

**LONG TERM CARE FACILITY**  
**ACKNOWLEDGEMENT OF RECEIPT OF DOCUMENTS**

By signing below, I \_\_\_\_\_, on behalf of my long-term care facility (the "Facility"), as defined below, agree that it has received and acknowledged the following policies, consents, notices, and other documents (collectively, the "Documents") provided to the Facility by CDR Health ("CDR"):

- Fact Sheet for Patients, Parents and Caregivers Emergency Use Authorization (EUA) of REGEN-COV for Coronavirus Disease 2019 (Covid-19)
- Informed Consent to Treat
- Privacy Policy, HIPAA Notice of Privacy Practices, Consent for CDR Maguire to Contact, Notice of Privacy Practices

Facility agrees that, prior to treatment, it will provide access and opportunity to read the Documents to residents, employees, and all other parties to be treated at the Facility. For residents at the Facility who cannot provide consent to treatment themselves, the Facility will provide the Informed Consent to Treat (the "Consent"), and Documents to the person authorized to consent to treatment for that resident ("Authorized Person") and will send all completed Consents via e-mail prior to CDR's visit and treatment. Facility further agrees to provide CDR with a list of residents that require Consent from an Authorized Person and have not obtained Consent.

Administrator Signature:

Date:

Administrator Signature:

Date:

Facility Name:

Facility Address:

Facility Phone Number:

**FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS  
EMERGENCY USE AUTHORIZATION (EUA) OF REGEN-COV™  
(casirivimab and imdevimab) FOR CORONAVIRUS DISEASE 2019 (COVID-19)**

You are being given a medicine called **REGEN-COV (casirivimab and imdevimab)** for the treatment or post-exposure prevention of coronavirus disease 2019 (COVID-19). SARS-CoV-2 is the virus that causes COVID-19. This Fact Sheet contains information to help you understand the potential risks and potential benefits of taking REGEN-COV.

Receiving REGEN-COV may benefit certain people with COVID-19 and may help prevent certain people who have been exposed to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection, or may prevent certain people who are at high risk of exposure to someone who is infected with SARS-CoV-2 from getting SARS-CoV-2 infection.

Read this Fact Sheet for information about REGEN-COV. Talk to your healthcare provider if you have questions. It is your choice to receive REGEN-COV or stop at any time.

**WHAT IS COVID-19?**

COVID-19 is caused by a virus called a coronavirus, SARS-CoV-2. People can get COVID-19 through contact with another person who has the virus.

COVID-19 illnesses have ranged from very mild (including some with no reported symptoms) to severe, including illness resulting in death. While information so far suggests that most COVID-19 illness is mild, serious illness can happen and may cause some of your other medical conditions to become worse. People of all ages with severe, long-lasting (chronic) medical conditions like heart disease, lung disease, and diabetes, for example, and other conditions including obesity, seem to be at higher risk of being hospitalized for COVID-19. Older age, with or without other conditions, also places people at higher risk of being hospitalized for COVID-19.

**WHAT ARE THE SYMPTOMS OF COVID-19?**

The symptoms of COVID-19 include fever, cough, and shortness of breath, which may appear 2 to 14 days after exposure. Serious illness including breathing problems can occur and may cause your other medical conditions to become worse.

**WHAT IS REGEN-COV (casirivimab and imdevimab)?**

REGEN-COV is an investigational medicine used in adults and adolescents (12 years of age and older who weigh at least 88 pounds (40 kg)) who are at high risk for severe COVID-19, including hospitalization or death for:

- treatment of mild to moderate symptoms of COVID-19
- post-exposure prevention of COVID-19 in persons who are:
  - not fully vaccinated against COVID-19 (Individuals are considered to be fully vaccinated 2 weeks after their second vaccine dose in a 2-dose series [such as the Pfizer or Moderna vaccines], or 2 weeks after a single-dose vaccine [such as Johnson & Johnson's Janssen vaccine]), **or**,
  - are not expected to build up enough of an immune response to the complete COVID-19 vaccination (for example, someone with immunocompromising

conditions, including someone who is taking immunosuppressive medications),  
**and**

- have been exposed to someone who is infected with SARS-CoV-2. Close contact with someone who is infected with SARS-CoV-2 is defined as being within 6 feet for a total of 15 minutes or more, providing care at home to someone who is sick, having direct physical contact with the person (hugging or kissing, for example), sharing eating or drinking utensils, or being exposed to respiratory droplets from an infected person (sneezing or coughing, for example). For additional details, go to <https://www.cdc.gov/coronavirus/2019-ncov/if-you-are-sick/quarantine.html>, **or**
- someone who is at high risk of being exposed to someone who is infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, as nursing homes, prisons,).

