NYSPI IRB Approved
7361
11/21/2018 -> 11/20/2019

Cover Sheet for "Are Bright Lights and Regulated Sleep Times Effective Treatment for Depression?" (IRB #7361)

Overview: This outline is a guide for you to use while considering whether to participate in this research study. The consent that follows includes much more information about the study and its risks, which you will need to make a decision. Please read this outline and the consent carefully, and only sign it if you are comfortable doing so.

- You are being asked to participate in a research treatment study because you are depressed.
- Your treatment will involve keeping specified sleep times and sitting in front of bright lights wearing tinted or untinted goggles.

Type of treatment: The treatment portion of this study will last up 6 weeks followed by six month**s** during which helpful treatment can be continued or other treatment can be tried. Prior to treatment, blood and urine tests as well as a heart test and physical examination will determine whether you are healthy and not pregnant (if you are a fertile female). Treatment will be with bright lights and specific changes to your sleep, partially determined by how you answer questions about when you do or like to do things and partially by when you would like to be asleep. The specific timing and manipulation of allowed sleep, bright lights and use of goggles will be randomly (like flipping a coin) determined. In order to manipulate your sleep, varying amounts of time remaining awake between allowed sleep will be required, for some patients required wake time might reach as long as 42 hours on one or more occasions. Extended wake times, if assigned, will always occur about a week apart. During the first week you will complete rating forms and speak with a study doctor by telephone daily and then weekly for the remainder of 6 weeks. Thereafter, your study doctor will continue to treat you for an additional six months during which there will be monthly determinations of how you are doing. During this time, while your study doctor will manage your treatment, you or your insurance will pay for any medicine or other treatment such as a light box. After this six months, if psychiatric treatment is still needed, your doctor will help you find further treatment.

Alternatives to participation: You do not have to participate in this research study to receive treatment for depression. If you decide not to participate, the doctor who evaluated you will help you find an alternative.

Risks: There are risks and discomforts associated with participating in this study (please read the "Risks" section of the detailed consent for a complete listing and explanation of risks). These include:

- Your depression may not improve
- Bright light can over-stimulate some people and can cause patients with bipolar disorder to switch from being depressed to being "high" (that is, hypomanic or manic)
- Missing sleep can also over-stimulate and induce switching to a "high" mood

Compensation: None

Voluntary Participation: Participation in this study is entirely voluntary. You do not have to participate if you do not want to and can stop participating at any time.

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CONSENT FORM

Are Bright Lights and Regulated Sleep Times Effective Treatment for Depression?

Purpose and Overview

The purpose of this study is to find out whether sleeping only at regulated times and sitting in front of a bright light wearing goggles is effective treatment for depression. You are being asked to participate in this study because you are depressed and do not have mood swings (bipolar disorder).

Voluntary

Participation in this research study is voluntary. If you decide not to participate, or if you later decide to stop participating, or your doctor removes you from study participation for any reason, you will not lose any benefits to which you are otherwise entitled. A decision not to participate or withdraw your participation will not affect your current or future treatment at the New York State Psychiatric Institute or Columbia University.

Alternatives to Participation

There are alternatives to your participating in this study. If you previously participated in another treatment study, you may be eligible for further treatment without taking part in this study. You can go to a private doctor or to a psychiatry clinic where you may receive any of the medications marketed for depression. Electroconvulsive treatment and focused psychotherapy are also accepted treatments for depression. Electrical stimulation of a nerve in the neck (called the vagus nerve) has also been approved by the FDA.

Study Procedures

In order to find out if you can be treated in this study, you will receive a complete psychiatric evaluation by a study psychiatrist. If the study psychiatrist decides you can participate, you will be given this consent form to read. If you then agree to participate and are satisfied that your questions have been answered, you will then sign the consent form. A member of the research team will then complete research rating forms, you will complete self-report ratings, about a tablespoon of blood will be drawn for routine laboratory testing (for example, to make sure your kidneys and liver are healthy), a doctor will perform a physical examination (for example, listen to your heart and lungs, look into your eyes) and you will provide a urine specimen (to be checked for kidney function, pregnancy if you are a woman of child-bearing age, and street drugs such as heroin and cocaine). These tests will determine if you have a medical disorder such as low thyroid function that might be the cause of your depression or that should be treated prior to your entry into this study. If you have one of these medical problems, your doctor will discuss this with you at the first visit after it is found, or telephone you if it requires quicker attention.

