

FDA DOCUMENTATION FOR THE GENERIC CLEARANCE OF FOCUS GROUPS (0910-0497)

Focus groups do not yield meaningful quantitative findings. They can provide public input, but they do not yield data about public opinion that can be generalized. As such, they cannot be used to drive the development of policies, programs, and services. Policy makers and educators can use focus groups findings to test and refine their ideas, but should then conduct further research before making important decisions such as adopting new policies and allocating or redirecting significant resources to support these policies.

TITLE OF INFORMATION COLLECTION:

Upper Limb Prosthetic User Needs and Preferences Study: Focus Group Protocol

DESCRIPTION OF THIS SPECIFIC COLLECTION

1. Statement of need:

Upper limb amputees' needs are not being fully met by current prostheses, as evidenced by prosthesis rejection, non-wear, and user reports on challenging activities. Emerging technologies such as novel robotic limbs, implantable electromyography (EMG) electrodes, and electrical stimulation for sensory feedback are promising solutions to some of the challenges faced by amputees, but pose additional risks. Prosthesis users and amputees who have rejected prostheses have previously been surveyed about specific technologies they would like, or specific lists of activities they may find difficult. These approaches do not fully capture user needs, because it is difficult for users to map technical advancements or specific activities to their individual experiences with a prosthesis. In a future study, we plan to clearly define upper limb prosthesis user needs and preferences using a national survey of individuals with upper limb amputation. In preparation for this study, we will conduct focus groups to develop the survey instruments and select benefits and risks that are most important to a group of amputees. Findings from this focus group study will contribute to the subsequent development of a large scale survey instrument, in which we will acquire a more complete understanding of how novel technologies could address real user needs and preferences to inform implementations of new technologies and regulatory decision-making. This future study, a collaboration with the VA/DoD, will have a sufficiently large sample size (approximately 1,000) to lead to statistical results that are generalizable to the affected population.

2. Intended use of information:

The aim of this survey is to prepare for a study on the needs and preferences of upper limb amputees, specifically to: 1) Identify user needs, and common language used to articulate these needs, through a series of focus groups on activities affected by amputation and prosthesis use, and experiences with prosthesis use; and 2) Assess preferences for emerging upper limb prosthesis technologies that interface with the peripheral nervous system, which will likely offer improved benefits, with increased risks. Findings from the focus group will aid in the development of a larger benefit-risk tradeoff survey.

3. Description of respondents:

There will be 3 focus groups. Each will consist of 6-8 participants, who will be upper limb amputees recruited via flyers at the proposed facility sites, prosthetic clinics, amputee interest groups, and using the Amputee Coalition's national email listserv, as well as through snowball recruitment, in which interested participants may give study information to their own contacts.

Each group will be heterogeneous in age (18 and older) and prosthesis use (myoelectric, cable-driven, hybrid, passive, or none).

4. Date(s) to be conducted and location(s):

Dates: June 2016

Location: Two focus groups will be conducted remotely using WebEx software. One focus group will be conducted at one of the following sites (based on recruitment geography): Johns Hopkins University, UCSF, or a prosthetics clinic.

5. How the Information is being collected:

Three focus groups of adult upper limb amputees will be convened to discuss unmet needs and preferences. First there will be a guided discussion (Appendix A) on challenges participants have had with their amputations, what they like and dislike about prostheses, experiences with pain, and what upper limb prosthesis users want from their prostheses. Subjects will also use point allocation to rank the importance of potential device benefits and risks. Prior to attending a focus group, participants will complete homework with an initial point allocation exercise on potential benefits and risks associated with surgery, prosthesis hardware, prosthesis control, sensory feedback, and ongoing health considerations (Appendix B). This homework will allow the focus group to quickly narrow a list of over 30 potential features to 12 of the most important features, which they will then assign importance weights. The features included in the homework were developed by a panel of physicians, engineers, researchers, regulatory reviewers, and an occupational therapist, with additional insight from informal conversations with two upper limb prosthesis users.

During the focus group sessions, audio recordings and transcripts of the focus groups sessions will contain information about subject health status, ability, and preferences. Subjects will only use first names during the focus groups. Data will be protected in a locked file cabinet or password-protected, encrypted storage in a locked lab.

6. Number of focus groups:

3

7. Amount and justification for any proposed incentive:

Subjects will receive gift cards worth \$30 per hour spent in each session, and an additional \$10 gift card for completing the point allocation homework. Therefore, the maximum incentive per respondent is \$70 (two \$30 incentives for in-session participation and \$10 for homework).

