observe examples of the importance and impact of clinical research.
- Discuss the requirements for a study protocol from concept to launch.
- Review participant recruitment and elements of informed consent.
- Expand group study question to develop a full protocol that each group collaboratively designs.
- Explore virtual reality and other innovations in healthcare through hands-on experiences and observations.

ACTIVITIES FOR DAY 2

Welcome and introductions | Time:

Facilitators:

Logistics: Where are bathrooms and water located? Lunch will be brought to this room for the Lunch and Learn activity. We will travel to:

Materials needed:
- Provide binders at check-in.
  - Binders will be collected at the end of each day and then returned to the students at the beginning of the next day.
- Day 2 handouts in folder:
  - Final project instructions
  - Activity checklist
  - Journal pages
  - Presentations
  - Slide handouts

Introduction

- We are excited to have all of you here. Today will be heavy in education and filled with exciting skills labs.
- Today's objectives are:
  - Observe examples of the importance and impact of clinical research.
  - Discuss the requirements for a study protocol from concept to launch.
  - Review participant recruitment and elements of informed consent.
  - Expand group study question to develop a full protocol that each collaborative group designs.
  - Explore virtual reality and innovations in healthcare through hands-on experiences and observations.

Preparation (5 minutes):

- Provide individual binders

SESSION I LECTURE: "WHY IS CLINICAL RESEARCH SO IMPORTANT?" | TIME:

Objectives:

- Explore why clinical research is so important (examples of impact).
- Review elements of the study protocol template for the camp protocol activity.
- Illustrate an example of a study question and study hypothesis (botany example) using a control group.

Handouts:

- Slide handout for notetaking
- Blank study protocol (for group design)
- Sample study protocol

SESSION II LECTURE: "CONCEPT TO LAUNCH OF A CLINICAL TRIAL" | TIME:

Objectives:

- Discuss the requirements for a study protocol from concept to launch.
- Review participant recruitment and elements of informed consent.
- Discuss how data is collected and later analyzed for a study.

Handouts:

- Slide handout for notetaking
- Sample informed consent document

Demonstrating informed consent. Let's practice informed consent (We will do this in the _____). First let me perform informed consent on YOU with a sample informed consent form. This is also located under Day 2 in your binder.

Discussing study participant recruitment. Think about the population age groups, preferences, availability, ability to participate etc. Each group choose one and give group feedback on where they might find these patients and how to recruit them. Consider barriers and facilitators to their agreement to participate.

- Adult patients with newly diagnosed high blood pressure (study of a new drug)
- High school students with insomnia (study of avoiding caffeine for one week, keeping a sleep and drink diary)
- Elderly patients with Parkinson's disease (new dance intervention to assist in Parkinson's disease mobility)
- Alzheimer's patients (new music and bean bag toss to help Alzheimer's engage with caregivers and family members)
- Children with cystic fibrosis (new medication to improve lung function)

STATION ACTIVITIES

During this segment, students will rotate to the Protocol Development Station located in _____. Then different groups will rotate to the _____to practice informed consent. We will stay on schedule (see table below). Lunch is available between _____. Everyone will start in Station 1 (Protocol Development) to get settled and begin discussing their protocol. Students may take a break between _____. At _____, rotations will commence according to the schedule below.

Groups	Research office – informed consent	Work in small groups
all	10:30-11 a.m.	WORK ON PROTOCOL
1	11-11:30 a.m.	11:30 a.m. to 12:30 p.m. (Lunch)
2	11-11:30 a.m.	11:30 a.m. to 12:30 p.m. (Lunch)
3	11:30 a.m. to noon	11-11:30 a.m., noon to 12:30 p.m.(Lunch)
4	11:30 a.m. to noon	11-11:30 a.m., noon to 12:30 p.m. (Lunch)
5	noon to 12:30 p.m.	10:30 a.m. to noon (Lunch at 11:30 a.m.)
6	noon to 12:30 p.m.	10:30 a.m. to noon (Lunch at 11:30 a.m.)

STATION 1 ACTIVITY: DEVELOPING A STUDY PROTOCOL | TIME:

Facilitators:

Objectives:

- Groups develop a study protocol, using a provided template, based on their study question.
- At designated times, groups will rotate to the Research Office for an informed consent activity or will work on their study protocol with their groups.

