LESSON 4: Participating in Research

INTRODUCTION

Students begin by gathering their own behavioral, medical, and genetic information, and prepare a cheek swab DNA sample. Next, students consider using their information to participate in a number of simulated research projects. This leads to a discussion about how the amount of time, degree of involvement, level of risk, and reasons for participation can vary for different types of research studies. Finally, students think about the ramifications of the fast-growing technology of biobanking in the context of clinical research and discuss their personal views.

CLASS TIME

About one class period of 55 minutes.

KEY CONCEPTS

- Genes and the environment work together to influence an individual’s observable characteristics such as behavior, appearance, health, and disposition.
- There are many types of research that involve human participants.
- Different types of research involve different levels of participation, risk, and benefit.
- There are potential ethical, social, and legal ramifications to disclosing medical and genetic information.
- Biobanks are data repositories in which information is used by researchers for population studies and to develop treatments, medicines, or other products.

LEARNING OBJECTIVES

Students will know:
- There are many types of research that involve human participants.
- Different types of research involve different levels of participation, risk, and benefit.
- Biobanks are repositories for storing biological specimens and information.

Students will be able to:
- Weigh the harms and benefits of participating in simulated research projects.
- Weigh the harms and benefits of sharing genetic information.

Vocabulary words used in each lesson are in bold. Definitions can be found at the end of each lesson and in the Master Glossary in the Appendix.
MATERIALS

<table>
<thead>
<tr>
<th>Materials</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Student Handout 4.1—Health History and Behavior Survey</td>
<td>1 per student</td>
</tr>
<tr>
<td>Cotton swab</td>
<td>1 per student</td>
</tr>
<tr>
<td>Envelope</td>
<td>1 per student</td>
</tr>
<tr>
<td>Small sticky note</td>
<td>1 per student</td>
</tr>
<tr>
<td>Sheet of dot stickers</td>
<td>5-Each sheet can be shared among a few students</td>
</tr>
<tr>
<td>Studies—Research Study Seeking Participants (Studies #1–5)</td>
<td>1 copy of each study to be posted around the classroom</td>
</tr>
<tr>
<td>Teacher Resource 4.1—Participation Arrows</td>
<td>Post one arrow next to each research study</td>
</tr>
<tr>
<td>Computer with internet access to show videos</td>
<td>1</td>
</tr>
<tr>
<td>Video: How Do I Give DNA?</td>
<td>Access via internet</td>
</tr>
<tr>
<td>Video: People Matter—The Future of Research</td>
<td>Access via internet</td>
</tr>
</tbody>
</table>

FRAMING THE LESSON

In the previous lessons, the research study participants were from historical cases or they were unidentified. In this lesson, students consider the risks and benefits of sharing their own health history and genetic information, and decide whether or not they would personally participate in a research study.

TEACHER PREPARATION

- Make copies of Student Handouts.
- Post five research studies around the classroom.
- Make stacks of envelopes, cotton swabs, sticky notes, and sticker sheets.
- Post one “participation arrow” next to each study. Arrows can be made from painter’s tape or from Teacher Resource 4.1—Participation Arrows.
- Prepare computer and projection unit to show videos.

To further explore personalized genetics and direct-to-consumer genetic testing, please refer to Lesson One of NWABR’s Using Bioinformatics: Genetic Testing curriculum at http://www.nwabr.org.

PROCEDURE

Activity One: Research Studies and You

Part I: Gathering Information

This class activity and discussion focus on student attitudes toward different types of research involving human participants.

1. Explain to students that our knowledge is rapidly growing about how genetic information and the environment work together to influence each person’s appearance, behavior, health, and disposition.

2. Give each student a copy of Student Handout 4.1—Health History and Behavior Survey, an envelope, and a sticky note. Give them five minutes to fill out the survey. When they’re done, ask them to place it in the envelope.

3. Explain to students that they will next be collecting some of their own DNA to go with the survey. Show the How Do I Give DNA? video. Give each student a cotton swab and ask them to gently wipe the inside of their cheek as shown in the video. Have them put the swab inside the envelope with their survey.
4. Ask students to write their name on the sticky note and attach it to the outside of their envelope.

