| LONG VERSION | SHORT VERSION | FAQs / “MORE INFORMATION” |
| --- | --- | --- |
| Researchers are trying to learn more about cancer, heart disease, diabetes, and other health problems. | Researchers are trying to learn more about cancer, heart disease, diabetes, and other health problems. |  |
| Much of this research is done using human tissue. | Much of this research is done using human tissue, such as blood. |  |
| ‘Tissue’ means materials from the body, such as blood. Other examples include urine, skin cells, hair, nail clippings, or a small piece of a tumor, organ, or bone. |  | What is “tissue”? – ‘Tissue’ means materials from the body, such as blood. Other examples include urine, skin cells, hair, nail clippings, or a small piece of a tumor, organ, or bone. |
| Researchers often study tissue from people who have health problems and from people who do not. |  | Why would researchers want to study my blood? – Researchers often study tissue from people who have health problems and from people who do not. |
| We are asking you to let us store some of your blood so it might be used in these kinds of studies. | We are asking you to let us store some of your blood so it might be used in these kinds of studies. |  |
| This is because you agreed to take part in or may be eligible for a study done as part of the larger Murdock Study. | This is because you agreed to take part in or may be eligible for a study done as part of the larger Murdock Study. |  |
| It is your choice to take part in this storage project or not. | It is your choice to take part in this storage project or not. |  |
| This consent form gives information to help you decide. | This consent form gives information to help you decide. |  |
| It explains the purpose of the research, what it involves, the risks and benefits, other options you have, and your rights as a participant. |  | What kinds of information will I find in this consent form? – This form explains the purpose of the research, what it involves, the risks and benefits, other choices you have, and your rights as a participant. |
| Please read this form carefully and take all the time you need to make your choice. | Please read it carefully and take all the time you need to make your choice. |  |
| Be sure to ask us as many questions as you want. | Be sure to ask us as many questions as you want. |  |
| We urge you to talk with your family, friends, and doctor before making your choice. |  | Can I talk to other people before I decide? – We urge you to talk with your family, friends, and doctor before making your choice. |
| Everyone who takes part in research should know that: | Everyone who takes part in research should know that: |  |
| Research is meant to gain knowledge that may help people in the future. |  | If I don’t get any benefit, who will? – Research is meant to gain knowledge that may help people in the future. |
| You may or may not benefit from taking part. | You may or may not benefit from taking part. |  |
| Taking part may also involve some risks. | Taking part may also involve some risks. |  |
| Taking part in research is completely voluntary. You can choose not to take part. | Taking part is voluntary. |  |
| If you choose to take part, you can quit at any time. | If you choose to take part, you can quit at any time. |  |
| No matter what you decide, now or in the future, it will not affect your medical care. | No matter what you decide, now or in the future, it will not affect your medical care. |  |
|  |  |  |
| WHAT IS THE PURPOSE OF THIS PROJECT? | WHAT IS THE PURPOSE OF THIS PROJECT? |  |
| The purpose of this project is to collect and store tissue samples (such as blood) and health information. Researchers can then study the stored materials. | The purpose of the Murdock Study Biorepository is to collect and store tissue and health information so researchers can use them in future medical studies. |  |
| Through such studies, they hope to find new ways to detect, treat, and maybe even prevent or cure health problems. | (\*) Through these studies, researchers hope to find new ways to detect, treat, and maybe even prevent or cure health problems. |  |
| Some of these studies may be about how genes affect health, or how genes affect response to treatment. | (\*) Some of these studies may be about how genes affect health and disease. |  |
| (Genes, which are made up of DNA, have all the information needed to build and operate a human body.) |  | (\*) What are “genes”? – Genes, which are made up of DNA, have all the information needed to build and operate a human body. |
| Some of the studies may lead to new products, such as drugs or tests for diseases. |  | (\*) How will the Biorepository help people in the future? – Some of the studies may lead to new products, such as drugs or tests for diseases. |
| A “biorepository” is a collection of samples and information. This collection is called the Murdock Study Biorepository (or just “the Biorepository” in the rest of this form). |  | What is a “biorepository”? – A “biorepository” is a collection of samples and information. This collection is called the Murdock Study Biorepository (or just “the Biorepository” in the rest of this form). |
| The director of the Biorepository is [INSERT NAME]. |  | Who runs the Murdock Study Biorepository? – The director of the Biorepository is [INSERT NAME]. |
|  |  |  |
| WHAT IS INVOLVED? | WHAT IS INVOLVED? |  |
| If you agree to take part in this project, here is what will happen: | If you agree to take part, here is what will happen: |  |
| 1. We will ask you to sign this consent form. | 1. We will ask you to sign this consent form. |  |
| We will give you a signed copy to keep. | We will give you a signed copy to keep. |  |