REGEN-COV is investigational because it is still being studied. There is limited information known about the safety and effectiveness of using REGEN-COV to treat people with COVID-19 or to prevent COVID-19 in people who are at high risk of being exposed to someone who is infected with SARS-CoV-2. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

The FDA has authorized the emergency use of REGEN-COV for the treatment of COVID-19 and the post-exposure prevention of COVID-19 under an Emergency Use Authorization (EUA). For more information on EUA, see the “**What is an Emergency Use Authorization (EUA)?**” section at the end of this Fact Sheet.

#### **WHO SHOULD NOT TAKE REGEN-COV?**

Do not take REGEN-COV if you have had a severe allergic reaction to REGEN-COV.

#### **WHAT SHOULD I TELL MY HEALTH CARE PROVIDER BEFORE I RECEIVE REGEN-COV?**

**Tell your healthcare provider about all of your medical conditions, including if you:**

- Have any allergies
- Have had a severe allergic reaction including anaphylaxis to REGEN-COV previously
- Have received a COVID-19 vaccine.
- Have any serious illnesses
- Are pregnant or plan to become pregnant
- Are breastfeeding or plan to breastfeed
- Are taking any medications (prescription, over-the-counter, vitamins, and herbal products)

#### **HOW WILL I RECEIVE REGEN-COV (casirivimab and imdevimab)?**

- REGEN-COV consists of two investigational medicines, casirivimab and imdevimab, given together at the same time through a vein (intravenous or IV) or injected in the

tissue just under the skin (subcutaneous injections). **Your healthcare provider will determine the most appropriate way for you to be given REGEN-COV.**

- Treatment: If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer. Your healthcare provider will determine the duration of your infusion.
  - If your healthcare provider determines that you are unable to receive REGEN-COV as an intravenous infusion which would lead to a delay in treatment, then as an alternative, REGEN-COV can be given in the form of subcutaneous injections. If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time.
- Post-exposure prevention: If you are receiving subcutaneous injections, your dose will be provided as multiple injections given in separate locations around the same time. If you are receiving an intravenous infusion, the infusion will take 20 to 50 minutes or longer.
  - After the initial dose, if your healthcare provider determines that you need to receive additional doses of REGEN-COV for ongoing protection, the additional intravenous or subcutaneous doses would be administered monthly.

### **WHAT ARE THE IMPORTANT POSSIBLE SIDE EFFECTS OF REGEN-COV (casirivimab and imdevimab)?**

Possible side effects of REGEN-COV are:

- Allergic reactions. Allergic reactions can happen during and after infusion or injection of REGEN-COV. Tell your healthcare provider right away or seek immediate medical attention if you get any of the following signs and symptoms of allergic reactions: fever, chills, nausea, headache, shortness of breath, low or high blood pressure, rapid or slow heart rate, chest discomfort or pain, weakness, confusion, feeling tired, wheezing, swelling of your lips, face, or throat, rash including hives, itching, muscle aches, feeling faint, dizziness and sweating. These reactions may be severe or life threatening.
- Worsening symptoms after treatment: You may experience new or worsening symptoms after infusion or injection, including fever, difficulty breathing, rapid or slow heart rate, tiredness, weakness or confusion. If these symptoms occur, contact your healthcare provider or seek immediate medical attention as some of these symptoms have required hospitalization. It is unknown if these symptoms are related to treatment or are due to the progression of COVID-19.

The side effects of getting any medicine by vein may include brief pain, bleeding, bruising of the skin, soreness, swelling, and possible infection at the infusion site. The side effects of getting any medicine by subcutaneous injection may include pain, bruising of the skin, soreness, swelling, and possible infection at the injection site.

These are not all the possible side effects of REGEN-COV. Not a lot of people have been given REGEN-COV. Serious and unexpected side effects may happen. REGEN-COV is still being studied so it is possible that all of the risks are not known at this time.

It is possible that REGEN-COV could interfere with your body's own ability to fight off a future infection of SARS-CoV-2. Similarly, REGEN-COV may reduce your body's immune response to a vaccine for SARS-CoV-2. Specific studies have not been conducted to address these possible risks. Talk to your healthcare provider if you have any questions.