5. Tell students that the cotton swab inside the envelope is now holding cells that contain their DNA. The survey contains details about their health, behavior, and some genetic history.

6. Let students know that it is now possible to sequence a person’s entire genetic code for about $1,000, a price that is rapidly falling. Genetic technology is moving at such a pace that within their generation it may be so easy and affordable to read a person’s genome that genetic information may become part of each individual’s medical record. Remind students that, to varying degrees, both genes and the environment influence each person’s observable characteristics such as behavior, appearance, health, and disposition.

Part II: To Participate or Not

7. Now ask students if they would be willing to turn in their envelopes (share their personal information and DNA) with researchers who plan to use their health and behavioral information and/or DNA in research studies with the goal of making advances in human health and welfare.

8. Tell students that they will have the chance to consider participating in the five different fictitious studies posted around the classroom.

9. Give a brief overview of each study (see below), taking time to define vocabulary words as necessary. Make sure students understand that inclusion criteria are all of the conditions that must be met in order for someone to participate in a study, and exclusion criteria are any conditions that would disqualify someone from participating in a study. Study overviews:

   a. Study #1: Testing the effectiveness of eyelash growth serum on people who wear contact lenses and/or eyelash makeup (mascara) and people who wear neither.

   b. Study #2: Examining the link between eating nuts and blood sugar levels, as related to the prevention and management of Type II Diabetes.

   c. Study #3: Studying the link between the time of day and a person’s attention, focus, and thinking to develop better ADHD medication schedules.

   d. Study #4: Testing the safety of a Phase I malaria vaccine.

   e. Study #5: Examining the genetic basis of:

      o mental and physical traits that are keys to becoming a “superstar” athlete, and

      o mental and physical traits that are keys to extremely violent, even criminal behavior.

10. Give students 10 to 15 minutes to read the posted studies.

11. After students read as many studies as they can in the time available, ask them to place a small sticker somewhere along the arrow continuum, indicating their likeliness to participate in each study. (If teachers don’t have stickers, students may make a mark above or below the arrow using a pen or pencil.)

12. Now ask students to share in a class discussion the factors that influenced their decisions. If students need prompting, ask if the following factors influenced whether they would participate:

   a. A large number of people would be affected by advancements in this field (or a large number of people would not be affected).

   b. Life would be greatly improved by advancements in this field (or life would not be greatly improved).

   c. I (or people I care about) have a personal connection to this condition (or I do not have a personal connection to this condition).

   d. There is little risk to me (or there is a high risk to me), and the type of risk involved (i.e., medical or “social” risks like stigma, the risk of having personal information made public).

   e. I don’t have to contribute a lot of time, energy, or resources (or I do have to contribute a lot).

   f. I am willing (or I am unwilling) to have my tissue or blood samples added to a biobank.

Activity Two: Research and Community Partnership

13. Explain to students that there have been great advances in research involving human participants. The Belmont Report principles, regulatory bodies like Institutional Review Boards, and government oversight allow research to yield more benefits while lessening the risks for research participants. However, continued improvements are necessary to increase trust and public participation. For scientific advancements
to occur in health and medicine, the public must participate. Discuss the following questions, keeping in mind the research studies discussed in Part II:

a. If you chose to participate, would it be important for you to learn your own personal results after the study was completed? Would you want to know your status regarding genetic traits, behavioral patterns, health findings, etc.? Why or why not?

b. If the information in your envelope became available to the public, what might the consequences be? To insurance companies? To schools? To local health providers? To pharmaceutical companies? To the police?

14. Remind students that so far they have had their names attached to the envelopes. Ask students to remove the sticky note with their name on it from the envelope. The envelope now represents a de-identified sample. If it were used in a research study, researchers would not know who the sample came from. Ask students:

a. Among the studies you read in Part II, would you be more likely to participate in any of them if your information was de-identified?

b. Would you be willing to let the teacher collect your de-identified envelope to be used in future research? What if hundreds of other people (i.e., students from the entire school) were participating? Thousands of other people?

