Frequently Asked Questions about O&P Research

General Human Subject Research FAQs

What is human subject research?

The definitions below are from HHS 45 CFR 46.102, the Federal Law that mandates the creation and use of IRB's.

> ***Human subjects***: "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Activities in which a researcher collects private, identifiable information about third parties would meet the definition of 'human subjects.' Issues of importance for human subjects concern whether informed consent is administered and participation is voluntary, maintenance of confidentiality, whether issues of risk to individuals have been addressed adequately. Note that the definition applies to 'living' subjects. The regulations do not apply to individuals who are deceased. Analysis of Census data does not require IRB approval."
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> ***Research***: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. Research does not include standard clinical treatment and procedures UNLESS it involves a systematic investigation and/or the results will be published or presented in public. However, HIPAA protects data and information about patients, and HIPAA regulations should be consulted before using data routinely collected on patients in any type of study. Instead of IRB approval, approval by a *Privacy Board* may be required. Most surveys meet the definition of research, including internet and computer-based surveys. Student research may or may not meet the definition, and the IRB at the respective institution at which the student is enrolled should be consulted. There are issues related to the purpose, dissemination of results, privacy, vulnerable populations, confidentiality and the potential to harm subjects that may need to be reviewed. Evaluations of teachers, students, academic programs, and conferences or workshops do not constitute research, nor do sample surveys of employee satisfaction. But if the data are going to be used *to contribute to generalizable knowledge*, especially via presentation at a conference or publication, the activity is considered to be research. If you are unsure, contact an IRB."

Where can I find more information about conducting research with human subjects?

Universities, hospitals, and medical organizations have IRBs with jurisdiction over research funded from any source, and may be able to answer your questions. Independent IRBs exist and can be found by doing an internet search. Many IRBs require the completion of an online course from CITI which provides basic information about IRB requirements and results in certification for biomedical research

involving human subjects. For example, NCOPE requires all graduates of CAAHEP-accredited O&P programs as well as NCOPE residency directors to complete its CITI modules. If you plan to submit a protocol through an existing IRB, you should contact them to determine their requirements with respect to certification. Websites on federal regulations include the Department of Human Health & Services Office for Human Research Protection (OHRP) and the Federal Drug Administration device classification websites. The OHRP website also has a Frequently Asked Questions About Human Research document that may be helpful.

I would like to conduct a research study. Where do I begin?
It all depends on what is meant by "research." It could mean the development and evaluation of a component or a procedure that does not involve any human subjects, or it could mean undertaking a study that involves human subjects. In either case you could begin by examining research articles published in one of the O&P journals such as the *Journal of Prosthetics and Orthotics*. A search of the literature for previous work related to your idea could produce articles that would help you refine and improve your idea. Note the way in which the articles are structured. Usually there is a research hypothesis, a description of the methods, the presentation of results, a discussion of results, and a conclusion. Once you are familiar with the components of a research study, you might contact a university or manufacturing firm and explain your idea and base your next step on their response. You may find more information in the Academy's O&P Research Reference Guide.

How do I conduct a literature search? What resources are available?
The Academy has a number of references online. You may need your Academy member username and password to log on. Pages of interest developed by the Academy include:

O&P Research Reference Guide
A Guide to a Simple Research Project
Evidence-Based Practice Module on the Academy's Paul E. Leimkuehler Online Learning Center (OLC)

Several medical-related search engines, such as OVID exist for finding peer-reviewed literature, however, they often require membership. Researchers affiliated with an academic setting often have access to these. Those in a clinical setting may freely access one of the largest health research publication indices, Medline, through the PubMed website.

If I find a journal article, how do I obtain it?
Members of the Academy have access to the *Journal of Prosthetics and Orthotics (JPO)*. There are several freely available journals, such as *Journal of Rehabilitation Research and Development (JRRD)*, where no membership is necessary. Research funded by the National Institute of Health (NIH) is also freely available, so individual articles may occasionally be found. Similar to *JPO*, other journals, such as *Prosthetic Orthotic International*, require that you are either a member of the organization that publishes the journal (ISPO in this example) or that you pay for the article on a *per diem* or per article basis. Academy members also receive quarterly Literature Updates via email, which provide links to abstracts or the full-text article, in cases where the article is freely available.

