

# Module III: PAR in UCEDDs – We Continue with the Research Process

## ***1. Research Process:***

Objective:

- To understand the 10 basic components of the research process

***Select a topic or issue***

### **Question - How is an issue selected?**

Communities can share important concerns. Most members look for suggestions or ideas that can help. People with disabilities have many challenges. They often need better transportation. Many need training and choices in employment. Others need more reliable personal care attendants. Families often need help to get medical care and benefits. They look for ways to manage challenging behavior, find respite care, and obtain an appropriate education for their children.

Let's ask ourselves: What can we do about these issues? Which problem is the most important?

The first step in the research process begins with a question. Here is an example.

"How can I reduce the risk of losing vision and limbs for people with severe diabetes?"

This question then leads to other questions such as: "Who is most at risk?" "When is risk the greatest? What social or environmental factors contribute or alleviate the problem?"

We are a University Center of Excellence. We have a team of self-advocates, family members, agency representatives, and researchers. Together we can try to find some answers.

## ***2. Design the study***

**Questions - What method do we use to study the topic? How will we look at this issue question?**

There are many different ways to study an issue. Let's look at three of the most common methods.

- **Experimental**
- **Quasi-experimental**

- **Non-experimental**

### ***Experimental***

This method uses a simple experiment. First we think of a research question like the one above. Next, we find two groups of people who are alike in many ways. We want people with similar backgrounds, ages or incomes. We ask them to participate in the project and get their written consent. We will design a program or service that we think might help. One group will get the program. They are called the treatment group. The other group does not get the program. This group is called the control group. The two groups of participants will be treated exactly the same in every other way. This approach helps us prove that our method or treatment gave us the results we wanted.

**How do you create two groups that are same or *equivalent*?** In an experimental design method, we assign people “randomly” to each group. We pick from a common pool of people. For instance we could choose anyone listed in a telephone book. The key to the success of the study using a true experimental design is the random assignment of participants. This helps keep both groups equal. True experimental designs are considered to be the most accurate or exact or precise type of experiments. They are said to have the most rigor and are often called the “gold standard” of study methods against which all other designs are judged.<sup>1</sup>

**Here is an example:** An agency gave two hundred people with disabilities help to become employed. These people were randomly divided into two groups. One hundred (100) people were assigned to group A. They worked with a facilitator. He or she used a Career Development Model to teach self-determination behaviors. They met with the facilitator, once a week for four weeks. The control group of 100 individuals with disabilities (n=100) did not use the model. Both groups completed assessments before and after the four week period. These tests helped to gather information about their progress. The researchers wanted to see if the using the model made a difference. They hoped that there would be a bigger increase in the scores of group A.

### **Quasi-experimental**

A quasi-experimental design uses a similar logic. But in this method, participants are not randomly assigned. Usually this method is used when each person already belong to one of the two groups.<sup>2</sup>

**Example:** Suppose we want to compare two groups of children who take classes at the local high school. These children have not been “randomly” assigned to these classrooms. But we will assume that they are about the same. Researchers do the study. They cannot be as confident or certain about what may have caused their results.

---

<sup>1</sup> William M. Trochim, “The Research Methods Knowledge Base,” August 16, 2004, <<http://trochim.human.cornell.edu/kb/index.htm>> (3 March 2006).

<sup>2</sup> Schutt, R.K. 1999. *Investigating the Social World*, 2<sup>nd</sup> ed. Thousand Oaks, CA: Pine Forge Press.

### **Non-Experimental or Observational**

No treatments are given in a non-experimental study. The researcher measures something about the people being studied. He or she tries to understand their experience. They do not do anything “to or with” the people. These are studies of something that can be observed as it really is.<sup>3</sup> An observational study often makes use of data that already exist. Sometimes they collect extra information through observations. Then they study the relationship among the various pieces of information.

Example: Suppose researchers want to find out if the length of time personal care attendants (PCAs) spend working for people with disabilities is related to the person’s satisfaction with the care. So the more satisfied the person with a disability is with their care, the longer the PCA stays with them. Nothing about that relationship is altered or changed. The researcher might go on to study the differences among the amounts of time PCA’s spend working for with people with disabilities based on the particular disability category.