8. Questions of a Sensitive Nature:

There will be no questions of any sensitive nature.

9. Description of Statistical Methods (I.E. Sample Size & Method of Selection):

3 focus groups with 6 – 8 participants each. Patients/participants will be recruited from prosthetic clinics, amputee interest groups, and through snowball recruitment, in which interested participants may give study information to their own contacts.

The importance weights assigned to specific benefits and risks as a result of the point allocation exercise completed in the focus groups will be recorded. The responses will be reported using only descriptive statistics. The average number of points allocated to each benefit and risk will be compared, allowing for a direct comparison of the value placed on different benefits and risks. The importance of these benefits and risks will be used to determine which attributes to include in stated preference approaches to benefit and risk weighting in the larger survey.

BURDEN HOUR COMPUTATION (*Number of responses (X) estimated response or participation time in minutes (/60) = annual burden hours*):

Type/Category of Respondent	No. of Respondents	Participation Time (minutes)	Burden (hours)
Focus Group Participants			
Homework	24	1.0 (60 minutes)	24
Focus Group		2.0 (120 minutes)	48
Total	24		72

REQUESTED APPROVAL DATE: June 20, 2016

NAME OF PRA ANALYST & PROGRAM CONTACT:

PRA Analyst: Amber Sanford
 301-796-8867
Amber.sanford@fda.hhs.gov

Principal Investigator:
 Eugene Civilico, Ph.D
 Health Physicist
 FDA/CDRH/OSEL
 10903 New Hampshire Ave.
 WO62-1215
 Silver Spring, MD 20993
 301-796-0577 (v)
 301-796-9927 (f)
eugene.civilico@fda.hhs.gov

FDA CENTER:

Appendix A: Focus Group Script

- For an in-person focus group:
 - Ensure each participant who did not fill out the homework online has brought a completed homework packet at arrival. Each participant who filled out the homework online can pick up the printout of their completed homework from the moderator or assistant. If a participant does not have a completed homework packet, they may not participate.
 - Individually with each participant, review consent form and obtain informed consent, with opportunity for questions. Offer each participant a copy of the consent form.
- As a group, greet and thank participants for their participation. Introduce moderator and any assistant(s).
- Briefly explain purpose of research, optionally:

We're conducting research on what upper limb prosthesis users want from their prostheses. So we'll be asking about your experiences with amputation and prostheses.
- Provide initial information:
 - Approximately two hours
 - Any breaks
 - Any cell phone rules
 - For an in-person focus group, any information about restrooms, snacks, drinks, etc.
- Focus group details:
 - Ask participants to speak clearly and only speak one at a time.
 - Ask participants to fill out nametag (in-person) or display name (WebEx) with first name, only use first names, respect everyone's confidentiality and not repeat conversation details outside of focus group.
 - Establish moderator's role and encourage individuals to respond to each other and to speak directly to others in the group.
 - Express interest in both majority and minority viewpoints, common and uncommon experiences.
- Check that everyone is ready, and then turn recorder on.
- "This focus group is being conducted for the Upper Limb Prosthetic User Needs and Preferences Survey Study on DATE by MODERATOR and ASSISTANT. Start time CURRENT TIME."

SECTION A

- Introductions: first name, amputation level, prostheses used (if any).
- Topic 1: Biggest challenge participants have had with their amputations
As needed, follow-up probes, listening for specific types of activities:
 - Eating
 - Meal preparation
 - Dressing/grooming
 - House-keeping
 - Use of tools
 - Caring for others
 - Transportation

- Community
 - Communication
 - Sports/recreation
 - Professional/education
- Topic 2: For prosthesis users, what they like best about any prostheses they've used
 - Topic 3: For prosthesis users, what they like least about any prostheses they've used
As needed, follow-up probes, listening for specific challenges:
 - Strength
 - Range of motion
 - Endurance
 - Stability
 - Reflexes
 - Prosthesis moving the way I want it to move
 - Skillful with prosthesis/residuum
 - Sense of touch
 - Proprioception
 - Prosthesis feels like part of body
 - Prosthesis recalibration
 - Prosthesis maintenance
 - Topic 4: Whether participants have experienced pain, and whether that has had an impact on experiences with amputation and prosthesis use.
 - Topic 5: Participants' greatest worry or fear regarding amputation or prosthesis use.
 - Topic 6: Repeat study purpose (to understand what upper limb prosthesis users want from their prostheses), and invite any other comments to address this topic.