Where can I find funding sources for a research study?
There may be several potential sources. Partnering with a university can be very helpful since interested faculty may do much of the work required to prepare and submit a competitive proposal to a funding

entity outside of the university, or the faculty member may be aware of internal funding opportunities within the university. There are also two orthotic and prosthetic related sources:

Academy Research Funding Guide
The Orthotic and Prosthetic Education and Research Foundation (OPERF)

I am interested in surveying persons working in O&P for a research study. Can I obtain the Academy's email list to recruit participants?

Normally, the Academy uses its email list only for the official business of the Academy. The email addresses of its members are viewed as confidential information. If circumstances exist which may make it desirable to use the Academy email list, requests can be directed to the Executive Director of the Academy for review. An alternative means for contacting practitioners is through the OandP listserve.

I am applying for a research grant and am interested in receiving a letter of support from the Academy. Is this possible and if so, whom may I contact?

On occasion a researcher may find that his/her project may align well with the goals of the Academy and may wish to request a letter of support from the Academy for the concept of the research project to include with the grant application. In such instances, the researcher may send a formal request to the Academy for a letter of support. Any such request should include the grant proposal, information related to the specific grant for application, timeline, and primary investigator's contact information. This request should be directed to the attention of the Academy's Executive Director and must be approved by the Academy's Executive Committee and Research Council prior to issuance. The Academy reserves the right to decide whether or not to support any research based on its potential o to benefit the O&P community, the quality of the grant proposal, and how closely the research matches the mission and goals of the Academy. Providing a letter of support to one research team does not preclude the Academy from providing a letter of support to another research team competing for the same grant. Questions regarding this should be directed to the Executive Director of the Academy.

Institutional Review Board FAQs

What is an IRB and what is its purpose?

An Institutional Review Board (IRB) is a board consisting of at least five members representing various scientific and professional areas that reviews research plans to determine if the research could bring potential harm to the research subjects who will be involved in the research. It approves research protocols once a majority of the members believe the research plan meets certain requirements intended to protect the participants in research. Any use of federal funds for research requires IRB approval and a Letter of Informed Consent that is administered to participants. Details can be found in the Code of Federal Regulations Title 45, Part 46, and Title 21, Parts 50 and 56. Most academic institutions or medical facilities that conduct research on human subjects are connected to an IRB. Private IRBs do exist for researchers not connected to an organization with an IRB, however, these sometimes may have fees associated with review.

When is an IRB required?

An IRB is required whenever the definitions of "research" and "human subjects" applies (see "**What is human subject research?**"). If in doubt, contact your local IRB.

Where can I obtain more information about IRBs?

Universities, hospitals, and medical organizations have IRBs with jurisdiction over research funded from any source, and may be able to answer your questions. Independent IRBs exist and can be found by doing an internet search. Many institutions require the completion of the CITI training course which

provides basic information about IRB requirements and results in certification for biomedical research involving human subjects. If you plan to submit a protocol through an existing IRB, you should contact them to determine their requirements with respect to certification. Websites on federal regulations include:

- Department of Human Health & Services Office for Human Research Protection
- Federal Drug Administration Medical Devices
- National Institutes of Health Office of Human Subjects Research

How do I find an IRB to review my project?
Most universities and institutions that sponsor medical education programs have an IRB that will be able to review and approve projects. To locate and IRB, visit: OHRP Database for Registered IRBs

What if I want to use an IRB not affiliated with a particular university? Are there commercial IRBs?
Yes. A list of commercial IRBS can be found at http://www.circare.org/info/commercialirb.htm. Each identified commercial IRB has a hotlink to their homepage. A search can also be conducted at http://ohrp.cit.nih.gov/search/ provided you have the name of the IRB.

Would it help if my clinical practice set up its own IRB?
An IRB must meet federal guidelines and obtain a Federal Wide Assurance. It must be registered with the US Department of Health and Human Services (HHS) Office for Human Research Protection (OHRP). There are procedures for accrediting IRBs. Setting one up and maintaining it may require full-time professional staff with a background in the operation of an IRB, as well as finding at least five individuals qualified to serve on it. You will likely discover that it will not be cost-effective to set up your own IRB. Research hospitals and universities find them expensive to fund and maintain. Federal interpretation of the law and federal oversight of IRBs is dynamic, with requirements and definitions of best practices evolving continuously. The director of an IRB must pursue continuing education on IRBs to remain current.