You have been offered participation in this study because you are depressed. Once you have agreed to participate and signed the study consent form, you will be asked to answer questions about your mood, prior treatment, the times of the day you like to do things, a variety of common psychiatric symptoms and your interest and functioning in several life circumstances, like work and family. You will wear an activity monitor (which looks like a wrist watch) and keep a log of your sleep, mood and energy for about seven weeks. After 1-2 weeks (you can choose to wait up to 30 days before re-evaluation), you will be re-evaluated. If you remain significantly depressed at this re-evaluation, and remain agreeable, you will begin sleeping only at assigned times (regulated sleep therapy) plus sitting in front of bright

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lights wearing goggles. The timing of your allowed sleep and which of several types of goggles you will wear will be determined randomly (as if by a flip of a coin). Whatever timing and goggles you are assigned you will continue for the next six weeks, initially with daily telephone evaluations and from the end of week 1 through the end of week 6 weekly in person. At the time you are randomized and again at weeks 1 and 6 visits you will also be evaluated by a rater who does not know whether you have begun treatment or what treatment you may be receiving. It is important that you not let this rater know what your treatment is or whether you have begun or completed any treatment.

Saliva Collection

Saliva will be collected on two occasions, once every half hour for four hours prior to start of assigned sleep times and once every half hour for three hours about a week later. To collect saliva, you will be given tubes containing a cotton swab. At each collection time you will place a cotton swab in your mouth for two minutes, then place back in the tube labeling the time; when all tubes are collected they are stored in the refrigerator until you bring them to the clinic which will have them analyzed for a hormone called melatonin which is directly regulated by you internal biological clock. You will be asked to wear goggles for an hour prior to saliva collection and throughout the two collections.

Light and Regulated Sleep Therapy

Treatment will be with bright lights and regulated sleep times. To help us determine whether this approach is effective treatment and which times for sleep and bright lights and how best to use sleep and bright lights, by chance different patients will receive different instructions. All will be given specific times they are allowed to sleep and specific times to sit in front of the bright lights. For some**,** the specific sleep times may include one or more 48 hour period during which they are not allow to sleep as long as 42 hours. Any who are asked to miss sleep more than one extended period, these times of missed sleep will be separated by at least several days. You will be provided goggles both to wear in the evening during saliva collection for melatonin and when sitting in front of the bright lights. Prior to being told your specific times for allowed sleep and use of the bright lights, you will complete the Morningness-Eveningness Questionnaire; your answers will suggest where your biologic clock is currently set and partially determine the times you will be allowed to sleep and instructed to use the bright lights. You will also report the time you want to be sleeping which will also determine the sleep instructions and timing of your bright light use.

Risks and Inconveniences

General. A general risk is that you may remain depressed. It has not been determined whether the combination of wake therapy, light therapy and regular allowed sleep is effective for your disorder. Second, suicide is a risk in patients who are depressed. Patients with bipolar disorder may become manic. These risks will be minimized by: (a) exclusion of patients known to have bipolar disorder; (b) not participating in the study if you or your doctor consider you to be at significant risk to harm yourself or in need of hospitalization; (c) discontinuing study participation should you become significantly worse or significantly suicidal; (d) offer of hospitalization in the case of significant worsening/suicidal thoughts/behavior; (e) weekly visits and 24 hour phone availability of an experienced research psychiatrist.

Remaining awake for long periods. The major risk of remaining awake for long periods is mania. This possibility will be minimized by only including patients without a history of mania or hypomania (a period of being “high” without being manic), constant availability of access to a research psychiatrist by telephone.

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Light Therapy. Patients may become over-stimulated, and those with bipolar disorder may become manic. As this study will not include patients known to have bipolar disorder, this risk seems minimal, but likely not zero, especially since not all patients with bipolar disorder are known to have it. More commonly, over-stimulation is described as "like too much coffee" and can be eliminated by decreasing bright light exposure, either by decreasing the time in front of the light or increasing the distance from the light, or both. Occasionally, light exposure may also cause headache, nausea or eye irritation. Again, these will be counteracted by increasing the distance for the light, decreasing the time you sit at the light or both. Long-term research studies have found that light therapy is safe for the retina of the eye. Nevertheless, as a precaution, we will examine your retina to see whether there are already signs of damage, and you will not receive light therapy if you have retinal conditions such as retinitis pigmentosa or macular degeneration. As the lights used are similar to early morning light in intensity but without any ultraviolet radiation, they may be considered safer than going outside on a sunny day.

