UNIVERSITY OF CALIFORNIA LOS ANGELES
STUDY INFORMATION SHEET

Beacon Sensors & Telerehabilitation to Assess & Improve use of Devices (BeST-AID) for visual functioning

Ava K. Bittner, OD, PhD, and associates, from the Stein Eye Institute, Department of Ophthalmology at the University of California, Los Angeles (UCLA) are conducting a research study.

You were selected as a possible participant in this study because you recently saw your local ophthalmologist or optometrist who is prescribing a new magnification device to you to help with near reading. We are inviting eligible people to join this study who had had a recent visit in the low vision rehabilitation center at one of the following institutions: UCLA, University of Nebraska Medical Center, New England College of Optometry, or Southern California College of Optometry. Your participation in this research study is voluntary.

Why is this study being done?

This is a research study, designed to test and create new ideas that other people can use. The purpose of this research study is to find out whether it is possible to use the Internet and video-conferencing as a way to communicate remotely and provide instruction on the use of magnification devices (which includes hand-held or stand-based, optical or electronic magnifiers, as well as strong bifocals or near reading glasses) to people who have vision loss. These magnification devices are provided as part of standard of care treatment and are not experimental. Also, if you received a new hand-held magnifier, we would like to find out if it is possible to use a small Bluetooth beacon sensor device attached to your hand-held magnifier to learn about how often you use it.

What will happen if I take part in this research study?

If you volunteer to participate in this study, the researcher will ask you to do the following:

- First, we may ask you to tell us about your ability to complete daily activities and your general health by answering a few questionnaires over the phone, such as the Activity Inventory (AI). We will also ask you to take some reading tests by phone. We will schedule this for a time within the next week and it should take about 1-2 hours to complete.

- Next we will ask you to schedule a follow-up visit with your low vision optometrist or ophthalmologist at your convenience (ideally within 1-4 weeks after joining this study), at which your magnification device will be dispensed to you and you will receive training on how to use it in their office during that single visit, which is typically done as part of routine, standard of care (not a research procedure). We will ask your optometrist or ophthalmologist to share with us the results of your vision testing performed in-office, such as your visual acuity, contrast sensitivity, reading ability, and measurement of any

blindspots, which are all tests that are typically done as part of routine, standard of care.

- In addition, if you received a new hand-held optical magnifier at the follow-up visit, your low vision provider will ask you to attach a temporary (removable holder) small Bluetooth beacon sensor device to the part of the magnification device that you hold in your hand. It will record any changes in movement, humidity and temperature every few seconds, then send that information via Bluetooth to a loaner mobile data collection device that we will give you to use for the study. A custom application on the loaner mobile data collection device will only send information about temperature and movement to the study team's secure cloud server database. This data will not contain any information that can identify you. All you will need to do is keep the Bluetooth beacon sensor on your magnifier handle for four months, and the mobile data collection device continuously turned-on and plugged-in at a central location (within 20 feet) close to where you use the magnifier in your home. We will provide you with an addressed, pre-paid shipping box to send the mobile data collection device back to us after four months. Since Bluetooth beacon sensors have not been previously used to monitor the use of magnification devices, this part of the study is considered to be experimental and is not a part of usual practice. A Bluetooth beacon sensor will not be given to you if you did not receive a new hand-held magnifier to which it can attach.

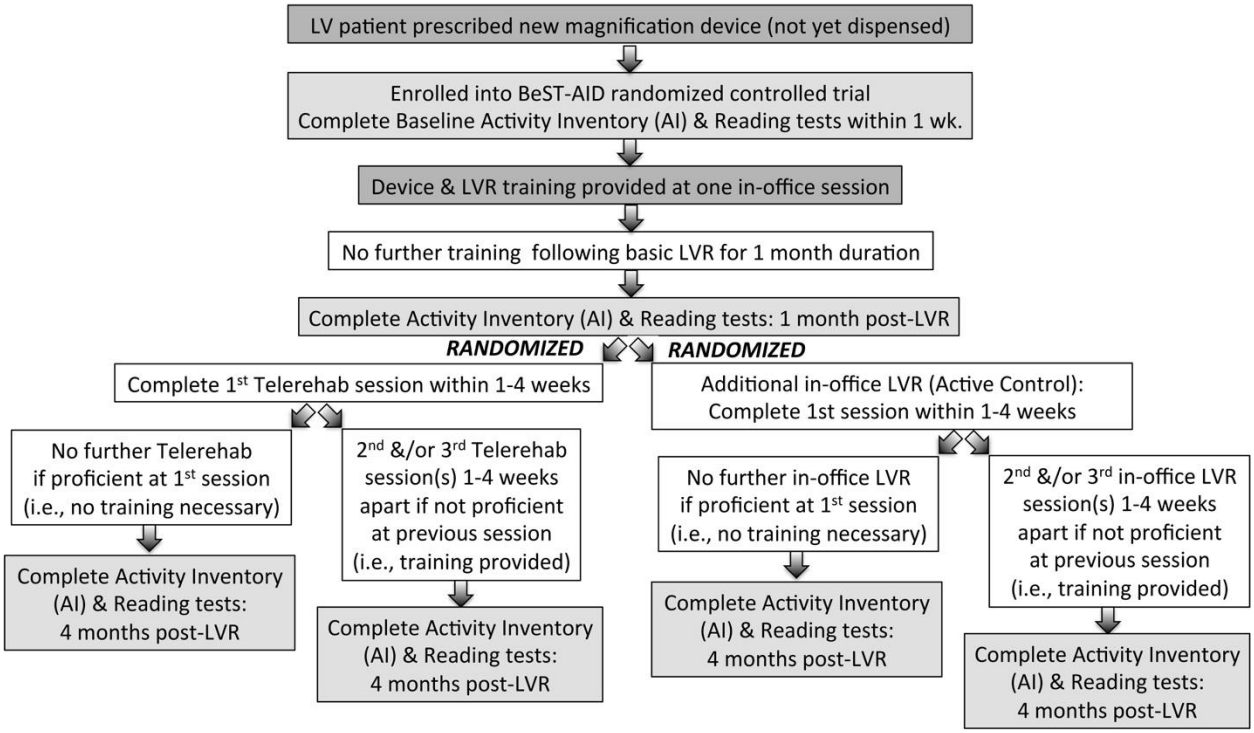
- For the first two weeks when you have the Bluetooth beacon sensor (if you have a new hand-held magnifier), we will ask you to keep a written log (diary) of all the dates and times when you use your hand-held magnifier for reading at home. Please use the magnifier just like you normally would. We will provide you with a stamped, addressed envelope so you can mail the diary log to us after two weeks.
- A month after your office visit to receive the magnification device and training, we will call you by phone to complete the same set of questionnaires about your daily activities, and ask you to retake the reading tests by phone while using your new magnification device.