15. Explain to students that it is becoming common practice for researchers to formally ask study participants whether their genetic information may be entered into a data repository called a biobank, though they are not generally required to ask permission if the genetic information has been de-identified. Researchers use information from biobanks for population studies and to develop treatments, medicines, or products. The potential uses for biobank information are limitless and not yet fully determined. Ask students to decide whether they would give permission for their samples to be added to a biobank if samples were de-identified. Why or why not?

Tell students that many scientists believe that biobanks are the future of research. Because biobank research is relatively new, few practice standards or detailed regulations exist and there are many ethical questions to consider.

16. Explain to students that in this part of the activity they will act as a community advisory board. A community advisory board represents the needs and concerns of the local community. A board works closely with researchers and clinical staff to provide the perspective of local patients, caregivers, families, and other stakeholders.

Many biobanks contain cells or tissues left over from surgeries and other medical procedures. Although procedures and rules vary among institutions, IRB approval is generally not required to use these tissues for medical research if they have been de-identified and are considered medical waste. Without the involvement of an IRB, no consent forms are required and the genetic material can be used in studies without an individual’s permission.

17. Have students form groups of four.

18. Ask them to work as a group to brainstorm practices scientists can follow to improve public trust and participation in biobanking tissue samples for research.

19. Come back together as a class and ask a group representative to contribute to a class list of “advice from the public to scientists.” If students do not come up with these ideas for their list, ask them whether the following factors would increase public trust and willingness to participate:

a. Ask permission to use samples, even though consent may not be officially required in every case.

b. Think about when and how you ask for permission so people can be informed and make thoughtful decisions without coercion or undue influence.

c. Communicate research findings so people learn about outcomes.

d. Let people know about any other ways the samples may be used.

e. Treat people like human beings, not research subjects.

20. Tell students that these ideas are also being discussed among scientists. Show the video People Matter—The Future of Research found at http://peoplematterproject.org.

21. Afterward, ask for reflections and comments. Invite students to share how they could take personal action as advocates, participants, members of community advisory boards, future researchers, and voters to ensure a favorable future for research.
Closure
22. At the end of the lesson, collect all of the envelopes containing the students’ cotton swabs and survey information. Discard or destroy the envelopes in a visible way.

EXTENSION
Tell students that current and future technologies make it possible to link biological samples, such as the cells on their cotton swabs, back to the donors. Even if the cotton swab samples are stripped of all identifying information—such as names and health record numbers—these samples contain each student's DNA, which is in itself a unique identifier. In a future when anonymity cannot be guaranteed, ask students whether they would choose to participate in research by donating their tissue to biobanks. Why or why not? Given their answers, what are some of the repercussions for medical research?

Ask students to consider where they may have left personal “envelopes” containing genetic information in the past. Oftentimes cells, tissues, and/or DNA can be collected without an individual’s permission because people are not considered “human participants” as long as identifying information has been removed. Data from these samples can be used in genome or population studies without the sample owner’s knowledge.

Consider these cases:
- Someone intentionally seeks out a genetic test by participating in a research study, or using a direct-to-consumer genetic testing website such as “23 and Me” or “Ancestry.com DNA.” Their results are now on file with an institution somewhere—at a hospital, in the provider’s database, with an insurer, or they are known by a spouse or other family member.
- An individual never sought out a genetic test, but may have inadvertently granted access to genetic information through a urine or blood test for a physical exam, newborn screenings, a hair sample left at a crime scene, or fetal cells their parents asked to be collected before they were born.

Visit the website “23 and Me” (https://www.23andme.com) to learn about the types of genetic tests available directly to consumers. This site also provides a useful explanation of the genetic testing process in the “How it Works” section.

CONNECTION TO FORMATIVE ASSESSMENT
Revisit the statements students sorted for the formative assessment. After completing this lesson, students should understand that Statement D is accurate.

GLOSSARY
Assent: A process in which the parent or guardian of a minor agrees to the minor’s participation in a research study. The participant is still required to give informed consent.

Biobank: A storage facility for biological materials used in medical research.

Coercion: The act of pressuring someone to do something using force, intimidation, or threats without respect for individual choice. This includes the idea that a person with few choices may find participation in a study to be so appealing that they feel they cannot decline, even if being in the study is not a good decision for other reasons.

