



## Notice of Privacy Practices

eStudySite

Privacy Official: Pat Kappen, 619-255-5903

**Effective Date: October 1, 2005**

**THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

**eStudySite is not a covered entity under the Health Insurance Portability and Accountability Act (“HIPAA”); therefore we are not required to follow the HIPAA laws. However, we must follow laws related to clinical research. In addition we may act as a business associate of a HIPAA covered entity such as your hospital or physician. Since we are committed to maintaining the confidentiality of your medical and related information we are providing you this Notice of our Privacy Practices.**

***We understand the importance of privacy and are committed to maintaining the confidentiality of your medical information.*** We create a research record with requirements that are specific to the research study in which you are participating. This may include a complete medical history, past medical history, family history, social history, review of symptoms and a physical examination. It will also include laboratory and radiology studies as well as any other tests that are required by the protocol. We need this record to document your participation in the research study and comply with certain legal requirements. At all times during the study we must comply with both federal and state laws concerning your history, physical, and the results of required diagnostic studies.

This notice will tell you about the ways in which we may use and disclose medical information about you (written, oral, or electronic). We also describe your rights and certain obligations we have regarding the use and disclosure of your medical information.

*If you have any questions about this Notice, please contact our Privacy Officer listed above.*



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## A. How eStudySite may Use or Disclose Your Health Information

eStudySite (eSS) collects health information about you and stores it in a study binder, a paper chart and/or on a computer. This is your research and medical record. In some cases we create a record of a screening exam we have performed to determine if you are eligible for a particular study. The medical record may either be our property or the property of the clinical trial sponsor; in some cases you have access to the record. The law permits us to use or disclose your health information for the following purposes:

1. Participation in the Study or Treatment by other providers. Under the terms of the research study that you have agreed to participate in, we may use medical information about you to provide you with medical treatment or services; we may disclose medical information about you to doctors, nurses, technicians or other personnel if you are hospitalized during your participation in the study. We will disclose information about you to those overseeing the conduct of the study, as described in the informed consent form document that you signed when you enrolled in the study.

eStudySite Database. We may include certain information about you in our research subject database. We maintain demographic information (such as your name, date of birth, race, ethnicity, where you live) and information regarding your health as well as what research study you are participating in. We may also disclose medical information to members of your family or others who can help you when you are sick or injured.

Occasionally, as a result of the screening exam we may refer you to a health care provider. Or you may, on your own, visit a health care provider or hospital/emergency room. Sometimes, if our screening exam is your only recent health care record, or if other circumstances require, your treating provider may ask for a copy of the screening exam and resulting record which we will release to ensure your health care provider has the information they need.

2. Payment. We use and disclose medical information about you to obtain payment for the services we provide. For example, we use your information to obtain payment from the company sponsoring the research trial. Generally this release of information is minimal and governed by research rules.

3. Health Care Operations. We may use and disclose medical information about you to operate eSS. For example, we may use and disclose this information to review and improve the quality of care we provide, or the competence and qualifications of our professional staff. We may also use and disclose this information as necessary for medical reviews, legal services and audits, including fraud and abuse detection and compliance programs and business planning and management. Although federal law does not protect health information which is disclosed to someone other than another healthcare provider, health plan or healthcare clearinghouse, under California law all recipients of health care information are prohibited from re-disclosing it except as specifically required or permitted by law.

4. Appointment Reminders. We may use and disclose medical information to contact and remind you about appointments. If you are not home, we may leave this information on your answering machine or in a message left with the person answering the phone.

5. Sign in sheet. We may use and disclose medical information about you by having you sign in when you arrive at our office. We may also call out your name when we are ready to see you.

6. Notification and communication with family. We may disclose your health information to notify or assist in notifying a family member, your personal representative or another person responsible for your care about your location, your general condition or in the event of your death. In the event of a disaster, we may disclose information to a relief organization so that they may coordinate these notification efforts. We may release medical information about you to the Legally Authorized Representative who you have authorized to receive such information, as is specifically outlined in the informed consent form that you signed when you enrolled in the study. If you are able and available to agree or object, we will give you the opportunity to object prior to making these disclosures, although we may disclose this information in a disaster even over your objection if we believe it is necessary to respond to the emergency circumstances. If you are unable or unavailable to agree or object, our health professionals will use their best judgment in communication with your family and others.