Additional Risks

Participation in this study may involve risks that we currently do not know. Some discomfort may be associated with the drawing of blood samples. A maximum of 1 tablespoon of blood will be taken unless there is a medical reason to obtain extra blood. There is a minor risk of bleeding, bruising, or infection at the site of the needle insertion. With any treatment there is the risk that the treatment may not help and the depression might become worse. Also, if a treatment is effective or partially effective there is the risk of worsening of symptoms if the treatment is stopped or the dose is reduced.

Benefits

Your depression may improve.

You will be informed if significant new information becomes known about treatment of depression or about the treatments used in this study, especially if such information might affect the willingness of some subjects to continue their participation.

Confidentiality

All study information is kept in locked cabinets at the Depression Evaluation service at the New York State Psychiatric Institute or in a secure HIPAA compliant computer accessable only by study staff. Records will be kept confidential to the extent permitted by law. Your name and other personal identifying information will be stored in an electronically secure database at New York Psychiatric Institute. Any publications will present only group data and not include information that could identify you. Records will be available to research staff, and to Federal, State and Institutional regulatory personnel (who may review records as part of routine audits). Also, you should be aware that there are legal advocacy organizations that have the authority under New York State law to access otherwise confidential subject records, though they cannot re-disclose this information without the subject's consent. Electronically stored/transmitted data will be password protected with access only to study personnel.

There are limits to confidentiality. For example:

If your answers indicate a serious problem that may jeopardize your safety or health, then the researchers will contact your physician or emergency personnel as seems appropriate to your well-being. Also, suspected or known neglect or sexual or physical abuse of a child, or threatened violence to self or others will be reported to the appropriate authorities.

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Study Compensation

Medications and tests that are part of the research study are provided free of charge, and neither you nor your insurance company or other third party payer will be billed for these, including hospitalization, if at the New York State Psychiatric Institute. Any medications or tests not required by the research will be paid for by you or your insurance company. In addition, following 6 weeks, regardless of initial treatment assignment, all participants will continue to be followed and complete monthly ratings for an additional six months; during this post-6 week six months, the cost of any prescription, whether for medication or light box will be your responsibility. After this six month post-12 week treatment period, should you and your doctor determine that further psychiatric treatment is indicated, your doctor will help you find an appropriate treater.

In Case of Injury

Federal regulations require that we inform participants about our institution's policy with regard to compensation and payment for treatment of research-related injuries. In case of injury, New York State Psychiatric Institute will provide short term emergency medical treatment, which has been determined to be necessary by New York State Psychiatric Institute's doctors. In addition, we will provide assistance in arranging follow up care in such instances. New York State Psychiatric Institute and Research Foundation for Mental Hygiene do not provide compensation or payment for treatment of research related injuries. However, you should be aware that you do not give up your legal right to seek such compensation through the court by participating in this research.

Questions

Your study doctor will answer any questions you may have now or in the future to the best of his/her ability. If you should have additional questions, you can contact the Principal Investigator, Jonathan W. Stewart, M.D., (646-774-8070).

If you have any questions about your rights as a research participant, want to provide feedback, or have a complaint, you may call the NYSPI Institutional Review Board (IRB). (An IRB is a committee that protects the rights of participants in research studies). You may call the IRB Main Office at (646)774-7155 during regular office hours. You will be notified of significant new findings that may relate to your willingness to continue to participate.

Women of Child-bearing Age

While these treatments are considered to be fairly safe during pregnancy, the study excludes women who are pregnant. Therefore, a pregnancy test will be performed and if it is positive, you cannot participate. Also, we ask that you use reasonable precautions not to become pregnant while participating and for a number of weeks after stopping any prescribed medication. Because the safety of missing a night of sleep, keeping specific sleep schedules or bright lights are unknown in pregnancy, you should not be pregnant or become pregnant while using these treatments. Should you become pregnant, you should immediately contact a study psychiatrist and discontinue any treatment until informed otherwise by a study psychiatrist.