De-identify: To remove personal information such as name, medical record number, or study code from a genetic sample so that the sample cannot be linked to a specific individual.

Exclusion criteria: Any of the conditions that would disqualify someone from participating in a study (see inclusion criteria).

Genetic predisposition: A greater likelihood of expressing a certain trait based on a person's genetic material (e.g., someone may carry a gene that is known to be related to an increased chance of breast cancer).

Genome: The complete genetic material of an organism.

Inclusion criteria: All of the conditions that must be met for someone to participate in a study (see exclusion criteria).

Ramifications: Consequences or results of actions, especially when not desired.

Undue influence: Is exerted when a person of higher power or authority takes advantage of another person; undue influence can often include coercion.
SOURCES

The five research studies found in this section are all fictional. Following is the source information used to create these fictional studies:

Eyelash Cosmetics, Contact Lenses, and Effectiveness of Latisse®
http://www.newsrx.com/library/topics/Alopecia-Areata.html
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2861943/
http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2861943/

Nut Consumption, Blood Sugar, and Diabetes Prevention
http://www.cdc.gov/diabetes/pubs/general11.html#what
http://jn.nutrition.org/content/138/9/1752S.full

Randomized, Open Label, Single Dose, Crossover Study to Evaluate Safety After Injection of Malaria Vaccine AB415.
http://www.seattlebiomed.org/disease/malaria
Please answer the following questions to the best of your knowledge. 
You do not have to share the results with anyone unless you choose to do so.

<table>
<thead>
<tr>
<th>Question</th>
<th>YES</th>
<th>NO</th>
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</thead>
<tbody>
<tr>
<td>1. Do you wear contact lenses?</td>
<td></td>
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<tr>
<td>2. Do you wear eyeliner, mascara, or other eyelash cosmetics?</td>
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<tr>
<td>3. Have you had, or do you have, chronic eye infections or problems?</td>
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<tr>
<td>4. Do you have Type II Diabetes?</td>
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<tr>
<td>5. Does anyone in your extended family have Type II Diabetes?</td>
<td></td>
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<tr>
<td>6. Are you allergic to any nuts?</td>
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<tr>
<td>7. Have you been diagnosed with ADHD?</td>
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<tr>
<td>8. Are you on medication for ADHD?</td>
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</tr>
<tr>
<td>9. Do you take any medications regularly?</td>
<td></td>
<td></td>
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<tr>
<td>10. Do you have any skin allergies or reactions?</td>
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<td></td>
</tr>
<tr>
<td>11. Do you play competitive sports?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>12. Have you ever been disciplined at school for fighting?</td>
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<td>Age:</td>
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<td>Ethnicity:</td>
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</table>
Eyelash Cosmetics, Contact Lenses, and Effectiveness of Latisse®

Background:
Eyelash hypotrichosis is the term for an inadequate quantity of eyelashes. Alopecia areata results in patches of hair loss, usually on the scalp, but also in other areas of the body including the eyelids. Eyelashes protect eyes by providing a natural protective barrier from sunshine, wind, foreign bodies, and perspiration. Eyelashes are sensitive to the touch and cause the eyelid to close reflexively when an object is near the eye. As a result, compared to those with healthy lashes, people with few or no lashes can experience more eye irritation, infection, and sensitivity, and show reduced reflexive blinking. Aside from the protective purpose of eyelashes, patients without eyelashes report feeling less attractive.

Causes of eyelash hypotrichosis and Alopecia areata are many, including family history, aging, chemotherapy, and other medical treatment. It is estimated that hypotrichosis and Alopecia areata affect to varying degrees more than four million people of all ages and sexes.

Current treatment:
Latisse (bimatoprost 0.03%) is a drug that was approved by the U.S. Food and Drug Administration (FDA) for increasing eyelash length, thickness, and darkness in patients with hypotrichosis of the eyelashes. One drop is applied each evening to the base of the upper eyelashes with a single-use applicator brush. It has been used in more than 30 clinical studies on hundreds of patients. For those who use Latisse, there is a 4% chance of the eyes becoming red and itchy and for there to be darkening around the lash area, but these effects are temporary, and go away after use is discontinued. There is a rare complication where iris color changes irreversibly. This side effect was only seen in patients who applied doses larger than that found in Latisse. Since the product’s release, it has crossed over into the cosmetic realm and is widely used to enhance healthy lashes by making them longer, darker, and thicker.