SECTION B

- Explain next section is for discussing the importance of potential prosthesis risks and benefits, and will use the homework they brought with them or that they filled out online.
- Explain this section has to do with new prostheses currently under development. These prostheses:
 - May use new approaches to give users improved control of the wrist and hand.
 - May provide different types of sensory feedback through the prosthesis.
 - May incorporate new robotic limbs.
 - May require additional surgery to install/use.
- Select 10 important features (approx. 2 per homework table) as a group and assign points to the selected features using the following process:
 1. a) Start on page 2 of homework, which has the first table. Each participant should give their most important feature from the homework, and explain why that feature was chosen.
 - ASSISTANT writes down each of the most important features on a sticky note tablet.
 - Check whether anyone has changed their mind about the most important features on list, or whether there are any comments about the features on the list.
 - Encourage group discussion to reach consensus on a single most important feature. If no consensus is reached, select the 2 features from the list that the group feels are the most important and skip the next line.

- b) Repeat the process for SECOND most important feature on the table.
2. Repeat the bracketed section for each table in the homework. After it has been completed for all tables, there should be 10 features. ASSISTANT should rewrite the 10 features on a new sticky note.
 3. The group discusses whether there are any features from the list that they would like to swap out for any features in any of the tables.
 4. The group assigns points to each of the 10 features selected from the homework tables. The more points given a feature, the more important it would be when choosing a new prosthesis. The group has 50 points to assign to the 10 features on the new list.

CONCLUSION

- Thank participants and explain how results will be used.
- “End time CURRENT TIME.”
- In-person focus group: Request participants’ homework on the way out and hand out compensation.
- Telepresence focus group: Confirm that recipients will receive compensation by mail.

[Following participant exit, moderator and assistant debrief with recorder still on.]

[Recorder off]

Appendix B: Point Allocation Homework INSTRUCTIONS

Thank you for participating in research on upper limb prosthesis user needs and preferences. You must complete a homework assignment before participating in the focus group. This homework should require less than one hour to finish. If you would like to record your answers to the homework by phone instead of using a computer or pen and paper to complete the homework, please contact Heather Benz at heather.benz@fda.hhs.gov to arrange a call.

CHOOSE ONE:

1. Online Homework

If you have a computer with an internet connection, you may complete the homework at this website: LINK. You are encouraged to use the website. You will not have to do any calculations, and your homework will be turned in automatically. If you complete the homework on the website, you do not need to fill in these printed pages. If you need any help with the website, please contact Heather Benz at heather.benz@fda.hhs.gov.

2. Paper Homework

Each page of this homework can be completed on its own, without looking at the other pages. There are five tables to fill out. Please completely fill out each table.

You will be thinking about new upper limb prostheses that are in development. These new prostheses come with new benefits and risks. You will decide how important these benefits and risks are to you.

These new prostheses may be different from existing prostheses in many ways, including but not limited to:

- They may be stronger limbs with different sockets.
- They may be controlled in new ways, and may give more control.
- They may give different types of sensory feedback through the prosthesis.
- They may require surgery to place sensors and stimulators inside the body. The surgery and devices may introduce new types of risks.

Each of the tables in this homework asks you to assign points to prosthesis features. The more points you give to a feature, the more important it would be to you when choosing a prosthesis. You may fill out the tables in any order. You may use extra paper to work on the tables. You must complete all of the tables before the focus group to participate in the focus group. You must turn in this homework in order to participate in the focus group study.

Panel 1: Risks

Imagine that you have 30 points to give to the 6 features described in the table [on this page](#). The more points you give a feature, the more important it would be to you when choosing a new prosthesis. In the table below, please write down the number of points you would assign to each feature. Please be sure that your total points add up to 30.