By signing this form, you are indicating that you have discussed this research study and consent form with an investigator, and he/she has answered all of your questions about the study to the best of his/her ability. Your study doctor will answer to the best of his/her ability any questions you may have about the study, your psychiatric condition or your reaction to the study procedures. If you have any further questions, you may call Jonathan W. Stewart, M.D., the Principal Investigator of this study, at **646-774-8070**.

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You will receive a copy of this consent form to keep.

Documentation of Consent

I voluntarily agree to participate in the research study described above.

Print name: _____

Signed: _____

Date: _____

Doctor's Affirmation

I have discussed the proposed research with this participant including the risks, benefits, and alternatives to participation (including the alternative of not participating in the research). The participant has had an opportunity to ask questions and in my opinion is capable of freely consenting to participate in this research.

Print name: _____

Person Designated to Obtain Consent

Signed: _____

Date: _____

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New York State Psychiatric Institute (NYSPI)
Authorization to Use or Disclose Health Information during a Research Study

Protocol Number: 7361 **Principal Investigator:** Jonathan W. Stewart, M.D.

Name of Study: Are Bright Lights and Regulated Sleep Times Effective Treatment for Depression?

Before researchers can use or share any identifiable health information ("Health Information") about you as part of the above study (the "Research"), the New York State Psychiatric Institute (NYSPI) is required to obtain your authorization. You agree to allow the following individuals and entities to use and disclose Health Information about you as described below:

- New York State Psychiatric Institute (NYSPI), your doctors and other health care providers, if any, and
- The Principal Investigator and his/her staff (together "Researchers"). Researchers may include staff of NYSPI, the New York State Office of Mental Health (OMH), Research Foundation for Mental Hygiene, Inc. (RFMH), and Columbia University (CU), provided such staff is a part of the study, and
- Providers of services for the Research at CU, NYSPI and/or RFMH, such as MRI or PET, or Central Reference Laboratories (NKI), if indicated in the consent form**.**

1. The Health Information that may be used and/or disclosed for this Research includes:

[4] All information collected during the Research as told to you in the Informed Consent Form.
[ ] Health Information in your clinical research record which includes the results of physical exams, medical and psychiatric history, laboratory or diagnostic tests, or Health Information relating to a particular condition that is related to the Research.
[ ] Additional information may include:

2. **The Health Information listed above may be disclosed to:**

[4] Researchers and their staff at the following organizations involved with this Research:
Nathan Kline Institute (where the laboratory specimens war analyzed)

[ ] The Sponsor of the Research,

and its agents and contractors (together, "Sponsor"); and
[4] Representatives of regulatory and government agencies, institutional review boards, representatives of the Researchers and their institutions to the level needed to carry out their responsibilities related to the conduct of the research.
[ ] Private laboratories and other persons and organizations that analyze your health information in connection with this study

[ ] Other (family members or significant others, study buddies, outside agencies etc.) Specify:

3. By giving permission to release your Health Information as described above, you understand that your Health Information may be disclosed to individuals or entities which are not required to comply with the federal and state privacy laws which govern the use and disclosure of personal Health Information by NYSPI. This means that once your Health

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Information has been disclosed to a third party which does not have to follow these laws (e.g., a drug company or the Sponsor of the Research), it may no longer be protected under the HIPAA or NYS Mental Hygiene Law requirements but is subject to the terms of the consent form and may be subject to other state or federal privacy laws or regulations.

4. **Please note that:**
   - You do not have to sign this Authorization form, but if you do not, you may not be able to participate in the study or receive study related care. You may change your mind at any time and for any reason. If you do so, you may no longer be allowed to participate in the study. If you withdraw this Authorization the research staff and the Sponsor, if this is sponsored research, may still use or disclose Health Information containing identifying information they already have collected about you as needed to maintain the reliability of the research. Any request to withdraw this Authorization must be made in writing to (enter name and contact information below):

     Jonathan W. Stewart, M.D.
     1051 Riverside Drive
   - While the Research is going on, you may not be allowed to review the Health Information in your clinical research record that has been created or collected by NYSPI. When this research has been completed you may be allowed to see this information. If it is needed for your care, your Health Information will be given to you or your Doctor.