Purpose:
To test the safety and effectiveness of Latisse in people who do and do not use eyelash cosmetics and/or contact lenses.
**Official title:**

Comparative Observational Analysis of Latisse Users

**Detailed description:**

This is a study comparing several groups of subjects who do and do not use contact lenses and eyelash makeup. Measurements of eyelash growth and observations of side effects will inform current recommendations and warnings associated with using Latisse.

**Study population:**

Healthy volunteers. Volunteers may or may not wear contact lenses, and may or may not use eyelash cosmetics.

**Inclusion criteria:**

Participant is willing and able to:

1. Give *informed consent* to participate.
2. Continue same daily regimen for 90 days.
3. Keep daily logs of observations of any side effects such as itching or burning eyes, discoloration of eyelids, discoloration of eye iris, or other changes.
4. Come in every 30 days to have eyelashes observed and measured.

**Exclusion criteria:**

1. Any active or ongoing medical problems of the eye.
2. Previously documented eye hypersensitivity to cosmetics, eye drops, or other products designed for the eye.

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**Exclusion criteria:** Any of the conditions that would disqualify someone from participating in a study.

**Inclusion criteria:** All of the conditions that must be met for someone to participate in a study.

**Informed consent:** A process that outlines required elements of research participation, including its risks and potential benefits, to help someone decide whether to participate. An informed consent form is used to convey essential information and is signed by the participant if he or she decides to join the study.
Nut Consumption, Blood Sugar, and Diabetes Prevention

Background:
Diabetes affects 25.8 million people in the United States—roughly 8% of the total population—and is the seventh leading cause of death in the country. Diabetes is a disease that results from the body’s inability to produce insulin, use insulin properly, or a combination of both. There are two types of diabetes: Type I and Type II. This study will focus on Type II Diabetes.

Type II Diabetes is characterized by the body’s inability to use insulin properly and results in high levels of blood sugar that can lead to many health complications and death. There are many factors linked with Type II Diabetes, including age, obesity, family history, and lack of physical exercise. Certain ethnicities, including African Americans, Hispanics, and Native Americans, have been shown to be at a higher risk for Type II Diabetes.

Current treatment:
Current treatment for Type II Diabetes includes monitoring diet and exercise, and taking oral medication to help regulate blood sugar levels. Recent studies have shown that ingesting nuts helps control blood glucose levels in non-diabetic and diabetic individuals. As a result, it is being recommended that individuals with diabetes include nuts in their daily diet.

Purpose:
To identify whether daily consumption of nuts affects blood sugar regulation that may result in diabetes prevention or management.

Official title:
Comparative Analysis of Nut Consumption and Blood Sugar Regulation

Detailed description:
This is a study comparing several groups of participants who do and do not have a diagnosis of diabetes. Their blood sugar level measurements will inform future guidelines for individuals with Type II Diabetes.
**Study population:**
Healthy volunteers and people with Type II Diabetes.

**Inclusion criteria:**
Participant is willing and able to:
1. Give **informed consent** to participate.
2. Provide family history regarding diabetes.
3. Follow a prescribed diet high in nuts for 30 days.
4. Prick their own finger to take and record blood sugar levels three times a day using a device provided by the study sponsor.
5. Come in once a week for further blood sugar level testing.
6. Consent to enter **de-identified** leftover blood samples into a national **biobank** for future research.

**Exclusion criteria:**
1. Previously documented adverse reactions to the ingestion of nuts, or nut allergies.

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**Biobank:** A storage facility for biological materials used in medical research.

**De-identify:** To remove personal information such as name, medical record number, or study code from a genetic sample so that the sample cannot be linked to a specific individual.