Points: ____	Whether surgery is needed Whether surgery is needed to place a medical device in your body to use one of the new prostheses. <ul style="list-style-type: none">• With any surgery, there is a risk of infection.• Surgery might cause short-term pain. Short-term pain may last 3-6 months.• There may be a risk of cutting a nerve during surgery. If a nerve is cut, you could lose some muscle control or some of your sense of touch.• If the device fails, you may need to have more surgery to have the device removed or repaired.• The prosthesis you choose may become outdated. Because of the surgeries you have gone through, you may not be a candidate for even newer prostheses.
Points: ____	Number and size of incisions If surgery is needed, there might be one or several incisions (cuts with a surgical tool) into your residual hand, arm, shoulder, or back. These incisions might be small or large. Large incisions may cause large scars that last for months or years. After surgery, each incision may require some care. There may be short-term pain in the area around each incision. With each incision, there is also a risk of infection.
Points: ____	Experiences during recovery from surgery <ul style="list-style-type: none">• With some of the new prostheses, you may be able to leave the hospital on the same day. With some other types of new prostheses, you may need to stay in the hospital for a few days to recover.• You may have limitations after surgery for some length of time. These limitations may last for days or months.• You may have pain, weakness, or unusual sensations, and may be unable to wear a prosthesis while you recover from surgery.
Points: ____	Skin injury You may have no skin irritation or injury with some prostheses. With other prostheses there may be a risk that your skin could be injured. In that case you could need treatment or need to refit the prosthesis.
Points: ____	Compensatory movements and overuse injuries With some prostheses, your movements will be similar to movements with an intact limb. These prostheses put you at less risk for long-term pain or injury. With some prostheses, you may use movements that are different from when a person is using an intact limb. These types of movements can lead to long-term pain or injury.
Points: ____	Risk of deciding not to use the prosthesis After you have surgery and learn to use the new prosthesis, you may decide you do not like the new prosthesis enough to use it. About 20 out of 100 people decide to stop using current prostheses that do not require surgery. The risk with new prostheses may be lower or higher.

Total points: 30

Panel 2: Prosthesis Interface

Imagine that you have 30 points to give to the 6 features described in the table [on this page](#). The more points you give a feature, the more important it would be to you when choosing a new prosthesis. In the table below, please write down the number of points you would assign to each feature. Please be sure that your total points add up to 30.

Points: ____	<p>Device location Where the medical devices for controlling the prosthesis and giving you a sense of touch are located. Some current prostheses use sensors on the skin surface. Using these prostheses does not require surgery. New prostheses may place medical devices inside the arm or in the back. These devices may be attached to muscles, nerves, or the spinal cord.</p>
Points: ____	<p>Prosthesis socket The new prostheses may be attached to your body in different ways:</p> <ul style="list-style-type: none"> • Some may use a typical socket or harness. • Some may use a more advanced harness. This harness would distribute the weight of the prosthesis around your arm, shoulder, and back. • Some may be attached using a surgery called “osseous integration.” The surgery would attach a post to your arm bone. You may be able to move your arm more freely, it may be easier to put the prosthesis on, and you may feel that the prosthesis attachment is more secure. You may have less pain and skin irritation. However, there is a risk of infection, the post might loosen or bend, and the bone could break.
Points: ____	<p>Comfort You may feel no discomfort with some prostheses. With other prostheses you may feel some discomfort or pain.</p>
Points: ____	<p>Ease of donning and doffing How easy it is for you to put on and remove the prosthesis. Some new prostheses may take only a few seconds to put on. Others may take as much as a few minutes to put on.</p>
Points: ____	<p>Time between intention to move and actual movement For some new prostheses, you will not notice a delay between when you want the prosthesis to move and when it moves. For some new prostheses, the delay might be more noticeable, as long as 2 seconds.</p>
Points: ____	<p>Arm ownership You may be more likely with some new prostheses to feel like your prosthesis is a part of your body. It might feel like it “belongs” to you. Because of this feeling, you may be more likely to forget that you have a prosthesis.</p>

Total points: 30

Panel 3: Prosthesis Usability

Imagine that you have 30 points to give to the 6 features described in the table [on this page](#). The more points you give a feature, the more important it would be to you when choosing a new prosthesis. In the table below, please write down the number of points you would assign to each feature. Please be sure that your total points add up to 30.