Materials needed:

- Handout: Study Protocol Template
- Sample study protocol using template

STATION 2 ACTIVITY: TOUR RESEARCH OFFICE AND PRACTICE INFORMED CONSENT | TIME:

Informal informed consent activity:

- A sample informed consent will be provided to the students and groups will take turns practicing informed consent on each other. Some will be the potential study participant, some will be participant family members, others will be the research team giving informed consent.
- Each group shares their thoughts on informed consent. Was it easy? Awkward? Thorough?

LUNCH AND LEARN | TIME:

Campers and camp staff facilitators have lunch between activities. Station 3 activities commence after lunch.

BREAK | TIME:

STATION 3 ACTIVITY: OHIO STATE COLLEGE OF NURSING TOUR AND LAB STATION ROTATIONS | TIME:

Facilitators:
Students will tour the Innovation Studio based on the timeframe scheduled for your groups.

Groups	Station 3: Innovation Studio	Station 1: Work on protocol
1	12:45-1:20 p.m.	1:20-2:45 p.m.
2	12:45-1:20 p.m.	1:20-2:45 p.m.
3	1:20-2 p.m.	12:45-1:20 p.m.; 2-2:45 p.m.
4	1:20-2 p.m.	12:45-1:20; 2-2:45 p.m.
5	2-2:45 p.m.	12:45-2 p.m.
6	2-2:45 p.m.	12:45-2 p.m.

The Innovation Studio is a unique maker space open to all students, faculty and staff, which houses an array of prototyping tools, including 3D printers, laser cutters, various hand tools and virtual reality. The studio hosts workshops with topics such as product design, pitch development, interprofessional collaboration and maker skills, and it provides project mentors and daily technical support. The mobile Innovation Studio travels across campus to help foster interprofessional collaboration while the permanent Innovation Studio resides at a permanent location in Jane E. Heminger Hall.

DAY 2 CLOSEOUT | TIME:

Facilitators:

Objective:

- Recap the day and prepare for Day 3.

Instructions:

- Recap Day 2.
  - What we learned today. Don't forget to document your learning in the checklist and reflect on your learning in the reflection prompts at the back of the binder.
    - Importance and process of clinical research studies
    - Transforming a study question (hypothesis) into a study protocol
    - Practiced informed consent in the _____
    - Learned about technology and innovations in the _____
  - Collect binders from participants.
- **Groups challenge:** Tomorrow you will be at _____. Since your protocols should be finalized, you should begin designing a poster presentation (for Day 4). Think about finding some pictures for your posters. If you need help printing them, email the documents or picture link to _____. We will have all the supplies you will need for your posters. These can be finalized the first part of the day on Day 4.

HANDOUT: INFORMED CONSENT FORM

Title of study: Comparison of Tylenol vs. Advil in headache recovery

Principal investigator: _____

Institution: _____

Contact information: _____

Introduction: You are invited to participate in a research study that aims to compare the effectiveness of Tylenol (acetaminophen) and Advil (ibuprofen) in relieving headaches. This study is being conducted by _____ at _____. Your participation is voluntary and you may withdraw at any time without penalty.

Purpose of the study: The purpose of this study is to determine which medication, Tylenol or Advil, is more effective in reducing headache symptoms. We hope to gain insights that can help improve headache treatment options.

Procedures: If you agree to participate, you will be randomly assigned to receive either Tylenol or Advil for headache relief. You will be asked to take the medication as directed and report your headache symptoms before and after taking the medication. You may also be asked to complete a questionnaire about your headache experience.

Duration: The study will last for _____ and you will be required to participate in ____sessions.

Risks and discomforts: Both Tylenol and Advil are commonly used medications with known side effects. Tylenol may cause liver damage if taken in high doses, especially with alcohol consumption

1. Advil may cause stomach pain, heartburn and, in rare cases, kidney damage
2. You should inform the investigator if you have any pre-existing medical conditions that may affect your participation.

Benefits: There may be no direct benefits to you from participating in this study. However, your participation may help improve headache treatment options for others in the future.

