

Information Sheet
for Participants of the California Encephalitis Project
California Department of Public Health

Dear study participant,

Encephalitis is often a severe brain illness that can be caused by a number of different infections. If an infection causing encephalitis is found, specific treatments are sometimes available, but in most cases no cause is ever found. Newer tests have improved our ability to find infections of the brain (e.g. diagnose), but many of these tests are generally only done at a few research labs.

The California Department of Public Health (CDPH), Viral and Rickettsial Disease Laboratory (VRDL) initiated *the California Encephalitis Project*. The purpose of this study is to learn more about the many causes of encephalitis and to improve our ability to find them.

The study will consist of the following steps:

- ❑ CDPH and CDC labs will test the unused portions of your cerebral spinal fluid, blood or other specimens of patients that your doctor has already taken as part of your routine medical care for infections that can cause this brain disease, encephalitis. This advanced testing will be in addition to diagnostic tests done as part of routine medical care. Some of the tests are experimental. We will be testing only the unused portions of your CSF specimens which are taken for routine medical care. You will **NOT** have any additional CSF samples drawn solely for the purposes of this study.
- ❑ We will **NOT** test any of your specimens for the human immuno-deficiency virus (HIV).
- ❑ Testing will be done at VRDL and other designated laboratories, such as at the CDC.
- ❑ All testing, that is a part of this project, will be done at **NO** charge to you or your insurance. You will **NOT** be paid for being in this study.
- ❑ Your doctor will be asked to complete a brief form about the symptoms, history of your illness, and about the testing done at the hospital lab.
- ❑ Test results will be sent to your doctor as they become available and he/she should discuss them with you. It will take us a few days to several weeks or months to get test results to your doctor. The time needed for testing varies by test.

California Encephalitis Project Outcome Study

- ❑ Project staff will contact you and/or doctor 3, 6 and 12 months from the time you became sick to find out about your recovery
- ❑ We would like to freeze and store your remaining specimens after testing is completed. This will allow us to do further testing in the future, as new tests for infectious agents causing encephalitis become available.
- ❑ The study is on-going.
- ❑ We would like to enroll you in the study for the entire period. Your active participation will involve three 20-minute phone calls spaced over a one year period
- ❑ We plan to keep information collected from this study for an indefinite period of time.

Since all specimens we will use are taken by your physician or other hospital personnel for routine medical care, risks to you from being in this study are small. The two possible risks are loss of patient privacy and use of research tests by your doctor for making clinical decisions.

The following will be done to protect you from these risks:

- ❑ Only authorized study personnel will have access to the names of patients in the project. The project records will be kept in a locked file. All project information stored in the computer will be protected by a password which only project personnel will have access to. Project records will be linked to the patient's specimens by a number and no names will be sent outside the state health department when used for research. Reports presented at meetings or papers published from this project will **NOT** contain any personal identifying information.
- ❑ Some of the tests used for this project are for research purposes only and should not be used for making clinical decisions. For this reason, when such tests are used, the reports sent to your doctor will include a notice about the research nature of the test.

The benefit for you from being in this study will be that additional testing may identify the cause of your illness that may otherwise be unknown. In addition, your participation in this project will help us learn more about infections causing this brain disease, encephalitis. This may improve our ability to find the cause of infection and possibly treat future cases of this serious illness.

Being in this study is your **choice and strictly voluntary**. You are free to refuse to participate in the study for any reason. You are free to withdraw at any time and for any reason. If you decide to withdraw, or have questions about the study or feel you've been harmed, you should contact **Heather Sheriff at (510) 307-8608** and we will discard your specimens and remove your records from project files. Deciding to withdraw from the study will **NOT** affect your medical care or patient's rights.

If new facts become known which may affect the risks or benefits of this study, we will let you know so that you can choose whether or not you want to stay in this study.

Your rights of privacy will be protected to the fullest extent of the law. All information obtained about you will be kept private as legally possible.

If you have questions about this study or if you have general questions about giving consent or your rights as a participant in this study, please contact the Project Coordinator, at (510) 307-8608.

You should also be receiving a copy of the Patient's Bill of Rights with this information sheet.

Thank you very much for agreeing to participate in this study. Please keep this information sheet for your records. Do not hesitate to call if you have any questions.

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CALIFORNIA RESEARCH PARTICIPANTS

BILL OF RIGHTS

Any person who is asked to participate as a human subject in a research study, or who is asked to consent on behalf of another, has the following rights:

- a) Be informed of the nature and purpose of the study
- b) Be given an explanation of the procedures to be followed in the study, and any drug or device to be utilized
- c) Be given a description of any attendant discomforts and risks reasonably to be expected from the study
- d) Be given an explanation of any benefits to the subject reasonably to be expected from the study, if applicable.
- e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
- f) Be informed of the avenues of medical treatment, if any, available to the subject after the study if complications should arise.
- g) Be given an opportunity to ask any questions concerning the study or the procedures involved.
- h) Be instructed that consent to participate in the study may be withdrawn at any time and the subject may discontinue participation in the study without prejudice.
- i) Be given a copy of the signed and dated written consent form.
- j) Given the opportunity to decide to consent or not to consent to a study without the intervention of any element of force, fraud, deceit, duress, coercion, or undue influence on the subject's decision.