Points: ____	Training time It may take you some time to learn to use the new prostheses. It may take you as little as one week to become comfortable using some of the new prostheses. It may take you as long as two months to become comfortable using some others.
Points: ____	Ability to do daily tasks You may be able to do new tasks with some new prostheses. These may include self-care tasks, household tasks, or office tasks.
Points: ____	Difficulty of doing daily tasks With some new prostheses, some of your daily tasks may be easier to do. For other new prostheses, some of your daily tasks may be harder to do.
Points: ____	Speed of doing daily tasks With some new prostheses, you may be able to do some of your daily tasks faster. For other new prostheses, you may do some of your daily tasks more slowly.
Points: ____	Compatibility with terminal devices The terminal device on a prosthesis is the part that is used like a hand. Some of the new prostheses may only have one option for the terminal device. Other new prostheses may let you change between more than one terminal device. For example, you may have access to different types of hands and grippers.
Points: ____	Resistance to environmental exposure Whether the prosthesis will break down in different conditions. Some new prostheses will: <ul style="list-style-type: none">• Be able to get wet• Work well even in a dry climate• Work well even when dirt gets on them• Continue to work even when they are hit repeatedly or used to pound on something repeatedly

Total points: 30

Panel 4: Prosthesis Hardware

Imagine that you have 30 points to give to the 6 features described in the table [on this page](#). The more points you give a feature, the more important it would be to you when choosing a new prosthesis. In the table below, please write down the number of points you would assign to each feature. Please be sure that your total points add up to 30.

Points: ____	<p>Prosthesis weight Some prostheses might weigh less than your arm would weigh. Others might weigh more than your arm would weigh.</p>
Points: ____	<p>Recalibration frequency You may need to run a program so the prosthesis understands your intended movements. You may also need to run a program so the prosthesis gives you the correct sense of touch. Some new prostheses may need to be recalibrated less often than once per day. Other new prostheses may need to be recalibrated more than twice per day.</p>
Points: ____	<p>Noise during use How much noise the prosthesis makes while you're using it. Some new prostheses may be as loud as a whisper. Other new prostheses may be as loud as a normal conversation while you're using them.</p>
Points: ____	<p>Speed, once movement has started How fast the prosthesis will move. With some new prostheses, you may be able to move as quickly as with an intact hand. For other new prostheses, you will move more slowly. It may take as long as 10 times the time it takes to do something with an intact hand.</p>
Points: ____	<p>Length of time between charging prosthesis The prosthesis will use a battery, which will need to be recharged routinely. You may have more than one battery so you can charge one while using another. For some prostheses, you may be able to go a full day before a recharge is necessary. For some, you may have to recharge the battery every 4 hours.</p>
Points: ____	<p>How often maintenances, replacements, repairs, or upgrades are required You might need to send your prosthesis back to the manufacturer for repairs. Some of the new prostheses might need monthly repairs. Other might need repairs as little as once per year.</p>

Total points: 30

Panel 5: Prosthesis Functionality

Imagine that you have 30 points to give to the 6 features described in the table [on this page](#). The more points you give a feature, the more important it would be to you when choosing a new prosthesis. In the table below, please write down the number of points you would assign to each feature. Please be sure that your total points add up to 30.

Points: ____	<p>Visual attention needed</p> <p>Most current prosthesis users must always watch their prostheses while they are using them to do something. You may be able to use some of the new prostheses without always watching them. You may be able to do this because you will feel where the prosthesis is positioned, as you would with an intact hand.</p>
Points: ____	<p>Device control</p> <p>How much control you will have over moving the prosthesis fingers and wrist. Some new prostheses may be similar to prostheses you use now, such as the ability to open and close a grasp. Other new prostheses might give you the ability to control individual fingers and the wrist. Moving each finger and the wrist would feel like using an intact hand.</p>
Points: ____	<p>Prosthesis gripping and lifting strength</p> <p>Some new prostheses may only be able to grip and lift light objects that weigh about 5 pounds. Other new prostheses may be able to lift very heavy objects that weigh 50 pounds.</p>
Points: ____	<p>Sensory feedback</p> <p>Current prostheses do not give you a sense of touch. Some new prostheses with implanted stimulators may give you a sense of touch, give you a sense of temperature, and let you feel where your fingers and wrist are when you move them.</p>
Points: ____	<p>Intuitiveness of sensation</p> <p>Some new prostheses may give you a sense of touch. However, where you feel the sense of touch may vary.</p> <ul style="list-style-type: none"> • For some new prostheses, the feeling may be indirect. For example, you may feel touch on your upper arm when your prosthesis fingertip has touched something. • For other new prostheses, the feeling may be direct and intuitive. For example, you may feel the fingertip touch on your fingertip.
Points: ____	<p>Precision</p> <p>How precisely you can control the prosthesis fingers. Some new prostheses may be precise enough to type on a computer keyboard with the fingers. Some new prostheses may be precise enough to type on a smaller cellphone keyboard with the fingers.</p>

Total points: 30