### **WHAT OTHER TREATMENT CHOICES ARE THERE?**

Like REGEN-COV (casirivimab and imdevimab), FDA may allow for the emergency use of other medicines to treat people with COVID-19. Go to <https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization> for information on the emergency use of other medicines that are not approved by FDA that are used to treat people with COVID-19. Your healthcare provider may talk with you about clinical trials you may be eligible for.

It is your choice to be treated or not to be treated with REGEN-COV. Should you decide not to receive REGEN-COV or stop it at any time, it will not change your standard medical care.

### **WHAT OTHER PREVENTION CHOICES ARE THERE?**

Vaccines to prevent COVID-19 are also available under Emergency Use Authorization. Use of REGEN-COV does not replace vaccination against COVID-19. REGEN-COV is not authorized for pre-exposure prophylaxis for prevention of COVID-19.

### **WHAT IF I AM PREGNANT OR BREASTFEEDING?**

There is limited experience using REGEN-COV (casirivimab and imdevimab) in pregnant women or breastfeeding mothers. For a mother and unborn baby, the benefit of receiving REGEN-COV may be greater than the risk of using the product. If you are pregnant or breastfeeding, discuss your options and specific situation with your healthcare provider.

### **HOW DO I REPORT SIDE EFFECTS WITH REGEN-COV (casirivimab and imdevimab)?**

Tell your healthcare provider right away if you have any side effect that bothers you or does not go away.

Report side effects to **FDA MedWatch** at [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088 or call 1-844-734-6643.

### **HOW CAN I LEARN MORE?**

- Ask your health care provider.
- Visit [www.REGENCOV.com](http://www.REGENCOV.com)
- Visit <https://www.covid19treatmentguidelines.nih.gov/>
- Contact your local or state public health department.

### **WHAT IS AN EMERGENCY USE AUTHORIZATION (EUA)?**

The United States FDA has made REGEN-COV (casirivimab and imdevimab) available under an emergency access mechanism called an EUA. The EUA is supported by a Secretary of Health and Human Service (HHS) declaration that circumstances exist to justify the emergency use of drugs and biological products during the COVID-19 pandemic.

REGEN-COV has not undergone the same type of review as an FDA-approved product. In issuing an EUA under the COVID-19 public health emergency, the FDA must determine, among other things, that based on the totality of scientific evidence available, it is reasonable to believe that the product may be effective for diagnosing, treating, or preventing COVID-19, or a serious or life-threatening disease or condition caused by COVID-19; that the known and potential benefits of the product, when used to diagnose, treat, or prevent such disease or condition, outweigh the known and potential risks of such product; and that there are no adequate, approved and available alternatives. All of these criteria must be met to allow for the medicine to be used in the treatment of COVID-19 or prevention of COVID-19 during the COVID-19 pandemic. The EUA for REGEN-COV is in effect for the duration of the COVID-19 declaration justifying emergency use of these products, unless terminated or revoked (after which the products may no longer be used).

## **REGENERON**

Manufactured by:  
Regeneron Pharmaceuticals, Inc.  
777 Old Saw Mill River Road  
Tarrytown, NY 10591-6707

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Patient Name: \_\_\_\_\_  
Patient DOB: \_\_\_\_\_

Internal Use Only: \_\_\_\_\_

### **INFORMED CONSENT TO TREAT**

I understand that REGEN-COV is not fully approved by the United States Food and Drug Administration (“FDA”) and has been approved on the basis of an Emergency Use Authorization (“EUA”) as a treatment for patients suffering from COVID-19 and as a prophylactic treatment for certain patients. The EUA covers:

**Treatment:** This EUA is for the use of the unapproved product, REGEN-COV (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, for the treatment of mild to moderate COVID-19 in adult and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death.

**Post-Exposure Prophylaxis:** This EUA is for the use of the unapproved product, REGEN-COV (casirivimab and imdevimab) co-formulated product and REGEN-COV (casirivimab and imdevimab) supplied as individual vials to be administered together, in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) for post-exposure prophylaxis of COVID-19 in individuals who are at high risk for progression to severe COVID-19, including hospitalization or death, and are: a) not fully vaccinated or who are not expected to mount an adequate immune response to complete SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications) and have been exposed to an individual infected with SARS-CoV-2 consistent with close contact criteria per Center for Disease Control and Prevention (CDC); or b) who are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting (for example, nursing homes, prisons).