Would I have any problem publishing my research if it did not have IRB approval?
If it involved human subjects, yes, it would be difficult to find a journal that would accept your research for publication. All reputable journals and health care publications require authors to provide a statement verifying that the protocol was approved by the equivalent of an IRB and that research subjects read and signed a Letter of Informed Consent. This applies to research based on surveys of health professionals, too. The International Committee of Medical Journal Editors (ICMJE) created the Uniform Requirements for Manuscripts that participating biomedical journals use to consider papers submitted for publication. You should also consult the specific journal to which you plan to submit your article.

What information will the IRB require?
A complete description of your project, including the title, purpose and duration of the project, along with information on how you will recruit and select your subjects, and where the study will take place should all be included. Clearly describe the scientific research design and what procedures will be used (e.g., interviews, questionnaires, laboratory testing). It will be very important to include background on the potential risks and benefits of your study to participants and what follow-up will occur with the subjects. You will also be required to develop a letter of informed consent that must be signed by the subject prior to data collection. More information may be found by contacting your local IRB and/or

going to the National Institutes of Health webpage about Criteria for Institutional Review Board (IRB) Approval of Research Involving Human Subjects.

What is a Letter of Informed Consent?
It is a letter that all research subjects must read and sign before any experiments in which they participate can be undertaken and any data collected. By signing it, research subjects indicate that they are aware that an experiment is being conducted, what will occur, and what the possible consequences to them may be. Elements that should be present in the letter include a.) a description of the research and its purpose; b.) risks or discomforts that may occur; c.) benefits that may occur to them or to others as a result of the research; d.) alternatives to participation; e.) an explanation of how confidentiality will be maintained; e.) what medical care will be provided if any research-related injuries occur; and f.) how they may drop out of the study as well as what is required on their part to remain in the study. IRB approval requires submission of the Letter of Informed Consent for review. Consent is a process which routinely includes a written statement however, it may be more complicated if literacy and/or cognition are issues and if minors are being studied. More information may be found at the National Institutes of Health (NIH) website about Guidelines for Writing Informed Consent Documents.

If I do go through an IRB, is it likely that my protocol will not be approved?
It is not uncommon for the IRB to send back a research proposal for further modifications prior to approval. Most O&P research involves "not greater than minimal risk," which helps to advance the proposal through the IRB approval process. Chances of receiving approval are often increased if you are able to pair with a researcher whose organization has a liaison to the local IRB, as he/she may be more familiar with the process and be able to better direct your application. Consult your local IRB if you have any questions regarding whether or not your protocol is likely to be approved.

How long does it take to get IRB approval?
Approval may take anywhere from a few weeks to a couple of months. Communication with the IRB staff is key to identifying timelines necessary to get through the IRB process in a timely manner. Incomplete applications (including insufficient copies) represent one of the main reasons applications are delayed.

When may I begin data collection for my study?
You must receive written approval from the IRB before beginning participant recruitment, data collection, or data analysis.

Can the IRB approve a project "retroactively?"
No. There is no provision in the federal regulations that allows for IRB approval of research that has already been conducted.

Is FDA approval required prior to submission for IRB approval?
This would be a rare situation. While orthoses and prostheses are classified by the FDA as "medical devices," they are usually grouped under Device Class I and are exempt from FDA regulation. One exception to this is that craniofacial orthoses used to treat plagiocephaly are categorized as Class II devices and do require FDA approval for fabrication and fitting. O&P devices are also not usually considered "investigative devices" unless they are placed inside the body. O&P devices do not meet the definition of "custom devices" by the FDA. If they did, there would be a defined policy for research involving them. They are defined as "customized devices," and thus escape the much closer scrutiny of the FDA's "custom devices." However, if you claim that the device or a substance will prevent, diagnose,

alleviate, treat, or cure a disease, then it may become subject to FDA regulation. Again, an IRB should be consulted if you are in doubt.

If I am doing a survey, do I need to submit my proposal to the IRB?
Yes, if the study meets the definition for research with human participants (see question #7 – When is an IRB required?). If in doubt, contact your local IRB.

I am a clinician interested in conducting research on one of the devices I routinely use that I obtain from a manufacturer. Specifically, I wish to examine what patients like and dislike about the device using a survey and also how frequently maintenance is needed on the device. Does this require IRB approval?
If it involves only the collection of data on the outcomes of your standard clinical practice, it does not require IRB approval unless you plan to publish the results, present them, or make them available to the public in some manner. However, you must make sure that you satisfy HIPAA requirements. If in doubt, contact your local IRB for further guidance.