| 2. We will get a blood sample from you. | 2. We will get a blood sample from you. |  |
| If you agree, we will draw 50 ml (about 3 tablespoons) of blood from a vein in your arm by needle stick. | We will draw about 3 tablespoons of blood from a vein in your arm. |  |
| From this sample, we may be able to extract things like plasma, serum, blood cells, DNA, and RNA. |  | What kinds of things will you get from my blood? – From this sample, we may be able to extract things like plasma, serum, blood cells, DNA, and RNA. |
| ‘DNA’ is short for deoxyribonucleic acid. DNA stores information in the form of a code. Parts of DNA that have complete messages are known as ‘genes.’ Genes give the instructions for building all the proteins that make our bodies work. Genes carry information that is passed on to future generations. |  | What is “DNA”? – DNA is short for deoxyribonucleic acid. DNA stores information in the form of a code. Parts of DNA that have complete messages are known as ‘genes.’ Genes give the instructions for building all the proteins that make our bodies work. Genes carry information that is passed on to future generations. |
| ‘RNA’ is short for ribonucleic acid. RNA delivers DNA’s genetic message to the part of a cell that makes proteins. RNA gives some information about which genes are turned on or off at one point in time. RNA is not passed on from generation to generation. |  | What is “RNA”? – ‘RNA’ is short for ribonucleic acid. RNA delivers DNA’s genetic message to the part of a cell that makes proteins. RNA gives some information about which genes are turned on or off at one point in time. RNA is not passed on from generation to generation |
| 3. We will get some information about you and your health. | 3. We will get some information about you and your health. |  |
| First, we will ask you for some basic information. This will include things like name, age, sex, and racial or ethnic group. We will also ask about your family’s health history. | We will ask you for some basic information, such as your name, age, race, and family’s health history. |  |
| If you agree, we will contact you no more than once a year to update this information. | We will contact you no more than once a year to update this information. |  |
| This will happen for as long as your sample is stored in the Biorepository, unless you tell us not to. |  | For how long will you contact me to update my basic information? – This will happen for as long as your sample is stored in the Biorepository, unless you tell us not to. |
| You can tell us now or in the future not to contact you. |  | What if I don’t want to be contacted? – You can tell us now or in the future not to contact you. |
| Second, we will get some information from your medical record. | We will get some health information from your medical record. |  |
| Examples include information about your health problems, lab results, medical procedures, and medicines. |  | What kinds of information will you get from my medical record? – Examples include information about your health problems, lab results, medical procedures, and medicines. |
| This is because future researchers need to know if you have any health problems. They may also need to know about any treatments you have had and how well the treatments worked. |  | Why do you need to look at my medical record? – This is because future researchers need to know if you have any health problems. They may also need to know about any treatments you have had and how well the treatments worked. |
| If you agree, we will use your medical record from time to time to update this information. | We will use your medical record from time to time to update this information. |  |
| This will happen for as long as your sample is stored in the Biorepository, unless you tell us not to. |  | For how long will you be using my medical record to update my health information? – This will happen for as long as your sample is stored in the Biorepository, unless you tell us not to. |
| You can tell us now or in the future not to look at your medical record. |  | What if I don’t want you to look at my medical record? – You can tell us now or in the future not to look at your medical record. |
| Third, we will get research data from any Murdock studies in which you take part. | We will also get research data from any Murdock studies in which you take part. |  |
| 4. We will store your sample and information in the Biorepository. | 4. We will store your sample and information in the Biorepository. |  |
| We will keep your blood and information in the Biorepository along with those from all the other people who take part. |  | Will my sample be the only one? – We will keep your blood and information in the Biorepository along with those from all the other people who take part. |
| We do not know exactly how many people will take part. We expect it will be many tens of thousands. |  | How many people will take part in the Biorepository? – We do not know exactly how many people will take part. We expect it will be many tens of thousands. |
| There is no limit on the length of time we will keep your blood and information. | There is no limit on the length of time we will keep it. |  |
| We will keep them as long as they are useful, unless you decide to stop taking part or we close the Biorepository. |  | How long will you keep my sample and information? – We will keep them as long as they are useful, unless you decide to stop taking part or we close the Biorepository. |
| 5. We will let researchers use the materials stored in the Biorepository for approved studies. | 5. We will let researchers use the materials stored in the Biorepository for approved studies. |  |