### **3. Secure funding**

#### **Question – How will we get the money to do our research?**

Doing research costs money. So at some point, we have to find money to support the work. Government agencies, universities, or corporations usually fund research projects. Sometimes they have their own ideas and questions about issues. They will provide resources to study those topics. For example, the US Department of Education might want discover how assistive technology is used by people with intellectual disabilities. They would publish a request for proposals (commonly called an RFP). Agencies or people with disabilities can apply for those funds by sending in a written proposal telling how they would do the research. At other times, funders might be open to a wider variety of research. Community members and researchers can then try to get these funds to study topics that people with disabilities, think are important.

---

<sup>3</sup> Teaching & Learning Research Methodologies, (University College Dublin, 2006), <<http://www.ucd.ie/teachings/res/non.htm>> (30 March 2006).

## 4. Get approval from the IRB

### Question – What is an IRB? How do you get their approval? Why is this important?

**Follow the protocol.** Each IRB asks for a research protocol. A protocol is a detailed plan. It tells how the research will be done. The plan explains each step of the study. It describes all of the materials that will be used. For example any questionnaires or surveys are included. This document tells how participants will be recruited into the study. It describes what they will be told about the study. It also describes the treatment or intervention they will receive. Finally it must describe the data (or information) that will be collected from or about the participants.

**Exempt research:** Very little research is “exempt” or free from review by an IRB. Sometimes data is being collected to help a program conduct an evaluation for improvement. Then the IRB may “waive” or expedite the study being reviewed. The term waived means that the IRB will pass the research proposal on through more quickly. If the researcher plans to present or publish the results of a study then the research will not be exempt.

Some types of research studies may not require an IRB review. Studies that are conducted in educational settings or involve the use of educational tests may be waived. Studies that rely mostly on surveys, interviews or observation of public behavior may not require a full review. Sometimes data is collected from documents or records that are publicly available. Those studies may be exempt. This usually depends on whether the information can be recorded so that subjects cannot be identified. It is always best to have your research proposals reviewed by an IRB. This helps to make sure that the study meets legal and ethical standards.

**An Expedited review:** Sometimes a study does not have to be viewed by the *entire* IRB committee. The chairperson or one member may approve the study. Examples include studies that only look at records, specimens or documents not used for research. It may include information from voice video, digital or image recordings made for research purposes.

**Full or Standard Committee Review:** This takes place when a study does not get an expedited or exempt review. The proposed study is discussed at the full committee meeting. The study must receive a pass vote from a majority of the members present.<sup>4</sup>

## 5. Recruit Participants

### Question – How do we find people to take part in our study?

There are many ways that Community Partners can help with recruiting participants into community studies.

---

<sup>4</sup> IRB, 7.3, 7.4 & 7.5

- **Advertisements:** We often advertise for people to take part in a study. We may use: newspapers, email, radio, television, bulletin boards, or posters.<sup>5</sup> These ads are part of the informed consent processes. They also help us select subjects. So the IRB will review all these ads. They want to make sure that information is not misleading or harmful. This is important when people have significant support needs. It is also true for people who are economically or educationally disadvantaged.
- **Databases.** Hospitals and universities may keep what is called a database. This is a list of people who have received services. It is usually kept in their computers. For example, a hospital or clinic will keep Medical Records. They may also keep a patient information list. We can search these databases to find potential participants. This requires IRB approval before we begin. You can ask if such a list is kept by the agency. But you cannot look at the list until you get IRB approval.
- **Physicians.** We can contact physicians or schools to obtain a list of people receiving services. We need approval from the IRB before we begin. The clinic or school may need to get a written release of information from a patient or parent. Only then could they can share their lists with us. If it costs too much time or money to do this the school or hospital may say no. Hospitals and clinics need to follow special rules in releasing information. The law that protects medical records is called HIPAA. That stands for the Health Information Portability and Accountability Act. Some HIPAA rules might prevent the doctor from sharing the records with us.<sup>6</sup>

## ***Obtain Informed Consent***

**Question – What is informed consent? How do we get people’s permission to include them in the study? How do we prove that we have it? Can people with developmental disabilities give informed consent? What special rules apply? How can Community representatives help?**

The words *informed consent* means that a person has agreed to be in the study after her or she was fully informed about what would happen. The person must be legally capable of giving consent. He or she must also be fully informed of their rights in the study. We must be able to prove that we have obtained their consent. Our methods must be fair. The steps in this process are:

- Give each person information about the study
- Tell them everything any reasonable person would need to know to make a good decision.
- Give them time to consider all their options
- Make sure the person is legally capable of giving consent.
- Answer any questions that he or she has asked
- Test to make sure they understand all the information.