Other medical conditions or factors (for example, race or ethnicity) may also place individual patients at high risk for progression to severe COVID-19 and authorization of REGEN-COV under the EUA is not limited to the medical conditions or factors listed above.

I understand that REGEN-COV may be administered through the vein (intravenous or IV) or injected in the tissue just under the skin (subcutaneous injection). I understand that the Clinic may administer REGEN-COV through subcutaneous injection or intravenously.

**I UNDERSTAND TREATMENT WITH REGEN-COV IS EXPERIMENTAL AND PRESENTS RISKS AS THE FDA HAS NOT FULLY APPROVED THE PRODUCT.**

**I HEREBY ATTEST THAT I HAVE BEEN GIVEN AND HAVE READ, OR HAD READ TO ME, THE FACT SHEET FOR PATIENTS, PARENTS AND CAREGIVERS/EMERGENCY USE AUTHORIZATION (EUA) FOR REGEN-COV.**

**I KNOWINGLY, WILLINGLY AND VOLUNTARILY CONSENT TO TREATMENT WITH REGEN-COV WITH THE FULL UNDERSTANDING AND ACCEPTANCE OF THE RISKS ASSOCIATED WITH RECEIVING CARE WITH THIS PRODUCT. I ACKNOWLEDGE THAT MY HEALTH CARE PROVIDER HAS EXPLAINED SUCH RISKS TO ME.**

Patient Name: \_\_\_\_\_  
Patient DOB: \_\_\_\_\_

Internal Use Only: \_\_\_\_\_

I, ON BEHALF OF MYSELF AND MY PERSONAL REPRESENTATIVES, EXECUTORS, HEIRS, FAMILY MEMBERS, SUCCESSORS AND ASSIGNS, HEREBY KNOWINGLY AND VOLUNTARILY WAIVE, RELEASE AND DISCHARGE AND COVENANT NOT TO SUE CDR Maguire Inc., CDR Health Care Inc. and its subsidiaries, affiliates and all of its employees, physicians, nurses, officers, directors, members, shareholders, agents and representatives (collectively, the "Clinic") from any liability, loss, cost, damage, expense, claim or suit whatsoever for any and all injury, loss, illness, death, harm, cost, expense, claim, or damage I may experience or incur related to the Clinic's use of REGEN-COV in its treatment of my condition.

I HAVE READ, OR HAVE HAD READ TO ME, THE ABOVE INFORMED CONSENT TO TREAT. I APPRECIATE THAT IT IS NOT POSSIBLE TO ANTICIPATE IN ADVANCE EVERY POSSIBLE COMPLICATION TO CARE. I HAVE ALSO HAD AN OPPORTUNITY TO ASK QUESTIONS ABOUT THE CONTENT OF THIS DOCUMENT AND THE TREATMENT SUGGESTIONS OF MY PHYSICIAN. I ACKNOWLEDGE THAT MY QUESTIONS HAVE BEEN ANSWERED TO MY SATISFACTION. BY SIGNING BELOW, I AGREE WITH THE CURRENT OR FUTURE RECOMMENDATION TO RECEIVE CARE AS IS DEEMED APPROPRIATE FOR MY CIRCUMSTANCE INCLUDING TREATMENT WITH REGEN-COV. I INTEND THIS CONSENT TO COVER THE ENTIRE COURSE OF CARE FROM ALL PROVIDERS IN THIS CLINIC FOR MY PRESENT CONDITION.

Patient

Parent/Guardian

Witness

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Name: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

Date: \_\_\_\_\_

## **PRIVACY POLICY**

### **INTRODUCTION**

CDR Maguire, Inc. and its affiliates (collectively referred to as “**CDR**,” “**we**,” “**our**” and “**us**”) are concerned about privacy issues and want you to be familiar with how we collect, use and disclose information. This Privacy Policy (this “**Policy**”) describes the types of information we may collect from you or that you may provide when you visit [www.patientportalfl.com](http://www.patientportalfl.com) (our “**Website**”) and discusses our practices for collecting, using, maintaining, protecting and disclosing that information.

Please read this Policy carefully to understand our policies and practices regarding your information and how we will treat it. This Policy applies to any personal information, and, in certain applicable instances, other information, collected on our Website and collected through our business operations. We use the information we collect from you to improve our Website and to provide you with a more personalized experience on our Website. If you do not agree with our policies and practices, your choice is not to use our Website. By accessing or using our Website, you agree to this Policy. This Policy may change from time to time (see **CHANGES TO OUR PRIVACY POLICY**). Your continued use of our Website after we make changes is deemed to be acceptance of those changes, so please check this Policy periodically for updates.