- After you complete the second set of questionnaires and reading tests by phone, we will determine your group assignment randomly, like drawing numbers from a hat. You will have equal probability of being assigned to one of the following two groups: In group 1, you would have additional follow-up visit(s) with your low vision provider in their office for in-person rehabilitation session(s), or for group 2, you will have a telerehabilitation session in your home using video-conferencing to communicate with your low vision provider. If you are in the telerehabilitation group, you do not need to have a computer, laptop, tablet, smartphone or Internet service to join the video-conference session since we will we will use the study loaner smartphone for video-conferencing. At the time of your scheduled telerehabilitation session, a member of the UCLA study team will call you by phone to confirm the appointment and then will use a remote control access program to start and end the video-conference session. At that time, you will be asked to put the study loaner smartphone in the loaner stand that will be given to you when you receive the smartphone, then we'll ask you to move the stand so we can see you using the magnifier during the telerehabilitation session only. When you receive the study loaner smartphone and stand, we will give you a sealed envelope with reading tests and you will be asked to open the envelope to use the reading tests during the telerehabilitation session. Both the telerehabilitation and in-office session should take about the same amount of time to complete, about 30-60 minutes.

- For both groups, we expect that the same rehabilitation training and reading evaluation will be given by your provider during either telerehabilitation or in-office visits. Your provider will assess your reading ability with your magnification device using standard reading tests and give some additional feedback as needed. If you have a new pair of strong bifocals or near reading glasses, your provide will ask you to measure the distance from your glasses to your reading material using a disposable tape measure we will provide to you. Your low vision provider may be able to offer you some suggestions to help you become better at using the magnification device for reading. We will ask you to complete this session with your low vision provider within 1-4 weeks after completing the second set of questionnaires and reading tests by phone. At the end of the session with your low vision provider, he or she will let you know if you should schedule another session for further evaluation and training within the next 1-4 weeks. You may be scheduled for up to three sessions via telerehabilitation or in-office visits, depending on your group assignment, during a period of 1-3 months. Your group assignment will not change while you are in the study.
- Usually within a day of each session with your low vision provider, one of our research assistants will contact you by phone to ask you some questions about your experience so you can have the chance to give us some feedback about the session. This survey should only take about 15 minutes to complete.

- Lastly, about 4 months after the office visit at which you first received the magnification device and initial training, we will call you by phone to complete the same set of questionnaires about your daily activities and general health, and ask you to retake the reading tests by phone while using your new magnification device.

- A diagram with a flow chart is provided below to show the two randomized group assignments and the timeline of study procedures, including low vision rehabilitation (LVR) provided in the study.



How long will I be in the research study?

Participation will take a total of about four months.

About six months after you complete this research study, we will call you to find out if you would like to join an optional follow-up study at that time, in which you would have a telerehabilitation session with your low vision provider. In about 10 months from now, we will provide more details about that additional study and find out if you would like to participate then.

Are there any potential risks or discomforts that I can expect from this study?

This research study involves minimal risk to you. To the best of our knowledge, the things you will be doing have no more risk of harm than you would have in everyday life.