| Researchers can apply to study the samples and information stored in the Biorepository. A research committee at the Biorepository will review each application. |  | How will researchers get access to the samples and information? – Researchers can apply to study the samples and information stored in the Biorepository. A research committee at the Biorepository will review each application. |
| An ethics review will also be done. This kind of review is to make sure that risks are minimized and that the rights and welfare of people who take part in research are protected. |  | How do I know the studies will be ethical? – An ethics review will also be done. This kind of review is to make sure that risks are minimized and that the rights and welfare of people who take part in research are protected. |
| If a study is approved, a part of your blood and some information about your health might be given to the researchers, along with samples and information from many other people. |  | What happens if a study is approved? – If a study is approved, a part of your blood and some information about your health might be given to the researchers, along with samples and information from many other people. |
| We will not give researchers your name or any other information that could identify you without your permission. | We will not give researchers your name or any other information that could identify you. |  |
| Materials stored in the Biorepository will be used mainly by researchers at Duke University. Researchers from other universities, the government, and drug- or health-related companies can also apply to use them. We will only let skilled researchers study the samples and information. |  | Who will you let study the stored materials? – Materials stored in the Biorepository will be used mainly by researchers at Duke University. Researchers from other universities, the government, and drug- or health-related companies can also apply to use them. We will only let skilled researchers study the samples and information. |
| 6. We may contact you in the future with offers to take part in more research. | 6. We may contact you in the future with offers to take part in more research. |  |
| We will not notify you every time your sample and information are used in a study. |  | (\*) Will you tell me every time my sample and information are used in a study? – No, we will not notify you every time your sample and information are used in a study |
| However, some researchers might apply to do a study for which they would need to contact you. For example, they might want to ask you to fill out a survey or do a phone interview. |  | What would this other research involve? – Some researchers might apply to do a study for which they would need to contact you. For example, they might want to ask you to fill out a survey or do a phone interview. |
| If a study like this is approved, someone from the Biorepository will contact you first. We will tell you about the study so you can decide if it is okay to give the researcher your name. If you agree, the researcher will then contact you to tell you more about the study. |  | Will researchers ever contact me directly? – Someone from the Biorepository will contact you first. We will tell you about the study so you can decide if it is okay to give the researcher your name. If you agree, the researcher will then contact you to tell you more about the study. |
| There will be a new consent process just for that study. You can decide then to take part or not take part. |  | If I give the OK for a researcher to contact me, does that mean I have to take part? – There will be a new consent process just for that study. You can decide then to take part or not take part. |
| We will make sure not to contact you about studies like this more than twice a year. | We will make sure not to contact you more than twice a year. |  |
| You can also choose, now or later, that you do not want us to contact you about studies like these. |  | What if I don’t want to be contacted about more research? – You can choose, now or later, that you do not want us to contact you about studies like these. |
| 7. Some of your genetic and health information may be placed in scientific databases. | 7. Some of your genetic and health information may be placed in scientific databases. |  |
| In order to speed research, it is often helpful for researchers to share the genetic information they get from studying blood or tissue samples. Other researchers can then compare that information to the genetic information from people in other studies. By sharing information, researchers can learn even more about human health and disease. |  | What is the purpose of these scientific databases? – In order to speed research, it is often helpful for researchers to share the genetic information they get from studying blood or tissue samples. Other researchers can then compare that information to the genetic information from people in other studies. By sharing information, researchers can learn even more about human health and disease. |
| If you agree, some of your genetic and health information may be released into one or more scientific databases. |  | What if I don’t want my information to be in a database? – Your genetic and health information would be released into scientific databases only if you agree. |
| There are many scientific databases where your information may go. Some are kept by Duke University, some are kept by the National Institutes of Health, and some are kept by private companies. |  | Who keeps these databases? – There are many scientific databases where your information may go. Some are kept by Duke University, some are kept by the National Institutes of Health, and some are kept by private companies? |