5. **This Authorization does not have an end date.**

6. **You will be given a copy of this form after you have signed it.**

I agree to the use and disclosure of Health Information about me as described above:

_____ _____

Signature of Participant/ Legal Representative Date

_____

Printed Name of Participant

_____

Relationship of Legal Representative to Participant (if applicable)

We also ask you or your legal representative to initial the statements below:

☐ **I have received a copy of the NYSPI/OMH Notice of Privacy Practices.**

New York State Psychiatric Institute - Notice of Privacy Practices

Effective Date: 3/1/2014

THIS NOTICE DESCRIBES HOW HEALTH INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE READ THIS NOTICE CAREFULLY.

About this Notice

This Notice of Privacy Practices informs you about the following:

- Who will Follow this Notice
- What Information is Protected
- How We will Use and Disclose Your Health information.
- When We will Obtain Separate Authorization from You for Use of Your Information
- Your Health Information and Privacy Rights
- How to Report a Problem
- How to Contact Us

We keep a record of any treatment and services you receive at this facility, and the information we collect during your participation in research. We may need this record to provide you with quality care and to determine your eligibility for research and your response to any research interventions. We are committed to protecting your health information and to following all state and federal laws regarding the protection of your health information. We are required by law to:

- make sure that health information that identifies you is kept private
- give you this notice of our legal duties and privacy practices with respect to health information about you
- follow the terms of the notice that is currently in effect

If you have any questions about his notice, please call the Privacy Officer at (646)774-8251.

Who Will Follow this Notice

- All NYSPI employees, staff, and other personnel of NYS Office of Mental Health (OMH).
- Any student, intern or member of a volunteer group we allow to help you while you are in our care
- Staff employed by Columbia University (CU), and/or Research Foundation for Mental Hygiene, Inc. (RFMH) who work at NYSPI and who are considered part of the NYSPI/ OMH workforce in relation to the creation, use, and disclosure of Health Information.
- Contractors, agencies, or other organizations that provide services to us or on our behalf and who have agreed, in writing, to protect your information and follow this Notice.

What Health Information Is Protected

Protected Health information (PHI) includes any information that relates to your past, present, or future health/mental health condition. Some examples of PHI may include:

- demographic information we collect (such as your name, address, or date of birth)
- unique numbers that may identify you (such as your social security number, your phone number, email address or your driver's license number)
- information indicating that you are a patient at NYSPI and/or involved in one of our research studies
- Information about your health care benefits under an insurance plan (such as whether a prescription is covered)
- A photograph or audiotape of you

At NYSPI, we understand that the information we collect about your health is personal and keeping that information confidential and secure is one of our most important responsibilities.

How We May Use and Disclose Health Information About You

Your Health Information may be used and released by staff working at NYSPI/OMH for the purposes of providing you with treatment, and there may be occasions where we need to use/ disclose your Health Information for administrative purposes, or operational purposes to evaluate the quality of the services you receive. No authorization is required in these circumstances. Health Information used and disclosed for research requires a special authorization from you.

Not all types of uses and releases can possibly be described in this document so we have listed some common examples of permitted uses and disclosures below:

FOR RESEARCH: At NYSPI, we perform mental health and substance abuse research and in that process may collect Health Information about you. Our researchers may share your health information with other researchers, clinicians, sponsors, regulatory authorities and others if you authorize them to do so.

All research conducted at NYSPI goes through a special process required by law that reviews protections for individuals involved in research, including privacy. We will not use your health information or disclose it for research reasons without either getting your prior written approval or determining that your privacy is protected.

Health Information about you may be disclosed without authorization to people preparing to conduct a research project - for example, to help them look for participants with specific medical needs, so long as the health information they review does not leave our facility and the project is reviewed by our special review process.

FOR TREATMENT: Caregivers, such as nurses, doctors, psychologists and social workers, may use your health information to determine and provide you with treatment. Individuals and programs at NYSPI and OMH may share Health Information about you to coordinate the services you may need, such as clinical examinations, therapy, laboratory test results, medications, hospitalization, or transfers or referrals for follow-up care.