**Exclusion criteria:** Any of the conditions that would disqualify someone from participating in a study.

**Inclusion criteria:** All of the conditions that must be met for someone to participate in a study.

**Informed consent:** A process that outlines required elements of research participation, including its risks and potential benefits, to help someone decide whether to participate. An informed consent form is used to convey essential information and is signed by the participant if he or she decides to join the study.

**Type II Diabetes:** A chronic medical condition that affects how the body metabolizes sugar (glucose). Type II Diabetes typically begins in adulthood and patients are not usually dependent on the use of insulin to control their sugar levels.
Understanding Daily Cycle of Attention and Cognition

Background:

ADHD is a common childhood disorder that can continue through adulthood. People with ADHD have difficulty with executive function regulation that results in problems with focus and organizational skills, hyperactivity, and impulsivity. The Centers for Disease Control estimates nearly one in 10 U.S. children have ADHD.

Current treatment:

The most common treatment for ADHD is to prescribe stimulant medications. These vary in effectiveness depending on dosage and if medication is “extended release” or “long-acting.” Common side effects include decrease in appetite, sleep problems, and rarely, tics.

Purpose:

To identify any hourly patterns of attention, focus, and thinking skills to identify ideal ADHD medication schedules.

Official title:

Diurnal Patterns of Attention and Cognition in Youth Ages 11–18

Detailed description:

This study will document the patterns of focused attention and cognition during a five-day period of students with and without an ADHD diagnosis. Students, parents/guardians, and teachers will fill out a daily survey documenting varying periods of focused attention and cognition over the course of five days.

Study population:

1. Students ages 11–18 with ADHD diagnosis; not medicated.
2. Students ages 11–18 with ADHD diagnosis; medicated.
Inclusion criteria:
1. Participant is willing and able to give informed consent to participate.
2. Participant’s parent/guardian and dominant classroom teacher are willing and able to give their assent for the participation.
3. Participant is willing to keep a log to document changes in ability to focus over the course of each day for five days.
4. Participant’s parent/guardian and dominant classroom teacher are willing to complete a survey of the participant’s behavior and perceived ability to focus at the end of each day for five days.

Exclusion Criteria:
1. Participant’s parent/guardian or dominant classroom teacher is/are not willing to complete a daily survey concerning participant’s behavior and perceived ability to focus at the end of each day for five days.
2. Participant uses marijuana or other illegal drugs during five-day period.

Assent: A process in which the parent or guardian of a minor agrees to the minor’s participation in a research study. The participant is still required to give informed consent.

Exclusion criteria: Any of the conditions that would disqualify someone from participating in a study.

Inclusion criteria: All of the conditions that must be met for someone to participate in a study.

Informed consent: A process that outlines required elements of research participation, including its risks and potential benefits, to help someone decide whether to participate. An informed consent form is used to convey essential information and is signed by the participant if he or she decides to join the study.
Randomized, Open Label, Single Dose, Crossover Study to Evaluate Safety After Injection of Malaria Vaccine AB415

Background:
Malaria is a tropical parasitic disease transmitted by the bite of female mosquitoes. The parasite lives in the red blood cells and eventually ruptures them causing anemia. Other symptoms include fever, joint pain, vomiting and headaches, which can lead to coma and death if untreated. Nearly 40% of the world’s population lives in tropical regions affected by malaria. One in five childhood deaths worldwide is attributed to this parasitic infection.

Current treatment:
Anti-malarial drugs offer some protection and treatment for the disease, but are limited due to developing drug resistance and the stage at which the disease is diagnosed. Prevention with insecticides and bed nets has been more successful, but is still limited due to cost and the evolution of mosquito insecticide resistance.

Purpose:
To test the safety of an experimental malaria vaccine.

Official title:
Randomized, Open Label, Single Dose, Crossover Study to Evaluate Safety After Injection of Malaria Vaccine AB415.

Detailed description:
This is a Phase I trial of Malaria Vaccine AB415. Participants will be given two injections (shots) over a one-month period to determine the safety of the vaccine. Participants will monitor the site of injection for inflammation and redness, and keep a journal documenting any possible side effects that might be attributed to the vaccine, such as headache, fever, or rash. After several rigorous animal studies including those with primates, this vaccine has been shown to have very few side effects, but there is still the possibility of unknown side effects in humans.
Study population:
Healthy volunteers ages 11–50.