7. Marketing. eSS generally does not engage in marketing your identifiable information. We may contact you to give you information about products or services related to your treatment, case management or care coordination, or to direct or recommend other treatments or health-related benefits and services that may be of interest to you, or to provide you with small gifts. We may also encourage you to purchase a product or service when we see you. If we receive any payment for these communications, we will tell you who is paying us, and we will also tell you how to stop them if you prefer not to receive them. We may make communications tailored to your needs if you have a chronic and seriously debilitating or life-threatening condition. (If we are remunerated for such communications, we will tell you and inform you how to stop them.) We will not otherwise use or disclose your medical information for marketing purposes without your written authorization.

8. Required by law. As required by law, we will use and disclose your health information, but we will limit our use or disclosure to the relevant requirements of the law. When the law requires us to report abuse, neglect or domestic violence, or respond to judicial or administrative proceedings, or to law enforcement officials, we will further comply with the requirement set forth below concerning those activities.

9. Research Oversight Activities. We may disclose medical information to a research or health oversight agency for activities authorized by law. These oversight activities include, for example, monitoring, audits and inspections. These activities are necessary for the government to monitor human research activities and compliance with human research protection regulations. Examples of these agencies would be the Office of Human Research Protections (OHRP) and the Food and Drug Administration (FDA).

10. Review of candidates for other studies. We may from time to time, review your records internally to determine if you are a candidate for other research trials. We will not disclose your information or enroll you in any trial without your specific consent. If we determine you are a candidate for another trial we will contact you and invite you to learn more. We may disclose your health information to researchers conducting research with respect to which your written authorization is not required as approved by an Institutional Review Board or privacy board, in compliance with governing law.

11. Public health. We may, and are sometimes required by law to disclose your health information to public health authorities for purposes related to: preventing or controlling disease, injury or disability; reporting child, elder or dependent adult abuse or neglect; reporting domestic violence; reporting to the Food and Drug Administration problems with products and reactions to medications; and reporting

disease or infection exposure. When we report suspected elder or dependent adult abuse or domestic violence, we will inform you or your personal representative promptly unless in our best professional judgment, we believe the notification would place you at risk of serious harm or would require informing a personal representative we believe is responsible for the abuse or harm.

12. Health oversight activities. We may, and are sometimes required by law to disclose your health information to health oversight agencies during the course of audits, investigations, inspections, licensure and other proceedings, subject to the limitations imposed by federal and California law.

13. Judicial and administrative proceedings. We may, and are sometimes required by law, to disclose your health information in the course of any administrative or judicial proceeding to the extent expressly authorized by a court or administrative order. We may also disclose information about you in response to a subpoena, discovery request or other lawful process if reasonable efforts have been made to notify you of the request and you have not objected, or if your objections have been resolved by a court or administrative order.

14. Law enforcement. We may, and are sometimes required by law, to disclose your health information to a law enforcement official for purposes such as identifying or locating a suspect, fugitive, material witness or missing person, complying with a court order, warrant, grand jury subpoena and other law enforcement purposes.

15. Coroners. We may, and are often required by law, to disclose your health information to coroners in connection with their investigations of deaths.

16. Organ or tissue donation. We may disclose your health information to organizations involved in procuring, banking or transplanting organs and tissues.

17. Public safety. We may, and are sometimes required by law, to disclose your health information to appropriate persons in order to prevent or lessen a serious and imminent threat to the health or safety of a particular person or the general public.

18. Specialized government functions. We may disclose your health information for military or national security purposes or to correctional institutions or law enforcement officers that have you in their lawful custody.

19. Worker's compensation. We may disclose your health information as necessary to comply with worker's compensation laws. For example, to the extent your care is covered by workers' compensation, we will make periodic reports to your employer about your condition. We are also required by law to report cases of occupational injury or occupational illness to the employer or workers' compensation insurer.

20. Change of Ownership. In the event that eSS is sold or merged with another organization, your health information/record will become the property of the new owner, although you will maintain the right to your records as previously described.



## **B. When eSS May Not Use or Disclose Your Health Information**

Except as described in this Notice of Privacy Practices, eSS will not use or disclose health information which identifies you without your written authorization. If you do authorize eStudySite to use or disclose your health information for another purpose, you may revoke your authorization in writing at any time.