Confidentiality: Your information will be kept confidential. Data collected will be stored securely and only accessible to the research team. Your identity will not be revealed in any reports or publications resulting from this study.

Compensation: You will not receive any monetary compensation for participating in this study.

Voluntary participation: Your participation is voluntary. You may withdraw from the study at any time without penalty. If you choose to withdraw, please inform the investigator.

Contact information: If you have any questions or concerns about the study, please contact _____ _____ at _____.

Consent: By signing below, you acknowledge that you have read and understood the information provided and you agree to participate in this study.

Participant's name: _____

Participant's signature: _____ **Date:** _____

Investigator's signature: _____ **Date:** _____

CREATING A CLINICAL RESEACH PROTOCOL

TEMPLATE

GROUP:

RESEARCH TOPIC

RESEARCH QUESTION

POSSIBLE INDICATIONS

BACKGROUND
A. Choose one indication and describe. **B.** Why did you choose this? **C.** What age group affected by this indication are you focused on? **D.** Other characteristics? **E.** How common is this indication?

INTERVENTION AND CONTROL
A. Intervention **B.** Control

OBJECTIVES AND OUTCOMES

Objective	Outcome

POSSIBLE RISKS

ELIGIBILITY

Who can be included?	Who should not be included?

RECRUITMENT
A. How will you recruit study participants? **B.** Motivation to participate **C.** Informed consent

PROCEDURES

DATA COLLECTION/ANALYSIS PLAN

REFERENCES

(Use consistent formatting like APA. Use mostly peer-reviewed journal articles and limit to three websites. Cite in background and do not use AI.)

Day 3 Toolkit Overview

Day 3 objectives:

- Review the importance of clinical research in pediatric participants.
- Identify the unique needs of pediatric patients and their caregivers, including during informed consent.
- Gain understanding of clinical research operations at Nationwide Children's Hospital.
- Explore innovations and simulations used in clinical research and healthcare.
- Develop a poster on the group clinical protocol.

In this section of the toolkit, you will find the following:

1. Day 3 lesson plan
2. Optional activity: Ethical Issues in Clinical Trials

Not provided but part of the camp:

- Day 3 front sheet agenda

Day 3

Date:

Time:

Location:

Objectives:
- Review the importance of clinical research in pediatric participants.
- Identify the unique needs of pediatric patients and their caregivers, including during informed consent.
- Gain understanding of clinical research operations at Nationwide Children's Hospital.
- Explore innovations and simulations used in clinical research and healthcare.
- Develop a poster on the group clinical protocol.

INTRODUCTION TO DAY 3 | TIME:

Facilitators:
- Distribute binders.
- Students will be working on their posters.
  - Review of objectives today:
    - Review the importance of clinical research in pediatric participants.
    - Identify the unique needs of pediatric patients and their caregivers, including during informed consent.
    - Gain understanding of clinical research operations at Nationwide Children's Hospital.
    - Explore innovations and simulations used in clinical research and healthcare.
    - Develop a poster on the group clinical trial.
- Today we will be taking you to two stations in your tours of _____ IGM/3D Printer/Innovation Center. After lunch, you will tour the Simulation Center, where you will see human adult and pediatric models that are used in training and learning procedures.
- Now let us introduce your panel who are going to provide additional information about clinical research and especially research as it pertains to children and rare diseases.

PEDIATRIC CLINICAL RESEARCH IMPACT PANEL | TIME:

Clinical research nurse
- Understand why clinical research is essential for children, including the safeguards in place to protect them and the importance of tailored approaches that address their unique needs
- Hands-on role in managing clinical trials for industry-sponsored trials (biotech companies)
- Day-to-day responsibilities in working with patients and researchers
- Career advice: skills needed to enter this field

Patient/caregiver
- Personal story: Pediatric study participant and their caregiver (parent) participate in telling their story.
- How research has impacted their health journey
- Message to students: why research matters on a personal level

GROUP PROJECT WORKING GROUPS | TIME:
- Students work on their posters illustrating their study protocols
- Device demonstration: medical device displays

LUNCH AND GROUP WORK | TIME:

HOSPITAL AND FACILITY TOURS

Walk to Steve and Cindy Rasmussen Institute for Genomic Medicine | Time:

Institute for Genomic Medicine tour | Time:
- Tour of the Institute with a focus on research technologies

Walk to Simulation Center | Time:

Simulation Center tour | Time:

Closing remarks | Time:
- **REMINDER:** Don't forget to put your activities in the camp checklist of skills and make notes in your reflection journals.
- **Group challenge:** Consider where your group is regarding completing your protocols and posters. Let facilitators know if you need special assistance with your projects. You will have time to finish your posters in the morning and will then present your posters in the afternoon. Parents are welcome to attend the presentations.

OPTIONAL ACTIVITY: ETHICAL ISSUES IN CLINICAL TRIALS
Clinical trials are essential for advancing medical knowledge, but they also raise several ethical issues that must be carefully managed. Here are some key ethical concerns:

1. **Informed consent:**
   - Participants must be fully informed about the trial's purpose, procedures, risks and potential benefits. They should voluntarily agree to participate without any coercion[1].

2. **Risk-benefit ratio:**
   - The potential benefits of the trial should outweigh the risks to participants. Researchers must ensure that the risks are minimized and justified by the anticipated benefits[2].

3. **Confidentiality:**
   - Protecting the privacy of participants is crucial. Personal data must be handled with strict confidentiality and only authorized personnel should have access to it[2].

4. **Vulnerable populations:**
   - Special care must be taken when involving vulnerable groups, such as children, pregnant women or individuals with cognitive impairments. These groups require additional protections to ensure their safety and ethical treatment[2].

5. **Ethical review:**
   - All clinical trials must be reviewed and approved by an independent ethics committee or institutional review board (IRB). This review ensures that the trial meets ethical standards and protects participants' rights[2].

6. **Transparency and reporting:**
   - Researchers must be transparent about their findings, whether positive or negative. This includes publishing results in a timely manner and disclosing any conflicts of interest[1].

7. **Right to withdraw:**
   - Participants should have the right to withdraw from the trial at any time without any negative consequences. Their decision to leave should be respected and not affect their future medical care[2].

These ethical principles help ensure that clinical trials are conducted responsibly and with respect for the rights and welfare of participants. If you have any specific questions or need more details on any of these points, feel free to ask.

References

[1] Ethics in Clinical Research: Foundations and Current Issues (https://school.wakehealth.edu/education-and-training/graduate-programs/clinical-research-management-ms/features/ethics-in-clinical-research)

[2] Ethical Principles in Clinical Research (https://ocrtraining.cit.nih.gov/sites/clinicalcenter/files/Grady,%20Christine-01-04-16-Full%20Slides.pdf)

OPTIONAL ACTIVITY

Each group is assigned an ethical issue and are asked to create a two-minute skit illustrating either the ethical issue being used correctly or incorrectly. Include a quick overview of the importance of adhering to ethical practices for their assigned ethical issue.

The skits will be performed in an activity at the end of the day. Students can guess which ethical issue was just illustrated in the skit.

Day 4 Toolkit Overview

Day 4 objectives:

- Learn about the variety of careers in clinical research by interacting with a career panel of experienced clinical researchers.
- Review results of the microbiology plating exercise on Day 1.
- Complete final posters outlining the details of the group protocol.
- Evaluate camp learning and satisfaction.
- Present posters orally to the groups, facilitators and attendees.
- Celebrate the developed skills and content learned during the four-day camp.

In this section of the toolkit, you will find the following:

1. Day 4 lesson plan
2. Handout: Planning Your Poster Presentation
3. Pre- and post-survey

Not provided but part of the camp:

- Day 4 front sheet agenda
- Presentations
    - Careers in Clinical Research
        - Objective: Discuss the multiple careers in clinical research

Day 4

Date:

Time:

Location:

Objectives:
- Learn about the variety of careers in clinical research by interacting with a career panel of experienced clinical researchers.
- Review results of the microbiology plating exercise on Day 1.
- Complete final posters outlining the details of the group protocol.
- Evaluate camp learning and satisfaction.
- Present posters orally to the groups, facilitators and attendees.
- Celebrate the developed skills and content learned during the four-day camp.