---

<sup>5</sup> Acceptable Methods to Recruit Subjects for Research, (University of St. Louis, 2006), <<http://www.slu.edu/research/irb/documents/RecruitmentMethods.doc>> (20 March 2006).

<sup>6</sup> Institutional Review Board Recruitment Practices, 14.3 <[http://www.uams.edu/irb/IRB\\_Policies.asp](http://www.uams.edu/irb/IRB_Policies.asp)> (University of Arkansas Medical Sciences, 2002)

- Make sure that he or she is willing to participate. Make sure no one has forced or pressured the person into giving their agreement.
- Have the person sign the consent form
- Make sure they are kept informed throughout the research study
- Confirm that this person remains willing to participate throughout the research study<sup>7</sup>

### ***Community Representatives and the Informed Consent Process***

1. Community representatives usually know the area and the people well. There are many ways that they can help with informed consent. They can make sure that words used in the consent document show respect. They can explain how to get someone's confidence and trust. They can help us avoid steps that may confuse or irritate people. They may be able to observe small changes in behavior that would tell them that someone is uncomfortable.
2. The information that a researcher considers critical may be extensive or difficult to understand. We must show evidence that the person understands what we are asking him or her to do. A representative can help write down their comments and questions. He or she may be able to translate materials into someone's native language or read the documents to them.
3. We want consent to be meaningful. People need information to make good decisions. People with disabilities can help us select the information. They can show us how to avoid overwhelming someone. They can help us find ways to confirm when a person understands. They can work with the research team to help resolve rumors.

The informed consent process begins when people first learn about a study. What people hear from this point on impacts what they think. It will also influence any decisions they make. Community representatives can help us plan how to introduce a new study.

### Creating Informed Consent Documents

Write so that a person with no medical background can understand the study.

- Use an appropriate reading level for the people you invite to participate.
- Test the materials and forms before they are used. This is called pilot testing. Find a person who knows the materials well. Have that person use the materials with someone who is very similar to the people in the study. Use the results to revise the materials. This will help make sure they can be understood.

---

<sup>7</sup> A Guide for Researchers, (Western Institutional Review Board, 2006), <<http://www.wirb.com/download/guide%20for%researchers%20090605.pdf>> (16 March 2006)

- Another way to do this is to use a focus group. Again we would find a group of people who are very similar to the people in the study. We can ask them to try the form or talk to each other about the form. Their feedback will help us make changes.

### ***Essential Elements of Informed Consent***

Selecting the information for the informed consent process is very important. The process usually has 9 key steps:

#### **1. Describe the research**

Begin with a general description of the research. Clearly explain that the person is being asked to participate in a research study. It is common for people to mistakenly believe they will receive a free service. They probably think that the treatment will be effective. Be clear that the safety and effectiveness of the treatment is unknown. That is why the study is being done. Make sure potential participants understand that these services are new. Describe the purpose and objectives of the research. Explain what you hope to accomplish. Tell what new information being sought.

Be sure to describe *all* the procedures in the study. This might include the number of blood samples, any diagnostic tests, the number of follow-up visits, or interviews. Make sure the person understands exactly what he or she will be asked to do. Make sure they know what will be involved in each step. Be especially careful to describe anything that is experimental. Let the person know how long each part will last.

Sometimes a medical study uses a placebo. The word placebo means to take the place of something. Sometimes people are given a harmless substance instead of a new drug in an experiment. This is done so that no one knows who gets the treatment. If you use a placebo you must make sure that the participants know that they may not get any treatment at all. Pay special attention to the informed consent process. Many people have difficulty understanding this idea.

Name the agency that is responsible for the research. Sometimes a study has a sponsor who pays for the research. Include that information. Name the members of the IRB or community advisory boards that reviewed and approved the research.

#### **2. Describe any reasonably foreseeable risks**

We want anyone who participates to be well aware of all possible risks that are likely to happen. We must consider all types of risks. Some will be physical. Some will involve what the person thinks or how he or she is viewed by others. For example: someone who participates in a study to prevent the HIV/AIDS virus may be at risk for social rejection. Notify people right away if any new risks are identified.

Good researchers eliminate as many risks as possible when they design the study. We must include information on each possible risk. This information must describe what

might happen and how likely that will be. We must describe how severe and how long the risk may be present. This includes any risk that may continue after the study is completed. We must think about what happens when a study is over. It is better to eliminate most risks before we begin.