| Some of these databases can be used by the public. Others are restricted and can only be used by approved researchers. |  | Who can look at the information in the databases? – Some of these databases can be used by the public. Others are restricted and can only be used by approved researchers. |
| Your name and other information that could identify you will never be released into a scientific database. | Your name and other information that could identify you will never be included. |  |
| Nobody will know just from looking at a database that the information is yours. |  | Will anyone who looks at the database know the information is mine? – Nobody will know just from looking at a database that the information is yours. |
|  |  |  |
| WHAT ARE THE POSSIBLE RISKS? | WHAT ARE THE POSSIBLE RISKS? |  |
| Physical Risks. Like any other time you have blood drawn, you may feel brief pain or have some bruising from the needle. | The most common risks related to drawing blood from your arm are brief pain and/or bruising. |  |
| Infection, excess bleeding, clotting or fainting is also possible, but unlikely. |  | Are there any other risks to having my blood drawn? – Infection, excess bleeding, clotting or fainting is also possible, but unlikely? |
| Privacy Risks. There is a risk that someone could get access to the data we have stored about you. | There is a risk that someone could get access to the data we have stored about you. |  |
| If those data suggested something serious about your health, it could be misused. For example, it could be used to make it harder for you to get or keep a job or insurance. | In some cases, it could be used to make it harder for you to get or keep a job or insurance. |  |
| There are laws against this kind of misuse. For example, North Carolina law says employers cannot deny someone a job based on genetic information (§95-28.1A). It also says insurers cannot charge more or refuse to cover someone based on genetic information (§58-3-215). |  | Does North Carolina have laws against genetic discrimination? – North Carolina law says employers cannot deny someone a job based on genetic information (§95-28.1A). It also says insurers cannot charge more or refuse to cover someone based on genetic information (§58-3-215). |
| But such laws may not give full protection. |  | Do laws against genetic discrimination mean there is nothing to worry about? – Although there are laws against the misuse of genetic information, they may not give full protection. |
| We believe the chance of your information being misused is very small, but we cannot make guarantees. | We believe the chance that this will happen is very small, but we cannot make guarantees. |  |
| Your privacy and the confidentiality of your data are very important to us and we will make every effort to protect them. | (\*) Your privacy is very important to us and we will make every effort to protect it. |  |
| These efforts are described in the next section, called “How Will Information About Me Be Kept Private?” |  | How will you protect my privacy? – There are more details about this in the next section, called “How Will Information About Me Be Kept Private?” |
| Scientific Databases. There is a risk that someone could trace the information in a scientific database back to you. | There is a risk that someone could trace the information in a scientific database back to you. |  |
| Even though your name or other identifiers will not be included, your genetic information is unique to you. | Even without your name or other identifiers, your genetic information is unique to you. |  |
| We believe the chance that someone will identify you is very small. | We believe the chance that someone will identify you is very small. |  |
| But the risk may grow in the future if people come up with new ways of tracing information. | But the risk may grow in the future if people come up with new ways of tracing information. |  |
|  |  |  |
| HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE? | HOW WILL INFORMATION ABOUT ME BE KEPT PRIVATE? |  |
| Federal privacy rules give safeguards for privacy, security, and authorized access. |  | Are there laws that protect my privacy? – Federal privacy rules give safeguards for privacy, security, and authorized access. |
| We will not give information that identifies you to anyone without your permission, except if required by law. |  | Will you give anyone else information that identifies me? – We will not give information that identifies you to anyone without your permission, except if required by law. |
| We will keep samples in locked freezers in locked buildings. |  | How will you keep the samples secure? – We will keep samples in locked freezers in locked buildings. |
| We will keep health information and research data on secure computers. These computers have many levels of password protection. |  | How will you keep the information secure? – We will keep health information and research data on secure computers. These computers have many levels of password protection. |
| We will remove your name and anything else that could directly identify you from your sample and information, and replace them with a code number. | We will remove your name and other identifiers from your sample and information, and replace them with a code number. |  |
| We will keep the master list that links the code number to your name separate from your sample and information. | We will keep the list that links the code number to your name separate from your sample and information. |  |