ACTIVITY 1: WELCOME AND INTRODUCTIONS | TIME:

Facilitators:

Logistics: Where are bathrooms and water located? Lunch will be brought to this room for the lunch and poster work.

Here we are on Day 4, we are excited that we are culminating our learned skills in clinical research. Today we will introduce you to a panel of guests who are experienced clinical research professionals. This will really open your eyes to the various job titles and career paths that are available for clinical research professionals. There is a variety of health-related majors that can get you closer to pursuing these careers as you progress through high school and plan post-high school education.

So, for today, we are aiming to: (Read objectives)

Objectives:
- Learn about the variety of careers in clinical research by interacting with a career panel of experienced clinical researchers.
- Review results of the microbiology plating exercise on Day 1.
- Complete final posters outlining the details of the group protocol.
- Evaluate camp learning and satisfaction.
- Present posters orally to the groups, facilitators and attendees.
- Celebrate the developed skills and content learned during the four-day camp.

Materials needed:
- Provide binders at check-in
  - Binders will be allowed to go home with students
- Day 4 handouts in folder:
  - Poster presentation handout
  - Skills checklist

ACTIVITY II: CAREERS IN CLINICAL RESEARCH | TIME:

Facilitators:

Objective:
- Learn about the variety of careers in clinical research by interacting with a career panel of experienced clinical researchers.

Presentation: "Careers in Clinical Research" | Time:
- Handout: slide handout

Introduction of panel members | Time:
- We would like to introduce you to the participants of our clinical research career panel. They will share with you how they got into their career, the different career pathways they have taken and a bit about what they are responsible for.
- Panel members are from academic institutions, pharmacy, biotechnology and clinical research organizations.
    - List the name and company of panelists.

Panel member presentations | Time:
- Handout: bios for facilitators and panel members
- Q&A

BREAK | TIME:

ACTIVITY III: GROUP POSTER WORK | TIME:

Objectives:
- Complete final posters outlining the details of the group protocol.

Description:
- Groups will resume working on their final posters. Supplies will be available for them to use and they will make final edits to their posters. A laptop and printer will be made available for last minute printing needs of the groups.

LUNCH AND LEARN: CONTINUE POSTER WORK/POST-TEST | TIME:

Objectives:
- Review results of the microbiology plating exercise on Day 1
- Complete final posters outlining the details of the group protocol

Description:
- Lunch will arrive and during that time, groups will continue to finish up their posters and make decisions on how the posters will be orally presented.
- During lunch, the facilitator will report out on the final incubation results of your microbiology project from Day 1.

ACTIVITY IV: POST-TEST AND EVALUATIONS | TIME:

Facilitators:

Objective:
- Evaluate camp learning and satisfaction

Description:
- As we finish up lunch, I want to take 15 minutes to ask you to scan the QR code and complete the camp post-test. We compare your Day 1 pretest to your post-tests so we can evaluate learning and skills building.
  - Facilitator will provide a QR code for post-test of knowledge on camp cognitive and skills building
- Also, an evaluation form is being passed out and will also be completed and collected by the camp facilitators to provide information on the overall experience in the camp.
- Remind student campers to go to their skills checklist to indicate skillsets learned each day for sharing with parents.

ACTIVITY V: BREAK, POSTER SET UP AND PRESENTATION PLANNING | TIME:

Location:

Facilitator:

Objective:
- Complete final posters outlining the details of the group protocol.

Description:
As student groups complete their posters, they will set them up outside of the conference room so that they can be viewed. Later, each group will bring in their posters and set them up at the central space indicated and come up to present their poster. All group members should be up by the poster to support each other. The groups can select one speaker or there may be speaking parts that the group divides up.

- Begin with the study question.
- Describe why the group was interested in the topic.
- Describe the intervention and overall study plan.
- Discuss how data would be collected and analyzed.
- Describe what the group learned about the process of developing a study question, a protocol and the poster.
- Answer questions from the audience.

Handout:
- Poster presentation script

ACTIVITY VI: 8-MINUTE POSTER PRESENTATIONS | TIME:

Objective:
- Present posters orally to the groups, facilitators and attendees.

