Broad Consent for Future Research Uses of Identifiable Information

Broad Consent is intended to comply with federal government requirements administered by the Health and Human Services Office for Human Research Protections and the Food and Drug Administration. It is also intended to meet the requirements of a Health Insurance Portability and Accountability Act (HIPAA) authorization for use and disclosure of Private Health Information (PHI) for future research purposes. The Community Counseling Training Center is responsible for ensuring that this Broad Consent Form meets applicable federal and state laws, as well as institutional policies.

Research with Private Information

Research using personal health information (such as information about your health status, medical test results, and what medical conditions you have), has led to important advances in medicine, science, and other areas. As explained in this form, we hope to make it easier for researchers to use your information in the future.

The rules for how information originally collected for one purpose (such as for client medical care or another research study) can be used for new research depend on whether the information may identify you personally, or whether things that identify you – such as your name, address and medical record number – have been taken off of the information . When all of the details that could reasonably be used to identify you have been removed from your information, we say they are "de-identified." Federal and state law allows researchers to use de-identified information without asking anyone for permission. This has been true for a long time, and research with de-identified information has benefited patients in many ways.

When your information can still be linked to you, we say they are "identified" or "identifiable." Research with identifiable information can be even more helpful to science and medicine, because it allows researchers to put together a lot of information about a person and understand even more about medical conditions and if and how treatments work. However, research with identifiable information bears more risk to people's privacy, and therefore, there are strict rules for this kind of research. When researchers ask you to say "yes" to allow your identifiable information to be used in a wide range of different types of research studies in the future, t**his is called "broad consent," and it is what we are asking you to agree to in this form.**

What are we asking you to do?

This form asks you to make an important choice about the use of your identifiable information. It asks you to decide if you are willing to give your broad consent now, to the future research use of your identifiable information.

If you say "yes," researchers in the future may use your identifiable information in many different research studies, over a long period of time, without asking your permission again for any specific study covered by this form. This could help science.

If you say "no," researchers in most cases will have to ask your permission to use your identifiable information in any future research study. Because this may be difficult or impossible, it could make scientific studies harder to do.

Please ask us about anything in this form that you do not understand, and only make a decision if you have had all your questions answered and have had enough time and opportunity to consider whether to agree to give this broad consent.

This form explains in more detail what saying "yes" or "no" to this broad consent will mean to you. If you don't choose either "yes" or "no" after reading this form and talking to our research staff, your identifiable information might still be used for some low risk research without your consent. It is better if you say "yes" or "no" on this broad consent form, so that your choice is clear.

Remember, this form applies only to research with identifiable information. Researchers can always use de-identified health information for research, without getting any person's consent and without asking an ethics committee for permission.

What is the Purpose of a Broad Consent?

If you say "yes" in this form, the Community Counseling Training Center as part of the Counseling and Higher Education Department within Northern Illinois University will store, use and share your identifiable information, and may do so for the purpose of medical, scientific and other research, now and into the future, for as long as they are needed for this purpose. If you say "yes" and give your broad consent in this form, we may share your identifiable information with other research, academic, and medical institutions, other researchers, drug and device companies, biotechnology companies and others.

What Types of Research May be Done?

Possible future research may include client-focused: Research about mental health diagnosis and treatment • Research about developmental disabilities • Studying the causes and progression of different diseases and conditions • Developing and testing methods to diagnose and treat different diseases and conditions • Specific research looking at diagnoses and conditions that are passed on in families and among populations larger than families • Research about drug abuse and alcoholism diagnosis and treatment • Research about HIV and sexually transmitted diseases • Family planning and reproductive health research (as examples).

Possible future research may include counseling-focused research about the counseling interventions, counseling relationship, counseling outcomes, counselor development, and counseling supervision (as examples.

If you say "yes" in this form, there are no plans to tell you about any of the specific research that will be done with your identifiable information. **The results of research done on your identifiable information will not be put into your medical records.**

Are There Risks of Harm?

The main risk in saying "yes" is that your privacy could be violated. We will do our best to protect your information from going to people who should not have it, including by removing information that could be used easily to identify you. The risk that your identifiable information will go to someone who should not get it is very small.

Another risk is that if you say "yes," your identifiable information could be used in a research project to which you might not agree, if you were asked specifically about it. The examples listed above should give you a good idea of the kinds of research projects that might be done. Also, a research ethics committee will make sure that this broad consent covers the research studies planning to use identifiable information from you.

Privacy and Your Protected Health Information (PHI)

The personal information that can identify you is protected by federal privacy and security regulations issued under the Health Insurance Portability and Accountability Act (HIPAA). This section of this form advises you on your rights under these regulations.

If you say "yes" in this form, we may share your identifiable information with researchers in the future, as described above. We may also share your identifiable information with regulatory authorities that oversee research, including the Food and Drug Administration (FDA) and the U.S. Department of Health and Human Services Office for Human Research Protections (OHRP), and with committees and people here at Northern Illinois University and in other places whose job is to review and oversee research.

Your medical information and records, once given to parties who are not bound by laws – such as the HIPAA regulations –that protect your identifiable information may no longer be protected from being used and shared without your consent.