| We will store this list on secure computers. These computers have many levels of password protection. |  | How will you keep the list that links the code number to my name secure? – We will store this list on secure computers. These computers have many levels of password protection. |
| Only a few of the Biorepository staff will have access to the list and all Biorepository staff sign a pledge to keep your identity a secret. | Only a few of the Biorepository staff will have access to the list and all Biorepository staff sign a pledge to keep your identity a secret. |  |
| Researchers who study your sample and information will not know who you are. We will give them only the code number and not any information that directly identifies you. |  | Will researchers know who I am? – Researchers who study your sample and information will not know who you are. We will give them only the code number and not any information that identifies you. |
| The researchers must promise they will not try to find out who you are. They must also promise to keep the coded materials secure. |  | How do you know researchers will keep the samples and information secure? – Researchers must promise to keep the coded materials secure. They must also promise they will not try to find out who you are. |
| Research records are separate from medical records. We will not place any information that we get or create as part of this project in your medical record. |  | Will you put research information in my medical record? – Research records are separate from medical records. We will not place any information that we get or create as part of this project in your medical record. |
| Your research record may be reviewed in order to meet federal or state rules. Reviewers could include, for example, people from a federal agency (such as the Food and Drug Administration) or the sponsor of a particular study. A reviewer who looks at your research record may also need to look at your entire medical record. |  | Who else might have access to my records? – Your research record may be reviewed in order to meet federal or state rules. Reviewers could include, for example, people from a federal agency (such as the Food and Drug Administration) or the sponsor of a particular study. A reviewer who looks at your research record may also need to look at your entire medical record. |
| If we give information to such a reviewer, it is no longer protected by patient privacy rules (called ‘HIPAA’). But it will be protected by other federal privacy rules. |  | What protections will I have if reviewers look at my records? – If we give information to a reviewer, it is no longer protected by patient privacy rules (called ‘HIPAA’). But it will be protected by other federal privacy rules. |
|  |  |  |
| WHAT ARE THE POSSIBLE BENEFITS? | WHAT ARE THE POSSIBLE BENEFITS? |  |
| You will most likely not benefit directly if you decide to take part in this project. | You will not get direct benefit from taking part. |  |
| The main reason you may want to take part is to help researchers make discoveries that might benefit people in the future. | The main reason you may want to take part is to help researchers make discoveries that might help people in the future. |  |
|  |  |  |
| ARE THERE ANY COSTS OR PAYMENTS? | ARE THERE ANY COSTS OR PAYMENTS? |  |
| There are no costs to you or your insurance for taking part in the Biorepository. | There are no costs to you or your insurance. |  |
| You will not be paid for taking part in the Biorepository. | You will not be paid for taking part. |  |
| If you are injured as a result of taking part in this project, you can get urgent medical care at [INSERT PLACE]. But there is no commitment by [LIST ENTITIES] to give monetary compensation or free medical care to you in the event of a project-related injury. |  | Will I get paid if I am injured? – If you are injured as a result of taking part in this project, you can get urgent medical care at [INSERT PLACE]. But there is no commitment by [LIST ENTITIES] to give monetary compensation or free medical care to you in the event of a project-related injury. |
| For questions about a project-related injury or to report a project related-injury, contact [INSERT NAME] at [INSERT NUMBER] during normal business hours. You can leave a message at this number after hours, on weekends, and on holidays. |  | Who should I call about a project-related injury? – For questions about a project-related injury or to report a project related-injury, contact [INSERT NAME] at [INSERT NUMBER] during normal business hours. You can leave a message at this number after hours, on weekends, and on holidays. |
| Your sample will be used only for research and will not be sold. |  | Will you sell my sample to anyone? – Your sample will be used only for research and will not be sold. |
| But you should know that research sometimes leads to discoveries that may one day have commercial value. For example, research could lead to new tests, drugs, or other medical products. |  | Could anyone make money from the samples and information? – Research sometimes leads to discoveries that may one day have commercial value. For example, research could lead to new tests, drugs, or other medical products. |
| If you take part in this project, that means you agree to let the Biorepository make your sample and information available for these uses. |  | What if I don’t want my sample and information used for commercial purposes? – If you take part in this project, that means you agree to let the Biorepository make your sample and information available for these uses. |
| In the event that research using samples stored in the Biorepository leads to a product that could be sold commercially, you should not expect to share in any profits. | If any of the research leads to new tests, drugs, or other commercial products, you should not expect to share in any profits. |  |