### **3. Describe the expected benefits**

Remember the research we do must be meaningful. List any benefits to the person or other people. Do not overstate or exaggerate the results. Be careful not to pressure people into participating. The rules state that we cannot promise someone health care as a benefit of our study that they have a right to receive anyway. They should be able to get that care without participating at all.

People with limited access to health care services are vulnerable. Offering health care to people who otherwise do not have access to this care is not ethical. This method is really an attempt to force the person into participating. We are responsible for making sure that decisions are not influenced by the opportunity to receive health care.

Benefits are usually available only during the study. When the research is finished, the benefits also end. This fact must be clear to everyone beforehand. Some people may decide to withdraw from the study. When someone withdraws or when a study ends, benefits may become available later if the treatment works. These benefits must be explained in the informed consent process. This is particularly important in studies of new treatments. If the treatment proves to be safe and effective, the participant must be informed of the availability of the treatment when the study ends.

### **4. Describe any incentives to participate in the study.**

The research must explain any payment or gifts that will be provided. We often compensate people for their time, travel, and inconvenience. The value should be fair and reasonable. We must not give an excess amount of reimbursement. We want to avoid even the suggestion that we might be trying to influence someone's decision.

Note: Make sure people understand the difference between benefits and compensation. Compensation is given during enrollment or after participation. Benefits, such as drugs, health care, and the like, are usually given only during the study.

### **5. Explain alternatives to participation, such as other studies or services in the area**

It is important to present choices other than doing the study. Describe the advantages and disadvantages of each choice. If the only choice presented is to participate we might be trying to influence a decision. For some research there is no alternative. The only choice would be not to participate. In biomedical research, the person must be informed of the regular health care

options available. These must be compared to the research options. In behavioral research, the person must be informed of other services in the area. This information gives the person the choice not to participate.

## **6. Explain confidentiality**

People have a right to keep their information private. We must tell each person who might be in the study about these rights. Describe the safeguards and risk involved in the study. Describe what will happen to the information once the study is over. Mention all the people or agencies that may review or have access to the records. Describe any limitations in our ability to keep the records safe. This is especially important when records are stored on computers. We must take special care to keep information secure. Public knowledge of participation may be damaging to the person or their community.

## **7. Explain any risks or discomforts people may encounter.**

Input from community representatives can be helpful. They can help us decide on the appropriate amount and type of compensation. This is done at the beginning of the study. The informed consent document must explain any risks or discomforts that are likely. We must describe how invasive it will be and how long it will take. We must also describe any costs to the individual. Finally we must describe what would happen in case of injury or complications. Tell who would pay for additional treatment and what that would involve. Include any compensation for injuries or health problems resulting from participation.

There are many policies on how to compensate people during research. Some policies will come from the hospital or university. Some may be national or may be from the sponsor. Community representatives should become familiar with these policies. Sometimes treatment can be provided free of charge. Funding for free services may be limited.

## **8. Explain whom to contact with questions or concerns**

Consider three groups of contacts in the informed consent document:

- The research team
- The ethics committees or IRB
- Any special groups (such as members of a special interest group)

This information should include a person's name, address and phone number. It should include any other way to make contact (example – email). The contact information must be practical. That means it should be very easy to use and it should work. It must also be culturally appropriate. For example: In some cultures a grandparent or an elder may be the person to make decisions rather than the person who participated. The name of the researcher should be provided. This person should be available to address questions, complaints, or any health care

problems. Include the name of the research sponsor. This gives people another option for communication.

People will usually contact the research site first. Participants can contact members of the IRB if they have concerns about participation or the quality of the care. Include the names of the members. Some agencies only require the name of the chairperson. Contact information for counseling groups or people with the same disease may be appropriate.

## **9. Explain that participation is voluntary**

Assure people that their participation is voluntary. Explain that they are free to stop at any time. We must explain that refusal to participate or a decision to withdraw will not result in any penalties or loss of benefits. Clearly state the importance and value of their participation. If the study is compromised, then opportunity, time, and money have been lost.<sup>8</sup>

### ***Informed Consent for People with Intellectual Disabilities***

We want to involve people with disabilities in the research process. This can be challenging. Sometimes people have learning problems. Some may not understand complex ideas. Others may not read. Some may not fully understand the implications of the research. Other need support in the decision-making process.

