

How You Can Help Advance Cancer Research

Providing Tissue Samples as Part of a Clinical Trial



Research Advocacy Network

This “tip sheet” is intended to provide answers and insight for using the brochure and maximizing the utility of the publication. It should be used by the healthcare provider and not distributed to patients.

Overall Tips

- As you know from your experience with patients, a cancer diagnosis is often a traumatic experience. The lack of highly effective and well-tolerated treatments is a major reason that all of us fear cancer. In order to design improved treatments, researchers must be able to study the cancer cells from actual patients to see what problems they show and how they respond to treatment. Patients who participate in a clinical trial that includes tissue samples may help to improve cancer treatments in the future that could benefit others – perhaps even their friends and family.
- Some patients will want to participate in a clinical trial with tissue samples; others will not. The choice to participate is an individual one and is likely influenced by the type of cancer a patient has and the invasiveness of the tissue sampling procedures. Some patients may be willing to provide an initial tissue sample that is used for diagnosis but may not want to provide a subsequent sample that would be used for research.
- If we accept that participation in a clinical trial that includes tissue samples is important in advancing cancer research, the next question becomes how to address this participation with your patients. When speaking with patients, many researchers report that it is best to motivate participation in a clinical trial, before addressing the need for tissue samples. Once patients become interested in the trial, they may perceive the samples as a necessary logistical component instead of as a barrier.

Answers to Questions in the Brochure

• What is the purpose of the research and what do you hope to learn?

The purpose of the research study can be found in the Primary Objective or Study Objective section of the protocol.

• Am I likely to benefit from providing tissue samples?

In general, patients will not necessarily benefit directly from providing tissue samples. However, in rare cases, the tissue sample may provide information relevant to the patient's disease or treatment that can then be shared with the physician. The protocol may specify the process by which the patient's physician can receive this information; if it does not, you may want to ask the principal investigator or the organization sponsoring the trial. However, it is important that patients understand that participation in the study and provision of tissue samples is unlikely to benefit them directly. Information derived from the tissue samples could lead to treatments that would benefit the patient's family and friends, as well as future generations. It is also possible that the information may benefit the patient in the future if they have a recurrence.

• From which part of my body will the tissue sample(s) be taken?

This will depend on the type of cancer, the amount of tissue needed, current levels of technology and other factors. The protocol will describe the part of the body from which tissue is to be taken, the procedures to take the sample, and the risks involved.

• How will the tissue sampling procedure be performed?

This will also depend on many factors, as listed in the preceding answer. The website by Dr. Ed Uthman listed in the sources section at the end of this tip sheet provides a patient-friendly overview of different types of tissue sampling procedures. However, note that these procedures are listed under the heading Biopsies, which technically refers only to samples obtained for diagnostic purposes. The procedures, however, are the same. The websites are listed on a separate sheet at the end of this document that can be copied and given to patients.

• Will the tissue sampling procedure hurt?

The amount of discomfort the patient experiences will depend on the type of procedure performed, as well as patient-specific factors such as tolerance level for pain or discomfort. The patient should ask you, as a part of the healthcare team, for more information about the planned sampling procedure. Also see question above.

• Is the tissue sampling procedure risky to me?

In general, tissue sampling procedures are not unduly risky to patients. However, the patient should be encouraged to discuss potential risks with the doctor. Some of the websites listed at the end of this tip sheet list risks and may be helpful for patients.



- Information for patients about clinical trials can be found on the National Cancer Institute and United States Food and Drug Administration websites listed at the end of this document.
- Information about providing tissue samples can be found on the Research Advocacy Network website listed at the end of this document.
- A patient may have already provided a tissue sample as part of his or her diagnostic procedures and thus may only be looking at one additional sample.
- Use of the term biopsy may make some patients uncomfortable, as it is psychologically associated with “looking for cancer.” Therefore, it may be better to use the phrase tissue sample. A biopsy is defined as the removal of tissue or cells from the body for examination under a microscope, typically to check for signs of cancer. Tissue samples obtained for research may be used to examine the action of a potential therapeutic agent on the cells.
- The person who discusses clinical trial participation and tissue samples with patients should be thoroughly familiar with the study protocol. This tip sheet offers general suggestions, but the specific features of each trial will differ.
- At the end of the brochure, there is a space for the name and contact information of the person from whom patients can receive further information. Please add this information to each brochure.