Inclusion criteria:
Participant is willing and able to:
1. Give informed consent to participate.
2. Receive two injections over a one-month period and be available for three follow-up visits and blood draws during the following three-month period.
3. Keep a detailed journal documenting the condition of the injection site and any side effects.
4. Give consent to enter de-identified leftover blood samples into a national biobank for future research.

Exclusion criteria:
1. Nursing or pregnant women, or women planning on becoming pregnant during the trial.
2. Participants involved in any other clinical trials.
3. Participants who have had adverse reactions to vaccines in the past, or have serious health concerns that may be complicated by participation in this vaccine trial.

Biobank: A storage facility for biological materials used in medical research.
De-identify: To remove personal information such as name, medical record number, or study code from a genetic sample so that the sample cannot be linked to a specific individual.
Exclusion criteria: Any of the conditions that would disqualify someone from participating in a study.
Inclusion criteria: All of the conditions that must be met for someone to participate in a study.
Informed consent: A process that outlines required elements of research participation, including its risks and potential benefits, to help someone decide whether to participate. An informed consent form is used to convey essential information and is signed by the participant if he or she decides to join the study.
Open label: The term for a study in which participants and staff know which study arm (treatment or placebo) participants are in; there is no “blinding.”
Randomization (randomized): The process of assigning study participants to two or more alternative treatments by chance, such as by flipping a coin or rolling a die.
Comparative DNA Analysis of Samples to Isolate Markers for Genetic Predisposition

**Background:**

Genetic testing is used to identify particular changes within chromosomes, genes, or proteins. The most common use of these tests is to identify whether an individual carries a gene for a particular disease or genetic condition. However, genetic tests can also be used to determine whether an individual is genetically predisposed to a particular trait or characteristic. A genetic predisposition is when a person has a greater likelihood of expressing a certain trait based on her genetic material, such as having a gene that is known to be related to an increased chance of breast cancer.

**Current treatment:**

Not applicable to this research study.

**Purpose:**

To examine the genetic basis of mental and physical traits that may be key to becoming a “superstar” athlete, or engaging in extremely violent and even criminal behavior.

**Official title:**

Comparative DNA Analysis of General Population Samples and Specialized Population Samples to Isolate Genetic Predisposition Markers

**Detailed description:**

This study will compare the existence of known genetic markers within individuals in a specific population (athletes and individuals convicted of violent crimes) and those of the general population (individuals who do not fit into either of these categories).
Study Population:
1. Professional athletes who are considered “superstars” as determined by being in the top 5% of all professional athletes.
2. Individuals convicted of violent crimes.
3. Individuals ages 13–35 who have in the past participated or currently participate in athletic events.
4. Individuals ages 13–35 who do not participate or have not participated in athletic events.
5. Individuals ages 13–35 who have been in trouble for fighting, harassment, etc.
6. Individuals ages 13–35 who have not been in trouble for fighting, harassment, etc.

Inclusion criteria:
Participant is willing and able to:
1. Give informed consent to participate.
2. Provide a cheek-swab DNA sample that will be analyzed for both genetic markers.
3. Provide a behavior analysis survey.

Exclusion criteria:
1. Use of steroids within the last 12-month period.

Exclusion criteria: Any of the conditions that would disqualify someone from participating in a study.

Genetic predisposition: A greater likelihood of expressing a certain trait based on a person’s genetic material (e.g., someone may carry a gene that is known to be related to an increased chance of breast cancer).

Inclusion criteria: All of the conditions that must be met for someone to participate in a study.

Informed consent: A process that outlines required elements of research participation, including its risks and potential benefits, to help someone decide whether to participate. An informed consent form is used to convey essential information and is signed by the participant if he or she decides to join the study.
**Instructions:** Cut out the arrows and attach one to each research study seeking participants.

Would definitely NOT participate

Would definitely participate

Would definitely NOT participate

Would definitely participate

Would definitely NOT participate

Would definitely participate

Would definitely NOT participate

Would definitely participate

Would definitely NOT participate

Would definitely participate