This permission will last as long as we have a scientific and research need to use and share your identifiable information (including identifiable health information).

If results are published of studies done with your identifiable information, your name will not be used in those publications.

Are There Any Benefits?

You will not personally benefit from saying "yes" in this form. Research with your identifiable information may help others by improving our understanding of health and disease, improving health care and making safer or more effective medical therapies, and developing new scientific knowledge.

Are There Alternatives to this Broad Consent? Is There a Choice?

You are free to say "no" to the use of your identifiable information. Saying "yes" to this broad consent is voluntary. If you say "no," you will not lose any access to health care or benefits to which you are otherwise entitled, and saying "no" will not change your relationship with your health care providers. No matter what you decide, your decision will not affect your rights to obtain medical care or other services.

If you say "no,' you will not be able to participate in the primary study of counseling outcomes.

Can You Change Your Mind and Reverse Your Decision to Give this Broad Consent?
If you say "yes" now, you can later change your mind, but there are some limits. If you change your mind, contact the Community Counseling Training Center at 815-753-9312. The Community Counseling Training Center will not begin new research uses of your identifiable information, but information will continue to be used in studies that started before you changed your mind. If your identifiable information have already been given to another researcher, person, institution, or company, it may not be possible to limit their continued and new uses.

If you change your mind, the Community Counseling Training Center may de-identify your information and use them in the future and will not use your identified information for future research.

Will it Cost Anything?
Whether you say "yes," "no," or do not respond to this form, there are no costs to you.

Is There Any Payment or Compensation for saying "yes"?
If you say "yes," your identifiable information may be used to create products or to deliver services, including some that may be sold and/or make money for others. If this happens, there are no plans to tell you, or to pay you, or to give any compensation to you or your family. Most uses of information do not lead to commercial products or to profit for anyone.

Regardless of whether you say "yes" or "no" on this form, or whether you don't respond at all, if your de-identified information are used to create products or deliver services, there are no plans to pay you or give any compensation to you and your family.

If You Say "Yes," Will You Learn More about Your Health?
Because this is a broad consent, there are no plans to tell you about any specific research studies that might be done with your identifiable information, and there are no plans to give you any results from these studies.

If future research with your identifiable information gives results that do have meaning for your health, the researchers may – but are not required to – contact you to let you know what they have found. If the researchers return test results to you, it may be because they think you could have a health risk and want to recommend that the test should be re-done by a certified clinical laboratory to check the results. If this happens, then you may want to get a second test from a certified clinical laboratory, consult your own doctor, or get professional counseling. You may have to pay for those additional services yourself.

Options For Responding to this Request for Broad Consent: What Will Happen?
As explained above, the law allows de-identified information to be used without permission. Therefore, this form is asking only about the future use of your identifiable information.

If you give a definite and clear "Yes" or "No" to this broad consent, then researchers now and in the future will have a clear idea about what they are allowed and not allowed to do with your identifiable information. Not giving any answer will also have implications, as described below.

IF YOU SAY "YES"

• Your identifiable information will be stored, used and shared for the kinds of future research described in this broad consent form, without anyone asking your permission for each new study.

• Identifying information may also be removed from your information, allowing them to be used for any future research or other purpose.

IF YOU SAY "NO"

• The researchers and institutions identified above will not store, use or share your identifiable information for the research described in this broad consent form.

• However, identifiers may be removed from your information, allowing them to be used for any future research or other purpose.

• Researchers could come to you again later and ask to store, use and share your identifiable information for research.

IF YOU DO NOT SAY "YES" OR "NO"

• If you do not mark "yes" or "no" on this form (if you do not return it, or leave it blank), then it will be the same as if you were never asked to make a choice.

• This means that your identifiable information may be used for future research if:
  - o The researchers ask you to say yes to a specific research study, and you agree.
  - o An IRB allows your identifiable information to be used in a study that is low risk to you without asking for your consent.
  - o Another legal exception applies.

• Identifiers may be removed from your information, allowing them to be used for any purpose.

• Researchers could come to you later and ask again for your broad consent.

Questions

If you have any questions about this broad consent, please contact the Director of the Community Counseling Training Center at 815-753-9312.

If you want to report or have questions about an injury that you believe you or others have suffered as a result of your agreeing to this broad consent, please contact the Chair of the Department of Counseling and Higher Education at 815-753-1448.

You may discuss your rights as a person who has agreed to, refused, or declined to respond to an offer of broad consent with any representative of Institutional Review Board of Northern Illinois University at 815-753-8588.

Please ask us to explain anything in this form that you do not clearly understand. Please think about this broad consent and/or discuss it with family or friends before making a decision to say "Yes" or "No."

STATEMENT OF AGREEMENT
I say yes. The broad consent has been explained to me, and I agree to give my broad consent to the future research uses of my identifiable information. My participation is voluntary, and I may withdraw at any time without any penalty or loss of benefits to which I am entitled.

OR

STATEMENT OF REFUSAL
I say no. The broad consent has been explained to me, and I **do not agree** to this broad consent.