



PMG RESEARCH OF RALEIGH, LLC

CONFIDENTIALITY STATEMENT

Effective Date: 04-27-2015

PLEASE READ THE FOLLOWING CAREFULLY. THIS CONFIDENTIALITY STATEMENT DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION.

CONFIDENTIALITY STATEMENT

If you have any questions about this Confidentiality Statement (“Statement”), please contact PMG Research of Raleigh, LLC (“PMG”) by telephone at (336) 608-3500 and ask for the Privacy Officer, by email at privacyofficer@pmg-research.com or in writing at PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104.

YOUR PROTECTED HEALTH INFORMATION

This Statement applies to your protected health information (“PHI”), such as your name, address, telephone number, social security number, health information, health status, and the health care and clinical trial services in which you participate at PMG. This Statement explains how we may use and disclose your PHI. It also describes your rights and our obligations regarding the use and disclosure of PHI. Except where permitted or required by law, any uses or disclosures of PHI will be made only with your written authorization.

HOW WE MAY USE AND DISCLOSE PROTECTED HEALTH INFORMATION

We may use and disclose PHI without your written authorization for any of the following reasons:

Participation in Research Studies

We may use PHI to provide you with medical treatment or services as part of the research studies we conduct and you have chosen to participate in. We may disclose PHI to doctors, nurses, technicians, coordinators, office staff, or other personnel who help conduct our research studies.

For example, our staff may use your medical history to decide which research study is best for you. The doctor conducting the research study may explain your condition to another doctor to help determine the most appropriate care for you and to make recommendations regarding your participation in the research study. Our staff may disclose your PHI to a healthcare provider who performs certain procedures in a research study you participate in.

Health Care Operations

We may use PHI to evaluate the performance of our staff in caring for you, to help us decide what additional research studies we should offer, to learn how we can become more efficient, for quality assessment purposes, and for legal services and compliance programs.

Research Purposes

We may use and disclose PHI to organizations that sponsor our research and organizations that monitor our research. These third parties may include, but are not limited to, the pharmaceutical sponsor, contract research organization (company that works on behalf of the pharmaceutical sponsor), Institutional Review Board (protects research subject rights), the Food and Drug Administration, laboratories, and diagnostic centers.

To Our Service Providers

We provide some services through third party service providers. We may give these service providers PHI about you so that they can do the job we have asked them to do. For example, we might use a copy services to make copies of requested medical records. When we do this, we require the service provider to safeguard the PHI about you.

In Order to Contact You

PMG is interested in developing a relationship with you and for that reason, we may contact you to remind you that you have an appointment at our office, to inform you about test results, to clarify information you have provided, or to tell you about research studies, products, or services that might interest you. Please notify us if you do not wish to be contacted for appointment reminders or if you do not wish to receive communications about research studies or health-related products and services. If you advise us in writing (at the address listed at the top of this Statement) that you do not wish to receive such communications, we will not use or disclose your contact information for these purposes.

REVOCAION OF AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Your authorization of our use or disclosure of PHI does not expire. You may revoke your authorization of our use and disclosure of PHI at any time by giving us written notice. Your revocation will be effective when we receive it, but it will not apply to any uses and disclosures that occurred before that time.

If you revoke your authorization, we will not be permitted to use or disclose PHI for purposes of research, payment, or health care operations; therefore, we may choose to discontinue your participation in our research studies and any research-related treatment.

SPECIAL SITUATIONS

We may use or disclose PHI without your permission for the following purposes, subject to applicable legal requirements and limitations:

Health or Safety Threats

We may use and disclose PHI when necessary to prevent a serious threat to your health and safety or to the health and safety of others.

We may disclose PHI for public health reasons in order to prevent or control disease, injury, or disability or to report births, deaths, suspected abuse, neglect, or non-accidental physical injuries to the extent such disclosures are permitted and/or required by law.

Required By Law

We will disclose PHI when required to do so by federal, state, or local law.

If you are or were a member of the armed forces or part of the national security or intelligence communities, we may be required by military command or other government authorities to release PHI. We also may release PHI about foreign military personnel to the appropriate foreign military authority.

If you are involved in a lawsuit or a dispute, we may disclose PHI in response to a court or administrative order.

We may release PHI if asked to do so by a law enforcement official in response to a court order, subpoena, warrant, summons, or similar process, subject to applicable legal requirements.

Health Oversight Activities

We may disclose PHI to a health oversight agency for audits, investigations, inspections, or licensing purposes. These disclosures may be necessary to enable state and federal agencies to monitor the health care system and government programs and to ensure compliance with civil rights laws.

Coroners, Medical Examiners, and Funeral Directors

We may release PHI to a coroner or medical examiner. This may be necessary, for example, to identify a deceased person or determine the cause of death.

Information Not Personally Identifiable

We may use or disclose PHI in a way that does not personally reveal your identity.

Family and Friends

We may disclose PHI (except information regarding HIV status, mental disorders, and substance abuse information) to your family members or friends if we obtain your verbal agreement to do so or if we give you an opportunity to object to such a disclosure and you do not raise an objection. We also may disclose PHI to your family or friends if, based on our professional judgment, we can infer from the circumstances that you would not object. For example, we may assume you agree to our disclosure of PHI to your spouse when you bring your spouse with you into the exam room during a clinic visit.