Description:

- Each group will provide a 5-8-minute presentation of their posters covering the topics listed above and on the script handout.
- Students will field questions from the audience and the career panel about their proposed research studies.

ACTIVITY VII: CELEBRATIONS AND CERTIFICATES | TIME:

Facilitators:

Objective:

- Celebrate the developed skills and content learned during the four-day camp.

Description:

- Debrief on lessons learned.
- Pass out camp certificates.
- Collect evaluations and any post-test handouts (for campers without phones who could not use Qualtrics).

HANDOUT: PLANNING YOUR POSTER PRESENTATION

Group name: _____

Group members:

-
-
-
-
-
-

Study question:

We chose this study question because:

In our designed study we plan to:

-
-
-
-

We will be collecting data by: (explain)

Key learning our group experienced in this project:

-
-

PRE- AND POST-TESTS

Day 1 Pretest (sliding scale 0-10):

How confident do you feel with the following:

1. Developing a research question
2. A descriptive analysis of a survey question
3. Laboratory techniques for micropipetting and microbiology
4. Study participant recruitment and obtaining informed consent
5. Creating a study protocol
6. Understanding research in vulnerable populations
7. Understanding the different clinical research professions
8. Summarizing a research project for a poster presentation

Day 4 Post-test (sliding scale 0-10):

How confident do you feel with the following:

1. Developing a research question
2. A descriptive analysis of a survey question
3. Laboratory techniques for micropipetting and microbiology
4. Study participant recruitment and obtaining informed consent
5. Creating a study protocol
6. Understanding research in vulnerable populations
7. Understanding the different clinical research professions
8. Summarizing a research project for a poster presentation

QUALTRICS SURVEY

What made attending the camp easier for you? (select all that apply)
- Reliable transportation
- Supportive household
- Topic was of interest
- Other

What were some barriers to attending the camp? (select all that apply)
- Unreliable transportation
- Unsupportive household
- Lost interest in the topic
- Other

Please rate the following (very unsatisfied, unsatisfied, neutral, satisfied and very satisfied):

- **Day 1:**
  - Content
  - Activities
  - Location

- **Day 2**
  - Content
  - Activities
  - Location

- **Day 3**
  - Content
  - Activities
  - Location

- **Day 4**
  - Content
  - Activities
  - Location

- **Other**
  - Group project
  - Exposure to technology
  - Materials provided
  - Career engagement/hearing about other roles
  - Food
  - Staff/facilitators

What did you like the most about the camp?

How could the program be improved for future participants?

How motivated are you to consider clinical research as a future career? (0-10 sliding scale)

Would you recommend this camp to your friends and families? (yes, no)

STAFF PARTICIPANT SURVEY

Did we meet the objectives for Day 1:

- Forming a camp community, facilitators, HS camp participants, small groups
- Practicing descriptive statistics through an icebreaker activity in small groups
- Gaining a basic understanding of clinical research, importance of bioethics and good clinical research practices for human subjects
- Beginning with the end in mind: developing future study questions in small workgroups
- Demonstrating hands-on laboratory techniques for micropipetting and microbiology culture plating

Did we meet the objectives for Day 2:

- Visualizing the importance and impact of clinical research
- Discussing the development of a research study—from concept to launch
- Planning study participant recruitment
- Discussing elements of informed consent
- Expanding study questions to a study protocol (group activity)
- Experiencing virtual reality in the healthcare setting

Did we meet the objectives for Day 3:

- Exploring pediatric research topics and impacts
- Observing the use of technology in the clinical research setting: 3D printing and patient simulation laboratories
- Practicing the informed consent process in pediatric research

Did we meet the objectives for Day 4:

- Discussing career activities with a panel of CRPs from different roles who present stories of their career progression
- Developing a poster presentation for their study protocol that has been collaboratively developed.
- Presenting posters of group work
- Evaluating the program and celebrating lessons learned

Did lesson plans facilitate success?

Did we have enough volunteers for all four days?

Did we have any safety concerns for students?

How can we better reach other communities within our catchment area?

What were some facilitators to conducting the camp?

What were some barriers to conducting the camp?

How could the program be improved for future camps?