FOR PAYMENT: NYSPI/OMH may release information about you to your health plan or health insurance carrier to obtain payment for our clinical services. For example, we may need to give your health plan information about medications that you received so your health plan will pay us for treatment or services we provided. We may also share your information, when appropriate, with other government programs such as Workers' Compensation, Medicaid, or Medicare to determine if you are eligible for, or to coordinate, your benefits, entitlements, and payments. We may need to disclose a limited amount of information about you to explore your financial situation for possible sources of payment for your care, but we will only do so as permitted under law. We may also tell your health plan about a treatment you are going to receive to obtain prior approval or to determine whether your plan will cover the treatment. If you are due a refund of money because you have overpaid for our services, we may share a limited amount of your information with the NYS Office of the State Comptroller to obtain that refund for you.

While the institution does not seek reimbursement from health plans for research services there might be instances where the research team might recommend medical services for conditions identified during your participation in research. For example, we may need to give your health plan information about a clinical exam or medications that you received so your health plan will pay for treatment or services that you might need.

FOR OPERATIONS: NYSPI/OMH may review information about you to ensure that the services provided to you are appropriate, safe and are of high quality. For example, we may use your information to evaluate our treatment and service programs or to evaluate the services of other providers that use government funds to provide health care services to you. We may combine health information about many individuals to research health trends, or determine what services and programs should be offered, or whether new treatments or services are useful. We may share your health information with our business partners who perform functions on our behalf. OMH requires that our business partners abide by the same level of confidentiality and security as OMH when handling your information.

TO KEEP YOU INFORMED: Unless you provide us with alternative instructions, we may contact you about reminders for visits, treatment, or research appointments. For our clinical patients, we may also
contact you to tell you about health related benefits or services that may be of interest to you or to give you information about your health care choices.

FACILITY DIRECTORIES: At NYSPI, we use an inpatient directory. If you are an inpatient and do not object, we may put your name and location in our patient directory for disclosure to callers or visitors who ask for you by name. Additionally, your religious affiliation may be shared with clergy.

OTHER GOVERNMENT AGENCIES PROVIDING BENEFITS OR SERVICES: We may release your health information to other government agencies that are providing you with benefits or services when the information is necessary for you to receive those benefits or services.

AS REQUIRED BY LAW: We will disclose health information about you when required to do so by federal, state, or local law.

TO AVERT A SERIOUS THREAT TO HEALTH OR SAFETY: We may release your health information if it is necessary to prevent a serious threat to your health or safety or to the health and safety of the public or another person.

FOR PUBLIC HEALTH ACTIVITIES: We may disclose health information about you to public health agencies, subject to the provision of applicable state and federal law, for the following kinds of activities:

- to prevent or control disease, injury or disability
- to report births and deaths
- to report child abuse or neglect to agencies authorized by law to receive these reports
- to report reactions to medications or problems with products to the Food and Drug Administration (FDA);
- to notify people of recalls of products they may be using
- to notify a person who may have been exposed to a disease or may be at risk for contracting or spreading the disease or condition
- to notify the appropriate government authority if we believe a patient has been the victim of abuse, neglect or domestic violence; we will only make this disclosure if you agree or when required or authorized by law

FOR HEALTH OVERSIGHT ACTIVITIES: NYSPI/OMH may share your health information within OMH and with other agencies for oversight activities authorized by law. Examples of these oversight activities include audits, inspections, licensure, or investigations.

LAWSUITS AND DISPUTES:
If you are involved in a lawsuit or dispute, we may release health information about you in response to a court or administrative order. We may also release health information about you in response to a court order, subpoena, discovery request, or other lawful process by someone else involved in the dispute, but only if efforts have been made to tell you about the request or to obtain an order protecting the information required.

Some studies have Certificates of Confidentiality which are issued by the National Institutes of Health (NIH) to protect identifiable research information from forced disclosure. They allow the investigator and others who have access to research records to refuse to disclose identifying information on research participants in any civil, criminal, administrative, legislative, or other proceeding, whether at the federal, state, or local level.

FOR LAW ENFORCEMENT: We may release health information to a law enforcement official:

- in response to a court order, subpoena, warrant, summons, or other similar process
- to identify or locate a suspect, fugitive, material witness, or missing person
- about the victim of a crime if, under certain limited circumstances, we are unable to obtain the person's agreement
- about a death we believe may be the result of criminal conduct
- about criminal conduct at the hospital
- in emergency circumstances to report a crime, the location of the crime or victims, or the identity, description or location of the person who committed the crime

CORONERS, MEDICAL EXAMINERS AND FUNERAL DIRECTORS: We may release health information to a coroner or medical examiner to carry out their duties as authorized by law (for example, to identify a deceased person or determine the cause of death). We may also release health information to funeral directors as necessary to carry out their duties.