For situations in which you are incapable of giving consent due to incapacity or medical emergency, we may, using our professional judgment, determine that disclosure to a family member or friend is in your best interest. We will disclose only PHI relevant to the person's involvement in your care. For example, we may inform the person who accompanied you to the emergency room that you fainted during a blood draw and provide updates on your progress and prognosis. We also may use our professional judgment and experience to make reasonable inferences that it is in your best interest to allow another person to act on your behalf, for example, to pick up filled prescriptions, medical supplies, or x-rays.

OTHER USES AND DISCLOSURES OF PROTECTED HEALTH INFORMATION

We will not use or disclose PHI for any purpose other than those identified in the previous sections without your specific, written authorization. We must obtain your authorization separately or as part of a general or specific consenting process. You may revoke your authorization in writing at any time. If you revoke your authorization, we

will no longer use or disclose PHI; your revocation will not apply to any uses and disclosures that occurred before our receipt of your revocation. If we have HIV or substance abuse information about you, we cannot release that information without your written authorization on our Medical Records Release and Request Forms that comply with the law governing HIV or substance abuse records.

YOUR RIGHTS REGARDING PROTECTED HEALTH INFORMATION

You have the following rights regarding PHI:

Right to Inspect and Copy

You have the right to inspect and/or copy PHI, such as your participant study file that we use to make decisions about your care and your participation in research studies. You must submit a written request to Privacy Officer, PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104, in order to inspect and/or copy PHI. We will allow you to inspect and/or copy your records within 30 days of our receipt of your written request. If you request to inspect and/or copy PHI that is not maintained or accessible to PMG on-site, we will allow you to inspect and/or copy your records within 60 days of our receipt of your written request. If you request a copy of your PHI, we may charge a fee for the costs of retrieving, copying, and mailing. We may deny your request to inspect and/or copy PHI in certain limited circumstances. If your request is denied, PMG will provide a written notice of the basis for denial. If you are denied access to your PHI, you have the right to request that the denial be reviewed. If such review is required by law, we will select a licensed health care professional to review your request and our denial. The person conducting the review will not be the person who denied your request, and we will comply with the outcome of the review.

Right to Amend

If you believe PHI we have about you is incorrect or incomplete, you may ask us to amend the information. To request an amendment, complete and submit a written request to Privacy Officer, PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104. We may deny your request for an amendment if it is not in writing or if it fails to include a reason to support the request. In addition, we may deny your request if you ask us to amend information that:

- we did not create, unless the person or entity that created the information is no longer available to make the amendment,
- is not part of the PHI that we keep,
- you would not be permitted to inspect and copy, or
- is accurate and complete.

Right to an Accounting of Disclosures

You have the right to request an accounting of disclosures. This is a list of PHI disclosures we have made concerning you for purposes other than research study eligibility and/or participation, payment, and health care operations. To obtain this list, you must submit your request in writing to Privacy Officer, PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104. Your written request must state a time period, which may not be longer than six years and include dates before April 14, 2003. Your request should indicate the form in which you would like to receive the list (e.g., on paper or electronically). 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 PHI we use or disclose about you. To request such restriction with respect to our use and disclosure of PHI, complete and submit a written request to Privacy Officer, PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104. We are not required to approve request. If we approve your request, we will restrict our use and disclosure of PHI pursuant to your request, unless such use or disclosure of PHI is necessary to provide you with emergency treatment.

Right to Request Confidential Communications

You have the right to request that we communicate with you about medical matters by a certain means or at a certain location. For example, you can ask that we only contact you at work or by mail. To request that we communicate with you on a confidential basis, send your written request to Privacy Officer, PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104. You will not be asked to disclose the reason for your request. We will accommodate all reasonable requests. Your request must specify how or where you wish to be contacted.

Right to a Paper Copy of This Statement

You have the right to receive a paper copy of this Statement. You will receive a copy of this Statement the first time you come to PMG for an appointment. You may ask us to give you an additional copy of this Statement at any time. Even if you have agreed to receive this Statement electronically, you still are entitled to a paper copy of this Statement. To obtain a paper copy, ask your local site representative or contact PMG directly in writing at Privacy Officer, PMG Research of Raleigh, LLC c/o PMG Research, Inc., 4505 Country Club Road, Suite 110, Winston-Salem, NC 27104 or by



telephone at (336) 608-3500.

CHANGES TO THIS STATEMENT

We reserve the right to change this Statement and to make the revised or changed Statement effective for medical information we already have about you as well as any information we receive in the future. We will post a summary of the current Statement in the office with its effective date in the top right hand corner. You are entitled to a copy of the Statement currently in effect.

COMPLAINTS

You have the right to complain to PMG or to The Department of Health and Human Services (“DHHS”) if you feel that your privacy rights have been violated. You will not be retaliated against in any way if you file a complaint. To file a complaint with either PMG or DHHS, you may submit your complaint in writing to either of the following addresses:

Attn: Privacy Officer PMG Research of Raleigh, LLC C/o PMG Research, Inc. 4505 Country Club Road, Ste. 110 Winston-Salem, NC 27104 (336) 608-3500	The Department of Health and Human Services 200 Independent Avenue, S.W. Washington, D.C. 20201 (202) 619-0257 (877) 696-6775
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RESEARCH CARE

The research care that you receive at PMG should not substitute for your primary care physician. We strongly advise that you maintain a relationship with a primary care provider for routine health care. With your permission, PMG can transfer study-related medical records to your primary care physician.