| Development of new products usually relies on the study of samples from hundreds or thousands of people, not on any one person. |  | Why don’t you plan to share any profits? – Development of new products usually relies on the study of samples from hundreds or thousands of people, not on any one person. |
| The Duke University Health System and/or the developers will assert all rights of ownership in the samples, as well as all rights arising from use of the samples. |  | Who owns the samples and any discoveries? – The Duke University Health System and/or the developers will assert all rights of ownership in the samples, as well as all rights arising from use of the samples. |
|  |  |  |
| WILL I FIND OUT THE RESULTS OF THE RESEARCH? | WILL I FIND OUT THE RESULTS OF THE RESEARCH? |  |
| Research Results. You should not expect to get individual results from research done using your sample. | You should not expect to get individual results from research done using your sample. |  |
| Researchers must study samples and information from many people over many years before they can know if the results have meaning. |  | Why won’t I get individual research results? – Researchers must study samples and information from many people over many years before they can know if the results have meaning. |
| The results will not affect your care right now. We will not give the results to your doctor and we will not put them in your medical record. |  | Will my doctor get the results? – The results will not affect your care right now. We will not give the results to your doctor and we will not put them in your medical record. |
| You can get general news about the kinds of studies being done through the Biorepository at [INSERT URL]. | You can get general news about the kinds of studies being done through the Biorepository at [INSERT URL]. |  |
| Incidental Findings. There is a small chance that researchers could learn something about your health that you and your doctor did not know before. For example, they might find that you have a gene that is already known to increase risk for a disease. |  | Could researchers discover something that my doctor doesn’t already know? – There is a small chance that researchers could learn something about your health that you and your doctor did not know before. For example, they might find that you have a gene that is already known to increase risk for a disease. |
| We will offer to tell you a finding like this only if it is about a disease that is likely to cause early death if not treated. |  | Will you tell me if you find out something serious about my health? – We will offer to tell you a finding like this only if it is about a disease that is likely to cause early death if not treated. |
| We will send a letter by certified mail asking you to contact [INSERT NAME]. [INSERT NAME] will arrange a time for you to meet with him or another health care provider to go over the information. We will not give out the findings over the phone or by mail. |  | How will you let me know if you find out something serious about my health? – We will send a letter by certified mail asking you to contact [INSERT NAME]. [INSERT NAME] will arrange a time for you to meet with him or another health care provider to go over the information. We will not give out the findings over the phone or by mail. |
|  |  |  |
| WHAT ARE MY OPTIONS? | WHAT ARE MY OPTIONS? |  |
| Taking part in the Biorepository is your choice. You can choose to take part or not take part. | The decision to take part in the Biorepository or not is up to you. |  |
| Taking part in the Biorepository means letting us get and store a blood sample, along with some basic health information, for possible use in future research. You can also choose to take part or not in the following: |  | What does it mean to “take part” in the Biorepository? – Taking part in the Biorepository means letting us get and store a blood sample, along with some basic health information, for possible use in future research. |
| Letting us contact you no more than once a year to update your personal information |  | Is annual contact required? – Letting us contact you no more than once a year to update your personal information is optional. |
| Letting us use your medical record from time to time to update your health information |  | Is medical record access required? – Letting us use your medical record from time to time to update your health information is optional. |
| Letting us contact you no more than twice a year with offers to take part in more research |  | Is contact about more research required? – Letting us contact you no more than twice a year with offers to take part in more research is optional. |
| Letting some of your genetic and health information be released, with no direct identifiers, into both publicly accessible and restricted scientific databases |  | Is putting information into scientific databases required? – Letting some of your genetic and health information be released, with no direct identifiers, into both publicly accessible and restricted scientific databases is optional. |
| You can still take part in the Biorepository even if you do not agree to any of the optional parts. |  | If I want to take part, do I have to agree to everything? – You can still take part in the Biorepository even if you do not agree to any of the optional parts. |
| You can change your mind at any time, about any of your optional choices or about taking part in the Biorepository at all. There are more details about this in the section below called “What If I Change My Mind?” | If you choose to take part, you can change your mind at any time. |  |