I am a clinician and I have developed several new devices that I want to test on my patients. They include a pneumatic device that accommodates residual limb volume fluctuation in a transfemoral prosthesis and a new anti-rotation device which permanently attaches to a socket but is secured to the liner using a hook and loop material. Do I need IRB approval?
Many practitioners are also inventors. Based on the description above, these are not customized devices like sockets, but have more in common with manufactured products like feet and liners. In order to determine if IRB approval is required, several questions must be answered including: Do the devices involve the use of non-standard procedures or are they invasive in any way? Do you plan to advertise and market the devices? Is one of your goals to publish the results of your research? Could any of the elements presented in a Letter of Informed Consent influence an individuals' willingness to participate in your research? Is there a risk that the identity of the participants could be revealed or are any privacy issues involved? Will federal funding be sought for further development of the ideas? Will prisoners, minors, or patients with mental impairment be used as subjects? Is there any possibility that the devices could harm patients or create costs for them if they do not work as well as anticipated? (Remember that costs involve not only money, but also time, embarrassment, and frustration.) Does your state require an IRB approval even if no federal funding is anticipated? If the answer to any of these questions is "yes," then an IRB should be consulted for advice. If in doubt, contact your local IRB for further guidance.

HIPAA-Related FAQs
What should I be concerned about if I use data from my patient files in research?
HIPAA governs the allowable use and disclosure of protected health information (PHI). PHI refers to data which can be linked to a particular individual or enable an individual to be identified. Identifiers include name and social security number, elements of dates other than the year, telephone numbers, email addresses, medical record numbers, vehicle numbers, device identifiers and serial numbers, biometric identifiers, full face photographic images, and any other identifiers. Under HIPAA regulations, researchers must have valid authorization for all uses and disclosures of PHI. This means that the individual patient must give permission for PHI to be associated with any use of their medical data or their use to identify them in any way for research. Also, patient rights are an evolving area and state law plays a role; state laws may be more stringent than federal laws. An IRB or a Privacy Board should be queried prior to any use of patient data.

Can I use protected health information (PHI) in my research?
Protected health information (PHI) includes any individually identifiable health information. This may include, but is not limited to the following data: name, address, birthdate, medical records, medical diagnosis, physician name, or x-rays. Generally direct authorization from the subject is necessary to use PHI in research. During the "preparatory to research" a researcher may be granted access to PHI without subject authorization in order to determine if sufficient subjects exist for the study. However, the researcher may not remove any PHI from the medical record nor may they directly contact the potential subject. In the case where PHI will be used to conduct research, a waiver of authorization must be obtained through your local IRB or Privacy Board. This would likely be included in the IRB application and perhaps in an Informed Consent Document. The HIPPA Authorization form signed in the clinical setting may not be sufficient to cover any research conducted at that site, as it is usually worded to cover the release of information for treatment and billing purposes. Therefore, if you are uncertain whether or not authorization is required, you should contact your local IRB. More information about this may be found at the NIH website for Clinical Research and the HIPPA Privacy Rule.

What if I need to use PHI for my research but getting patient authorization is not possible?
You will need to get a waiver from either an IRB or a Privacy Board. The guidelines require that only the minimum amount of PHI necessary may be disclosed and your records must indicate that the disclosure was for research purposes.

What is a Privacy Board?
A Privacy Board consists of at least two members and meets the requirements at section 164.512(i)(1)(i)(B) of the Privacy Rule. A Privacy Board may act upon requests for waivers and alterations of the authorization requirement to permit covered entities to use and disclose PHI for research. Privacy Boards and IRBs may coexist. According to the NIH, "a Privacy Board must have members with varying backgrounds and appropriate professional competency as necessary to review the effect of the research protocol on the individual's privacy rights and related interests and include at least one member who is not affiliated with the covered entity, not affiliated with any entity conducting or sponsoring the research, and not related to any person who is affiliated with any of these entities." More information may be found at NIH's website for Privacy Boards and the HIPPA Privacy Rule.

What is a "limited data set?"
It is a set of data for which only the city, state, Zip Code, and dates of service remain to identify subjects. It represents a compromise between data sets having identifiable PHI and fully de-identified PHI. Use of it requires neither a waiver nor an authorization from an IRB or Privacy Board, but the user must enter into a "data use agreement" with the patient.