We need to think about rights and best practice. We want to support vulnerable people. We need to be respectful and use a non-patronizing manner. We also need to be careful. Many bad things have happened to people with intellectual disabilities in research studies. Past studies often involved invasive, painful or high-risk medical treatments. Some used forceful therapy. These studies were thought be high-risk. They came to be viewed as something that should be avoided whenever possible.

Today people with intellectual disabilities are frequently asked about the impact of supports. They can be important partners. This is especially true in studies of community-based services. New tools have emerged to assist researchers. We have a better understanding the risks and protections needed. Today we often include people with disabilities in research activities.

### ***Principals of Informed Consent***

Our society and law require people to give consent to major decisions concerning their interests and values. Legal consent has two important parts.

- **Consent:** The word consent means that we have a legally valid agreement from someone who is fully informed of the risks and benefits. Consent is shown by signing a document. The document has all the important information about what will happen in the study. It includes all the risks and benefits.

---

<sup>8</sup> FHI, 46-60

- **Assent:** The word assent means that the person has agreed to cooperate. They show by their behavior that they are willing to participate. Examples of assent include stepping forward, smiling, and shaking the head up and down.

The courts have limited the rights of some people with intellectual disabilities to give informed consent. In those cases a guardian is appointed. He or she makes legal or medical decisions. However, even when a guardian consents we must make sure that the person is willing to participate. A person with a cognitive disability retains the right to refuse to participate, even when a legally appointed guardian has given his or her consent. The person with a disability may simply say no or refuse.

***The IRB process should document:***

1. How researchers plan to obtain informed consent, and
2. How we will make sure that people with intellectual disabilities have voluntarily agreed to participate.

People with intellectual disabilities have as much interest in choice and control as any other person.

*The courts have found that people with intellectual disabilities have a stake in personal liberty. They deserve full protection under the law.*

People with intellectual disabilities should benefit directly from being in a study.

- They should not be asked to undergo time-consuming, painful or difficult procedures merely to satisfy someone's intellectual curiosity.

We must make sure of three elements before informed consent can be valid. These are: capacity, information and voluntariness.

- **Capacity:** This word means a person's ability to express consent in a clear and meaningful way. They must be able to show us that they fully understand the consequences of a decision.
- **Information:** We are required to provide the details needed for anyone to make a good decision. We must give enough information. When someone has an intellectual disability that means we may need to give more information. We cannot assume that the person understands what we imply. The information must be given at a level and in a manner appropriate to their understanding. We may need to include information about how to pay for and keep using an option after the study ends.
- **Voluntariness:** This word means to agree without any perceived or real coercion throughout the study.

The informed consent process for people with intellectual disabilities should address all three elements.

The greater the risks, the greater the effort that we must make to assure that consent is valid. The decision-making chart below can be used to help us consider this principle.

High Scrutiny – look closely at every detail of the decision	High risk decisions that are inconsistent with the person's known values and interests.
Moderate Scrutiny – look evenly at all parts of the decision	High risk decisions that are consistent with a person's known values Low risk decisions that are inconsistent with known values
Low Scrutiny – look briefly at key parts of the decision	Low risk decisions that are clear or consistent with a person's known values and interests

**Figure A: Risk/Values decision-making matrix**

Some people do not have the capacity to make independent decisions. They may not be capable of fully understanding a choice. They may understand the choice but may not be able to communicate clearly what it is they want. They may understand day-to-day decisions but may not have the educational skills needed to understand the consent document. In any of these cases they cannot give valid consent without help. They may need assistance to make decisions or express consent.

**Assistance should be “least restrictive”.**

- Only the minimal assistance needed should be offered. This allows the person to have as much independence in decision-making as possible. This also helps us to avoid influencing a decision through accidental pressure or relationship. We do not want the person to say yes only because they need to please us.
- Anyone who helps the person make a decision should ask that person about their views. We need to know what the person values. What are his or her usual choices?

***This process may be documented through:***

1. A written statement describing the attempts made. This would include the questions asked or responses given.
2. An audio or video-tape of the same
3. Documentation of attempts to confirm what the individual might choose. This is done by asking family members, friends or other people who know his or her interests well.

- We often hear people say that a decision was made in the best interests of someone. There is usually a difference between what we think might be best and what a person thinks. It is difficult or even impossible for one person to decide what is best for another. The best we can do is to decide what we think the other person might choose if they were fully informed.
- This requires knowing the individual's desires and his or her specific situation. We may need to consult with the person, their family members, educators, and other supporters.