The risks and discomforts associated with the telerehabilitation session are similar to those of a standard session performed in office. However, it is possible that the telerehabilitation training may not be as effective as in-person rehabilitation training, which could mean a delay in receiving effective rehabilitation by three months if you are randomly assigned to the telerehabilitation group. During the phone questionnaire, you may experience different feelings or emotions when we are asking you questions about your vision, health and/or ability to complete daily activities. To minimize possible discomfort associated with completing study interviews, you do not have to answer any questions that make you uncomfortable, you perceive as being personal or sensitive, or do not wish to share as part of the study. You may find the 1–2 hour telephone interactions to be tiresome, exhausting, and/or inconvenient. Keeping a diary log of all the times when you use a hand-held magnification device for the first two weeks may be time consuming and/or inconvenient. Although we will make every effort to protect your

confidentiality, there remains a small risk that information about you may become known to people outside of this study.

Are there any potential benefits if I participate?

The possible benefit of your being in this research study is the potential to learn to improve the use of your magnifier for reading. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this research study will benefit other people with similar conditions in the future.

What other choices do I have if I choose not to participate?

Your may schedule an appointment for an in-office visit to receive further training to use your magnification device for reading.

Will I be paid for participating?

As appreciation for your time to answer the questionnaires and the reading test by phone, a gift card to Target or Shell gas stations will be given after you complete each of the three study questionnaire sessions when the reading test is administered; i.e., a $10 gift card will be issued after completing the first questionnaires session at the start of your study participation, a $5 gift card will be issued after completing the second questionnaires session a month after you receive your new magnification device, and a $10 gift card will be issued after completing the third questionnaires session at the end of the four month study.

If the loaner mobile data collection device becomes lost or damaged during the study, you will not be held responsible for the cost. There will be no costs to you for either the study-related in-office visits to the low vision provider or telerehabilitation sessions in your home. Additional visits to see your provider for in-office training may be billed to your third party insurance payor if they are covered.

Will information about me and my participation be kept confidential?

The researchers will do their best to make sure that your private information is kept confidential. Information about you will be handled as confidentially as possible, but participating in research may involve a loss of privacy and the potential for a breach in confidentiality. Study data will be physically and electronically secured. As with any use of electronic means to store data, there is a risk of breach of data security. Confidential information will be disclosed only with your permission or as required by law. Clinically relevant results from research procedures will not be shared with you, but if one of the questionnaires identifies that you have severe depressive symptoms or suicidality, we will refer you to your general physician or internist locally. Your responses to the study questionnaires will not be linked to any information that could identify you since we will create a unique study ID number for you. Organizations that may review and copy your information include the Institutional Review Board and other representatives of this institution. If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential data will be kept securely in electronic databases in password protected computers or in locked private work offices. All data will be kept for

120 months and destroyed after that time by shredding paper files or deleting electronic files.

To do more powerful research, it is helpful for researchers to share information that does not contain any identifiable information about you. They do this by putting it into one or more scientific databases, where it is stored along with information from other studies. Researchers can then study the combined information to learn even more about health and disease. If you agree to take part in this study, some of your information might be placed into one or more scientific databases. There are many different kinds of scientific databases; some are maintained by UCLA, some are maintained by the federal government, and some are maintained by private companies. Different databases may have different ways of reviewing such requests. Researchers with an approved study may be able to see and use your information, along with that from many other people. Your name and other information that could directly identify you will never be placed into a scientific database. Researchers will always have a duty to protect your privacy and to keep your information confidential.

Information about you is protected by a federal Certificate of Confidentiality. This means that we can't be forced to release information about you for any legal proceeding, even if a court of law asks.
The Certificate allows us to use information about you for purposes of this research, or to disclose it for other research when allowed by law. The Certificate requires other researchers to also protect information we share with them.
There are limits to this protection. The Certificate does not protect your information when:

- You or your family voluntarily release information about yourselves.
- You consent to release of information (for example, the uses described in this form, or if you sign release forms for employment, insurance or medical care).
- A federal agency audits or evaluates research that it funds.
- Researchers are required to report possible intent to harm yourself or others, child abuse, elder abuse, or infectious disease cases.
- The Food & Drug Administration requires information as part of overseeing drugs, devices or other products.

Public Information about this Study:

ClinicalTrials.gov is a website that provides information about federally and privately supported clinical trials. A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What are my rights if I take part in this study?

- You can choose whether or not you want to be in this study, and you may withdraw your consent and discontinue participation at any time.
- Whatever decision you make, there will be no penalty to you, and no loss of benefits to which you were otherwise entitled.
- You may refuse to answer any questions that you do not want to answer and still remain in the study.

Who can I contact if I have questions about this study?

- **The research team:**
  If you have any questions, comments or concerns about the research, you can talk to the one of the researchers. Please contact:

  Dr. Ava Bittner, Associate Professor of Ophthalmology at UCLA, who may be reached at 310-206-4649, or Max Estabrook, the study coordinator, who can be reached at 310-206-9566 or 310-267-3977.

- **UCLA Office of the Human Research Protection Program (OHRPP):**
  If you have questions about your rights as a research subject, or you have concerns or suggestions and you want to talk to someone other than the researchers, you may contact the UCLA OHRPP by phone: (310) 206-2040; by email: participants@research.ucla.edu or by mail: 10889 Wilshire Blvd., Suite 830, Los Angeles, CA 90095-1406.