ORGAN DONATION: If you are an organ donor, we may release your health information to an organization that procures, banks, or transports organs for the purpose of an organ, eye, or tissue donation or transplantation.

NATIONAL SECURITY AND PROTECTION OF THE PRESIDENT: We may release your health information to an authorized federal official or other authorized persons for purposes of national security, for providing protection to the President, or to conduct special investigations, as authorized by law.

TO THE MILITARY: If you are a veteran or a current member of the armed forces, we may release your health information as required by military command or Veterans Administration authorities.

Your Health Information Rights

You have the following rights regarding your health information:

RIGHT TO INSPECT AND OBTAIN COPIES: You have the right to inspect and obtain a copy of Health Information that may be used to make decisions about your care. Usually, this includes medical and psychiatric records related to your clinical care and/or study participation. It does not include information that is needed for civil, criminal, or administrative actions or proceedings or components of the research record during a clinical trial or information that is not traditionally found in a health record. We may charge a fee for the costs of copying, mailing, or other supplies associated with your request.

To inspect or obtain a copy of health information that may be used to make decisions about you, you must submit your request in writing to: **Administrator, c/o NYSPI Medical Records Department.**

We may deny your request to inspect and obtain a copy in very limited circumstances. If you are denied access to your health information, you may request that the denial be reviewed. The Information Management Committee will review your request and the denial. The person (s) conducting the review will not include the person who initially denied your request. We will comply with the outcome of the review.

RIGHT TO AMEND: If you feel that the health information we have about you is incorrect or incomplete, you may ask us to amend that information. We may deny your request if you ask to amend information that: (1) was not created by us; (2) is not part of the Health Information kept by us; (3) is not part of the information which you would be permitted to inspect or copy; or (4) is determined to be accurate and complete. You have the right to request an amendment for as long as the information is kept by or for us.

To request an amendment, your request must be made in writing and submitted to **Administrator, c/o NYSPI Medical Records Department**. In addition, you must provide a reason that supports your request.

RIGHT TO AN ACCOUNTING OF DISCLOSURES: You have the right to request a list of information releases that we have made of your health information. The list will not include health information releases: (1) made for purposes of providing treatment to you, or releases made for other administrative/ operational purposes; (2) made for national security; (3) made to correctional and other law enforcement custodial situations; (4) made based on your written authorization; (5) made to persons who are involved in your care; or (6) made prior to April 14, 2003.

To request this list or accounting of disclosures, you must submit your request in writing to **Administrator, c/o NYSPI Medical Records Department.** Your request must state a time period which may not be longer than 6 years and may not include dates before April 14, 2003. Your request should indicate in what form you want the list (for example, on paper or electronically). The first list you request within a 12 month period will be free. For additional lists, we may charge you for the costs of providing the list. We will notify you of the cost involved and you may choose to withdraw or modify your request at that time before any costs are incurred.

RIGHT TO REQUEST RESTRICTIONS: You have the right to request a restriction or limitation on the health information we use or disclose about you for the purpose of treatment or health care operations. Your right to request any restrictions to use or disclosure for research purposes is dependent on the type of research you are involved in and will be explained to you in the authorization and/or consent document for the study. You also have the right to request that we restrict or limit health information about you that we may use or disclose to someone who is involved in your care, such as a family member. For example, you could ask that we not use or disclose information about the medication you are taking to your spouse or significant other.

We are not required to agree to your request. If we do agree, we will comply with your request unless the information is needed to provide you with emergency treatment. There is one exception to this: if you have paid for your treatment in full or out of pocket, and request a restriction on disclosure for payment or health care operations purposes to your health plan, we must agree to your request.

To request restrictions, you must make your request in writing to **your treating physician or the study Principal Investigator.** In your request, you must tell us: (1) what information you want to limit; (2) whether you want to limit our use, disclosure, or both; and (3) to whom you want the limits to apply (for example, disclosures to your spouse).

RIGHT TO REQUEST CONFIDENTIAL COMMUNICATIONS: You have the right to request that we communicate with you about your health matters in a certain way or at a certain location. For example, you can ask that we only contact you at a certain phone number or by mail.