Sometimes it is impossible to learn enough about a person'. Then the decision-maker uses his or her best judgment.

People with intellectual disabilities often need more information than others about specific rights or decisions.

- They may also need to be given general information or background facts that others are assumed to know (e.g., information about what research is and how it helps people or their families).
- Consent involves seeking out ways to enhance the person's knowledge base about their rights as a research study participant. This may be done through the use of a pictorial/text tool. This tool can outline the participant's rights, give examples and highlight the decision that can be made for each kind of information that is shared (e.g. what will happen, what might happen, what should happen, etc.).
- We should not confuse someone's lack of information with his or her ability to make decisions. Knowing is not the same as deciding.

***Valid consent is freely given. It is not forced.***

- Coercion involves not only physical or psychological pressure but also subtle forms of pressure that occur. Examples include situations in which:
  1. A person has grown up where opportunities for choice making are limited. He may say yes or no to every request.
  2. The researcher seems to be an authority figure. He uses his or her power and influence to suggest cooperation is best. The person may be conditioned to submit to authority figures or community helpers.
  3. The researcher is a friend. He or she manages a support service that the individual needs. It must be clear that the friendship or service will not end if the person says no. This situation is not about what the researcher would do. It is about what the individual thinks he may do.
  4. Sometimes the person asking for consent is well known to the individual with a disability. The response they would like that person to give is conveyed through non-verbal communication. Some people with intellectual disabilities may be unable to separate their responses from that of a family member or friend. They may be unable to make an independent decision. They may not be able to refuse a request from that person.

- People with intellectual disabilities have a right to exercise choice and control by participating in a research study. These rights must be balanced by the need to protect vulnerable individuals from exploitation and abuse. This means that we need to go slowly, communicate clearly and take our time. Only then can we understand the wishes of a person with an intellectual disability.<sup>9</sup>

### ***Obtain Informed Consent and the IRB***

Members of an IRB are usually familiar with past abuses like Willowbrook. They may be unfamiliar with new ways to share information and obtain consent. Documents that verify informed consent are typically written in legal terms. This is unlikely to be understood by most people. Many IRBs have created forms for documenting consent. These forms may not meet the special needs of people with intellectual disabilities. Members of an IRB may want you to have that person sign a document that they can't read or don't understand. We can share new alternatives.

We suggest that you offer the IRB some special training. This works best if it is done before a proposal is submitted. Use information from this curriculum. Highlight the unique needs of the population. This will help us prepare the membership for changes to the consent form. They can become aware of new ways to learn about capacity, share information and obtain voluntary consent.

## **Introduction to Health Insurance Portability and Accountability Act 1996 (HIPAA)**

### ***Question- What is HIPAA?***

HIPAA is a set of rules followed by doctors, hospitals and other health care providers. HIPAA took effect on April 14, 2003. HIPAA helps medical professionals respect the privacy of patients. When these rules are followed, all medical records, medical billing, and patient accounts meet standards. These standards govern what is written, how documents are handled and what information will remain private.

HIPAA requires that all patients be able access their own medical records. They can correct mistakes. They must be informed and decide which personal information is shared. Patients must be notified of privacy rules in writing. This has led to a complete overhaul of how hospitals keep records and bill for services. (hippa.101.com).

### **Question - How does HIPAA affect research?**

---

<sup>9</sup> Dinerstien, R.D., Herr, S.S., & O'Sullivan, J.L., 1999. Book. A Guide to Consent. The American Association on Mental Retardation. Washington D.C.

HIPPA controls two major areas in research. They are the informed consent process and the written informed consent document. HIPPA has an impact on what information can be shared with sponsors. It also limits what information can be shared with outside groups. Research falls under the “covered entities” portion of HIPAA. All people involved with research now have additional rules to follow. These rules protect the confidentiality of medical and research information.

HIPPA covers all research that has any personal identifiers. A personal identifier is any data that can be used to trace research information back to a person. These individuals can be living or dead. This includes data that is written or electronic. It includes all human samples.<sup>10</sup>

## **7. Data collection**

### ***Question: What are some ways that information is gathered?***

There are many ways to get information. The most common ways are:

- Searching through articles or books. This is called a literature search.
- Talking with people. This is usually called an interview.
- Getting responses to ideas in focus groups. This may include self-advocates and families.
- Completing telephone and mail, surveys. This includes online surveys.

The data that is collected is then put into a measurable format.