Outcome Measures- Related FAQs
Why should I use outcome measures in my practice?
Outcome measures can help you evaluate, document, and demonstrate the benefits of orthotic and/or prosthetic services relating to treatment goals. Some outcome measures may help to evaluate and document the need for continued orthotic and/or prosthetic services.

I'm interested in using outcome measures in my practice. How do I decide which one to use?
You need to think about what question you want answered and what type of measures you want to document. Objective measures will help to quantify treatment plans and goals related to each patient's needs. Start by first setting treatment goals for the patient. Then specific outcome measures may be

utilized to set the baseline measurement for the patient and should be consistently collected throughout the treatment process.

What is the difference between a clinical outcome measure and patient-reported outcome measure?
Clinical outcome measurements are objective measures that are taken for the purpose of evaluating an orthotic or prosthetic treatment. Examples include the "10-Meter Walking Test" and "Timed UP and Go." The patient would perform the activity with and without the intervention and a comparison can be made. Patient-reported outcomes are usually survey based and may be more subjective in nature. A patient-reported outcome measures the patient's perspective on the treatment. Questions that may be asked of the patient include, "Do you feel better about yourself? Are you able to perform ADL(s) better with your intervention? Did our services meet your expectations/goals?" Objective clinical measures will not be influenced by the patient's personal feelings, interpretations, or prejudice. Both clinical measures and patient measures may be assessed against published clinical data.

What is the difference between a validated and non-validated outcome measure? From a clinical perspective, does it matter which type of measure I use?
"Valid" indicates the extent to which a measure is actually measuring what it was intended to measure. A measure's level of validity depends on the way that it is performed and on the population on whom it was tested (e.g., transtibial amputees). A validated outcome measures can assist a clinician in optimizing patient care. It may also allow you to compare your patient to other similar patients for whom the measure was validated. The key is to choose an outcome measure that has been used to answer a question that you want to answer and that has been used for the population into which your patient falls.

I'm interested in using outcome measures in my practice. How do I find validated outcome measures related to O&P?
To learn more about outcome measures, please refer to an article in the *Journal of Prosthetics and Orthotics* (2006 Vol 18, Num 1S) http://www.oandp.org/jpo/library/2006_01S_008.asp in which the author describes more in-depth information about "Measurement of Health Outcomes: Reliability, Validity, and Responsiveness." For a list of specific outcomes and their methodology, there are several websites. One website specifically has a chart that names the outcome measurement tool, the goal of the test, and the specific tools required for collecting the data (www.rehabmeasures.org). The Academy's Paul E. Leimkuehler Online Learning Center (OLC) http://www.oandp.org/olc/ has courses specifically related to outcome measures. These are another valuable tool for learning more about specific outcome measures for O&P.

What is the best approach to choose an appropriate outcome measure for use in my practice?
Make sure you understand what you are trying to measure and what type of data you wish to obtain. Refer to the answer above for references as it is important to learn about each specific outcome measure and how it should be correctly administered. Be as consistent as possible in performing the outcome measurements with each patient. Have a standard way of collecting the data and documenting it within the patient's chart. You will want to have the patient perform the same outcome measurement repeatedly over a period of time to determine if changes or condition stability relate to the care provided. The article "Outcome Measurements and Daily Clinical Life—Can They Co-Exist," by James Wynne, CPO, FAAOP; Leigh Davis, MSPO, CPO; and Anna Peaco, CO; published in the November 2012 issue of the *Academy TODAY* may prove useful as you choose appropriate outcome measures for your practice.

I've collected data for an outcome measure. How do I determine what they mean?
For some outcome measurement tools, there are published articles with population specific data. The website www.rehabmeasures.org lists details of populations tested using specific outcome measures. When collecting data via outcome measures, aside from comparing your patient's results to populated research data, you can compare your patient's results over time.

Do I need my patient to sign any consent documents before I collect outcome data?
Generally speaking, patients will have signed treatment consent and HIPAA forms which are concerned with services provided clinically. If the outcomes you are measuring are a part of the service provision in their routine care and assist with clinical decision making then they are service provision and covered in the treatment consent and HIPAA process. If you intend to disseminate the information, or do anything with the collected data that is beyond routine care, then you may be engaging in other activities such as research. For further information please refer to the Human Subjects/IRB FAQs regarding data collection involving patients and/or contact your local IRB.