To request confidential communications, you must make your request in writing to your treating physician or the study Principal Investigator. We will not ask you the reason for your request and will accommodate all reasonable requests. Your request must specify how or where you wish to be contacted.

RIGHT TO NOTICE OF BREACH: If there is a breach of your unsecured protected health information which generally means your health information is not encrypted or otherwise can be read by anyone who looks at it), we must notify you that this has occurred.

RIGHT TO A PAPER COPY OF THIS NOTICE: You have a right to a paper copy of this notice. You may ask us to give you a copy of this notice at any time. Even if you have agreed to receive this notice electronically, you are still entitled to a paper copy of this notice.

You may obtain an additional copy of this notice at our website: http://nyspi.org/clinical_services.html or by asking the clinical or research staff you work with.

***If you do not object and the situation is not an emergency and disclosure is not otherwise prohibited by stricter laws,* we are permitted to release your health information under the following circumstances:**

- **To Individuals Involved in Your Care:** We may release your health information to a family member, other relative, friend, or other person who you have identified to be involved in your health care or research participation.
- **To Family:** We may use your health information to notify a family member, a personal representative or a person responsible for your care, of your location, general condition, or death.
- **To Disaster Relief Agencies:** We may release your health information to an agency authorized by law to assist in disaster relief efforts.

Your research staff can talk to you more about this. Be sure to the staff know if you have any concerns about, or object to, these types of disclosures.

What is NOT Covered Under this Notice

- **Confidential HIV Related Information:** Under New York State Law, confidential HIV-related information (information concerning whether or not you have had an HIV-related test, have HIV infection, HIV-related illness, AIDS, which could indicate that a person has been potentially exposed to HIV), can only be given to entities allowed to have it by law or allowed to have it by a release that you have signed.

- **Alcohol or Substance Abuse Treatment Information:** If you have received alcohol or substance abuse treatment from an alcohol/substance abuse program that receives funds from the United States government, federal regulations may protect your treatment records from disclosure without your written authorization.

The NYS Office of Mental Health's Requirements

NYSPI, as a facility of OMH, is required by state and federal law to maintain the privacy of your health information. We are required to give you this notice of our legal duties and privacy practices with respect to the health information that OMH collects and maintains about you. We are required to follow the terms of this notice.

This notice describes and gives some examples of the permitted ways that your health information may be used or released. Release of your information outside of the boundaries of OMH related treatment, payment, or operations, or as otherwise permitted by state or federal law, will be made only with your written authorization. You may revoke specific authorizations to release your health information, in writing, at any time. If you revoke an authorization, we will no longer release your health information to the authorized person, except to the extent that we have already used or released that information in reliance on your original authorization. You understand that we are unable to take back any disclosures we have already made with your permission, and that we are required to retain our records of the care we have provided to you.

We reserve the right to revise this notice. We reserve the right to make the revised notice effective for health information we already have about you as well as any information we create or receive in the future. We will post a copy of the current notice in the facility and will provide a copy of our revised notice to you upon request. In addition, each time you are admitted to the facility for treatment as an inpatient or outpatient, we will offer you a copy of the current notice in effect. The notice will contain on the first page, in the top center, the effective date.

For More Information or to Report a Problem

If you believe your privacy rights have been violated, you may file a complaint with any or all of the agencies listed below. There will be no penalty or retaliation for filing a complaint:

New York State Psychiatric Institute
Privacy Officer c/o Quality Management Department
1051 Riverside Drive
New York, N.Y. 10032
Telephone: (646) 774-8251
Fax: (646) 774-8633

Office for Civil Rights
Telephone: (866) OCR-PRIV / (866) 627-7748 or
TDD: (877) 521-2172
(886) 788-4989 TTY

Privacy Liaison
Secretary of Health and Human Services
200 Independence Avenue, SW,
Washington, D.C. 20201
Toll Free Phone: (877) 696-6775
TTY: (800) 877-8339
www.hhs.gov/ocr/hipaa

How To Contact Us

To obtain more information about NYSPI/OMH's privacy practices, to receive additional copies of this notice, to receive request forms to access or to amend your health information, please contact:

New York State Psychiatric Institute
Privacy Officer
c/o Quality Management Department
1051 Riverside Drive
New York, N.Y. 10032
Telephone: (646) 774-8251
Fax: (646) 774-8633