- **How soon will I be able to engage in my normal activities after the tissue sampling procedure?**

This will depend on the type of tissue sample provided. In some cases, the tissue sampling procedure would not be expected to affect the patient’s activities at all, whereas in other cases, the patients may need to remain in the hospital for several days after the procedure and slowly resume normal activities over the course of a week (e.g., open lung tissue sampling procedure).

- **How many tissue samples are you requesting of me? Will they be taken at different times? If yes, how many and how often?**

This should be specified in the study protocol. Often, protocols will have a section entitled Schedule of Assessments that will list the scheduled time for each tissue sampling procedure.

- **What if I provide one tissue sample then decide I do not want to provide any more?**

Patients can always decide to stop participating in the study and can refuse to provide tissue samples at any time.

- **Do I have to make a special trip to the hospital or clinic to provide the tissue sample or will it be done as part of my regularly scheduled appointments?**

This will depend on the protocol, as well as the type of procedure. Often, protocols will have a section entitled Schedule of Assessments that will list the scheduled time for each tissue sampling procedure. It can then be determined whether these could correspond with regularly-scheduled appointments.

- **Can my tissue samples be used for more than one study?**

Under some conditions, patients may be able to request that additional tissue be taken for use in a different study. However, you may want to ask whether they have a specific study in mind. If not, you may want to put them into contact with a tissue bank that will be able to use additional tissue.

- **Will I be able to find out the results of the tests conducted on my tissue samples?**

In general, the results of the research tests conducted on tissue samples are provided as averages for the entire group under study and not for individual patients. Additionally, the meaning of each patient’s results (e.g., high or low levels of a certain protein in their cancer cells) will probably not be known for some time, often years. Studies take time to conduct and the cancer community must be shown to have confidence in the results before any information can be used to make individual patient treatment decisions or prognoses. Healthcare providers should be prepared to tell the patient, based on the protocol, if and when any results will be made available to the patients or their physicians. This information may also be listed in the consent form.

- **Will my insurance cover the costs or is this included in the study?**

If the tissue sample is for research purposes only, the procedure will be covered by the study and the cost should be spelled out under the “Cost Section” in the Informed Consent Document. In order to adequately address cost and payment issues, the study coordinator or nurse should be thoroughly familiar with the study protocol.



Sources of Information For Patients About Tissue Sampling and Clinical Trials

Tissue Sampling Procedures

Note that the many of the procedures listed on these sites can be the same for tissue that is sampled for diagnostic and research purposes.

Mayo Clinic. Biopsy procedures used to detect cancer. Available at: <http://www.mayoclinic.com/health/biopsy/CA00083>. Accessed August 14, 2008.

Uthman EO. The biopsy report: a patient's guide. Types of biopsies. Available at: <http://www.cancerguide.org/pathology.html>. Accessed August 14, 2008.

Clinical Trials

Coalition of Cancer Cooperative Groups. Available at: <http://www.cancertrialshelp.org/>. Accessed August 15, 2008.

United States Food and Drug Administration. Clinical trials. Available at: <http://www.fda.gov/oashi/clinicaltrials/default.htm>. Accessed August 15, 2008.

National Cancer Institute. What is a clinical trial? Available at: <http://www.cancer.gov/clinicaltrials/learning/what-is-a-clinical-trial>. Accessed August 15, 2008.

Providing Tissue for Research

National Cancer Institute. Providing tissue for research. What you need to know. Available at: <http://www.cancer.gov/clinicaltrials/resources/providingtissue>. Accessed September 2, 2008.

Research Advocacy Network. Why is it important for me to consider donating my tissue for research? Available at: <http://www.researchadvocacy.org/publications/posters.php>. Accessed August 14, 2008.

Research Advocacy Network. The importance of tissue samples in research. Available at: <http://www.researchadvocacy.org/publications/posters.php>. Accessed August 14, 2008.

Research Advocacy Network. Understanding pathology and tissue research. Available at: <http://www.researchadvocacy.org/publications/posters.php>. Accessed August 14, 2008.

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