Other uses and disclosures of medical information not covered by this notice or the laws that apply to us will be made as outlined in the Authorization to Use and Share Protected Health Information (PHI) section of the informed consent form that you signed when you enrolled in the research study.

## **C. Your Health Information Rights**

1. Right to Request Special Privacy Protections. You have the right to request restrictions on certain uses and disclosures of your health information, by a written request specifying what information you want to limit and what limitations on our use or disclosure of that information you wish to have imposed. We reserve the right to accept or reject your request, and will notify you of our decision. However, usually your rights are limited when you enroll in a research study. Your study consent explains this in greater detail.

2. Right to Request Confidential Communications. You have the right to request that we communicate with you about research matters at a phone number or address of your choosing. At the time of enrollment into the study, you must give the study nurse the preferred address and phone number. Also, you must notify eStudySite with any changes to your contact information while you are participating in the study.

We will comply with all reasonable requests submitted in writing which specify how or where you wish to receive these communications.

3. Right to Inspect and Copy. You have the right to inspect or receive a copy of the medical information that we collect about you during your participation in a research study. However, you may not be able to receive this information until the research study is over. To access your medical information, you must submit a written request detailing what information you want access to and whether you want to inspect it or get a copy of it. We will charge a reasonable fee, as allowed by California and federal law. We may deny your request under limited circumstances such as during the course of the research study you are enrolled in. If we deny your request to access your child's records or the records of an incapacitated adult you are representing because we believe allowing access would be reasonably likely to cause substantial harm to the patient, you will have a right to appeal our decision. If we deny your request to access your psychotherapy notes, you will have the right to have them transferred to another mental health professional.

4. Right to Amend or Supplement. You have a right to request that we amend your health information that you believe is incorrect or incomplete. You must make a request to amend your record in writing, and include the reasons you believe the information is inaccurate or incomplete. We are not required to change your health information, and will provide you with information about eStudySite's denial and how you can disagree with the denial. We may deny your request if we do not have the information, if we did not create the information (unless the person or entity that created the information is no longer available to make the amendment), if you would not be permitted to inspect or copy the



information at issue, or if the information is accurate and complete as is. You also have the right to request that we add to your record a statement of up to 250 words concerning any statement or item you believe to be incomplete or incorrect. Any right to amend will be based on the research study requirements and protocols.

5. Right to an Accounting of Disclosures. You have a right to receive an accounting of disclosures of your health information made by eSS, except that eSS does not have to account for the disclosures provided to you or pursuant to your written authorization, as part of the research study you are enrolled in, or as described in paragraphs 1 (treatment), 2 (payment), 3 (health care operations), 6 (notification and communication with family) and 16 (specialized government functions) of Section A of this Notice of Privacy Practices or disclosures for purposes of research or public health which exclude direct patient identifiers, or which are incident to a use or disclosure otherwise permitted or authorized by law, or the disclosures to a health oversight agency or law enforcement official to the extent eStudySite has received notice from that agency or official that providing this accounting would be reasonably likely to impede their activities.

6. Right to a Paper Copy of this Notice. You have a right to a paper copy of this Notice of Privacy Practices, even if you have previously requested its receipt by e-mail.

If you would like to have a more detailed explanation of these rights or if you would like to exercise one or more of these rights, contact our Privacy Officer listed at the top of this Notice of Privacy Practices.

#### **D. Changes to this Notice of Privacy Practices**

We reserve the right to amend this Notice of Privacy Practices at any time in the future. Until such amendment is made, we are required by law to comply with this Notice. After an amendment is made, the revised Notice of Privacy Protections will apply to all protected health information that we maintain, regardless of when it was created or received. We will keep a copy of the current notice posted in our office (where applicable in our waiting) area and a copy will be available at each appointment. We will also post the current notice on our website.

#### **E. Complaints**

Complaints about this Notice of Privacy Practices or how eSS handles your health information should be directed to our Privacy Officer listed at the top of this Notice of Privacy Practices.

If you are not satisfied with the manner in which this office handles a complaint, you may submit a formal complaint to:

Department of Health and Human Services  
Office of Civil Rights  
Hubert H. Humphrey Bldg.  
200 Independence Avenue, S.W.  
Room 509F, HHH Building  
Washington, DC 20201

You will not be penalized for filing a complaint.