A good researcher searches through the literature. He or she reviews all readily available materials. These can include publications, newspapers, magazines, annual reports, on-line databases, and any other published materials. It is a very inexpensive method of gathering information. It does not always yield the best information. Literature searches over the web are the fastest. Library searches can take between one and eight weeks. A library that specializes in the research topic will have the best information.

Another important part of data collection is speaking with people who will be affected by or have been involved in the research. This will give us valuable information that can be used during the all stages of the research project. This helps us get at information that is not publicly available. Sometimes this information is too new to be found in the literature.

Creating focus groups is a good way to hear first hand from interested people. These may include people with disabilities, professionals and the community. A focus group uses questions and conversation to explore people’s ideas and attitudes. Group sizes depend on the subject. For example a small group may consist of 6 to 12 people. A large set of focus groups may fill a conference room. The key ingredients for effective focus groups are: 1) a trained facilitator, and 2) a diverse audience. The facilitator’s role is to lead the discussion by asking open-ended questions. They encourage responses and keep the group focused on the topics/issues.

---

<sup>10</sup> Health Insurance Portability & Accountability Act Training for Community Connectors (University of Arkansas Medical Sciences-Office of Community-Based Public Health, 2005).

Generally, the responses are recorded on large flip chart sheets and taped to the wall. These sheets provide written documentation after the meeting. Remember this information reflects the opinion of participants. It may not be valid because it is subjective. It may be helpful in guiding the researcher to do further study. It does not represent the entire population.

Another type of data collection is personal interviews. Talking with individuals, families and professionals can help us gain an in-depth understanding from their prospective. We will learn additional information that may affect the research. Personal interviews involve one person interviewing another person for personal or detailed information. Typically, an interviewer will ask questions from a written questionnaire and record the answers word for word. The written questionnaire helps us record the total number of responses to each question.

Personal interviews are generally used only when people are not likely to respond to other survey methods. Telephone surveys are the fastest method of gathering information from a relatively large sample. The interviewer follows a prepared script that is essentially the same as a written questionnaire. However, unlike a mail survey, the telephone survey allows the opportunity for some opinion probing. Telephone surveys can range from ten minutes to thirty minutes. The people making the call usually need to be paid for their time.

Mail surveys are a cost effective method of gathering information. They are ideal for large sample sizes. They work well when the sample comes from a wide geographic area. They cost a little less than telephone interviews. They take over twice as long to complete (eight to twelve weeks). With the phone surveys you have the information right away. When you conduct mail surveys there is usually a several week turn around time. However, because there is no interviewer, there is no possibility of interviewer bias. The main disadvantage is that there is no opportunity to ask for more detailed information.<sup>11</sup> (StatPac).

## **8. Intervention**

### **Question - What is an intervention?**

The word intervention means taking action to change what is happening or might happen to someone. This is usually done to prevent something unwanted. For example: we might offer an 8-week health promotion workshop, to increase healthy eating habits. We may do this to reduce the risk of heart disease and diabetes.

## **9. Data analysis**

Data is collected during and at the end of each intervention. After the data is collected, we organize and examine it so we can come to some conclusions. We might use charts, graphs, tables and narratives. Often we describe events in the order they happened to tell about our findings. We also may use statistics (data with numbers) and logical techniques to describe, summarize and compare information.

---

<sup>11</sup> Research Methods, (StatPac-Survey Software, 2006) <<http://www.statpac.com/surveys/research-methods.htm>> (8 February 2006).

## **10. Sharing results**

Another word for sharing our results is dissemination. Disseminating our results involves participation from both community members and researchers.

**Who gets the information about the findings of the research?** Study participants, community members, researchers, funders and the public does.

**How do they receive the information?**

Through various mediums: These include meetings, scientific journals and conferences, newspapers, television, and radio. We must also ask ourselves:

**Are the findings presented in an accessible and meaningful way?**

**Whose voice(s) is/are heard or shared? Are the findings scientifically valid? Will they also meet the needs of an academic audience?**

**What is the purpose of this dissemination activity?**

To make sure that our findings are useful to people in reaching decisions, making changes, or taking specific action. We want to assure that the information is available to those who can most benefit from it.

**What if the research findings are shared in economically disadvantaged communities? Will this reinforce negative stereotypes? Would it do more harm to the community to report such findings?**

***Comments & Questions***

***Final Comments & Questions***

***Administer Post-Workshop Questionnaire***