| No matter what you decide, now or in the future, it will not affect your medical care. There will not be any penalty to you and you will not lose any benefits you would otherwise be able to get. |  | (\*) Will there be any penalty if I change my mind? – No matter what you decide, now or in the future, it will not affect your medical care. There will not be any penalty to you and you will not lose any benefits you would otherwise be able to get. |
|  |  |  |
| WHAT IF I CHANGE MY MIND? | WHAT IF I CHANGE MY MIND? |  |
| If you agree to take part in the Biorepository, you are free to change your mind at any time. If you change your mind, please contact us at [INSERT NUMBER] and let us know. | Just call [INSERT NUMBER] and let us know. |  |
| At that time, we will send you a form so that you can tell us in writing what you want us to do. For example: | We will send you a form so you can tell us in writing what you would like us to do with any of your blood that we have not already given out for study. |  |
| No more contact. This means we would no longer contact you to update your personal information or with offers to take part in more research. But we would still have your okay to keep and use the sample and information we already have. We would also still have your okay to use your medical record to get updated information about your health. |  | What if I don’t want you to contact me any more? – You can tell use “no more contact.” This means we would no longer contact you to update your personal information or with offers to take part in more research. But we would still have your okay to keep and use the sample and information we already have. We would also still have your okay to use your medical record to get updated information about your health. |
| No more access. This means we would no longer contact you or get updated information from your medical record. But we would still have your okay to keep and use the sample and information we already have. |  | What if I don’t want you to use my medical record any more? – You can tell us “no more access.” This means we would no longer contact you or get updated information from your medical record. But we would still have your okay to keep and use the sample and information we already have. |
| Unlink. This means we would forever remove the link between the code number and your name. We would still have your okay to keep and use the sample and information we already have, but we would have no way to know that they are yours. We would also have no way to contact you or use your medical record. |  | What if I no longer want the Biorepository to be able to identify me? – You can tell us “unlink.” This means we would forever remove the link between the code number and your name. We would still have your okay to keep and use the sample and information we already have, but we would have no way to know that they are yours. We would also have no way to contact you or use your medical record. |
| No further use. This means we would no longer give researchers your sample or information. We would destroy any part of your sample left in the Biorepository. We would keep the information we already have for audit purposes only. Please note that if we have already given out some of your sample and information for study, we cannot call them back. Also, we cannot destroy knowledge already gained from the study of samples and information. But we would not give researchers your materials for any more studies. |  | What if I want to quit altogether? – You can tell us “no further use.” This means we would no longer give researchers your sample or information. We would destroy any part of your sample left in the Biorepository. We would keep the information we already have for audit purposes only. Please note that if we have already given out some of your sample and information for study, we cannot call them back. Also, we cannot destroy knowledge already gained from the study of samples and information. But we would not give researchers your materials for any more studies. |
|  |  |  |
| WHAT IF I HAVE MORE QUESTIONS? | WHAT IF I HAVE MORE QUESTIONS? |  |
| You should feel free to ask any questions. Your questions should be answered clearly and to your satisfaction. |  | What if there is still something I don’t understand? – You should feel free to ask any questions. Your questions should be answered clearly and to your satisfaction. |
| For questions about the project, contact [INSERT NAME], the Project Director, at [INSERT NUMBER] during normal business hours. | For questions about this project or a project-related injury, contact [INSERT NAME], the Project Director, at [INSERT NUMBER]. |  |
| You can also call [INSERT NAME], the Study Coordinator, at [INSERT NUMBER]. |  | Is there anyone else I can call with questions? – You can also call [INSERT NAME], the Study Coordinator, at [INSERT NUMBER]. |
| You can leave a message at these numbers after hours, on weekends, and on holidays. |  | What if it is after hours? – You can leave a message at these numbers after hours, on weekends, and on holidays. |
| For questions about your rights as a research participant, contact the Duke University Health System Institutional Review Board Office at (919) 668-5111. | For questions about your rights as a research participant, contact the Duke University Health System Institutional Review Board Office at (919) 668-5111. |  |

***(\*) Sentence is shown out of order here compared to where it appears in the actual consent form or FAQ document.***

|  |  |
| --- | --- |
|  | = text is an exact match |
|  | = text is an approximate match |