### **INFORMATION WE COLLECT ABOUT YOU**

When we collect information from you, our primary goal is to provide you with an efficient and more personalized experience on our Website. We may collect information about you, including Personally Identifiable Information (“**PII**”), from the information you voluntarily provide to us and through automatic data collection technology. PII is any information that can be used on its own or with other information to personally identify you as an individual. In some jurisdictions, PII may also include technical information such as Internet Protocol (“**IP**”) addresses. PII that you may voluntarily provide to us includes, without limitation, the following:

- Name;
- E-mail address;
- Phone number;
- Address;
- Birthday;

Information that we may collect through automatic data collection technology includes, without limitation, information about your internet connection, IP address, referrers, search terms, page views, operating system and browser type.

If you submit any PII relating to other people to us in connection with our Website, you represent that you have the authority to do so and to permit us to use such PII in accordance with this Policy.

## HOW WE MAY COLLECT YOUR INFORMATION

We may collect information in several ways, including:

- **Directly from you:** If you contact us, then we may collect information, including PII, through records and copies of your correspondence with us. We may also collect information, including PII, when you register to use our Website, post material, report a problem with our Website or respond to our questions via e-mail or feedback forms. If we collect information directly from you, then you may have the option to refuse to provide us with such information. However, if you decline to provide us information, then this may impact your ability to use our Website.
- **Offline:** You may provide information, including PII, to us when you contact a Website representative. For example, if you contact us by phone, we may record the conversation and keep summaries or notes of the call. We may also collect information when you complete a requisition form.
- **Through cookies (or browser cookies):** A cookie is a piece of data stored on the user's computer tied to information about the user. Cookies allow our Website to serve the user with specific information tied to the user and help facilitate ongoing access to our Website. You may refuse to accept cookies by activating the appropriate setting on your browser. However, if you select this setting, then you may be unable to access certain parts of our Website. This Policy covers the use of cookies by only us. We may use the following types of cookies on our Website:
  - Essential Cookies – These cookies allow you to browse our Website and use certain features. If you disable these essential cookies, then you may be unable to use certain features.
  - Preference Cookies – These cookies allow us to recognize your device so that you do not have to provide us with the same information more than once. If you disable these preference cookies, then our Website may not be able to remember certain choices that you previously made or personalize your browsing experience.
  - Performance Cookies – These cookies collect information about how you use our Website, such as which pages you most frequently visit. We use performance cookies to provide you with a high-quality experience by doing things such as tracking page load, site response times and error messages.
- **Through Flash cookies:** Certain features of our Website may use local stored objects (or Flash cookies) to collect and store information about your preferences and navigation to, from and on our Website. Flash cookies are not managed by the same browser settings as are used for browser cookies. For information about managing your privacy and security settings for Flash cookies, please see the **CHOICES AND ACCESS** section of this Policy.
- **Through server log files:** Our Website may use log files to collect information about your computer and internet connection, which may include information about your IP address, browser type, internet service provider, referring/exit pages, platform type, date/time stamp, and number of clicks. This information may be used to analyze trends, administer the site, track your movement in the aggregate, and gather broad demographic information for aggregate use.

- **Through web beacons:** Web beacons are small electronic files that permit us, for example, to count the number of users who have visited certain pages of our Website, open a particular e-mail or other related website statistics.
- **Through internet tags:** Internet tags are smaller than cookies and tell our Website server information such as the IP address and browser type related to your computer.
- **Through third parties:** Information that we receive from our business partners and third party servicers.

We will rely on consent, which in some cases may be implied, to use technical information that may be collected through our use of cookies, Flash cookies, server log files, web beacons or internet tags. You may withdraw consent at any time by contacting us as described in this Policy.

We may also use cookies, Flash cookies, web beacons, server log files and internet tags to collect information about your online activities over time and across third-party websites or other online services (behavioral tracking). Note that your browser settings may allow you to send a “Do Not Track” signal to websites you visit. If you elect to send a “Do Not Track” signal when you visit our Website, we will not track your visit to our Website. To find out more about “Do Not Track” signals, visit <http://www.allaboutdnt.com>.

The information that we may collect automatically is statistical data and may, depending on applicable law, include PII, and we may maintain it or associate it with PII we collect in other ways. It helps us to improve our Website by enabling us to estimate our audience size and usage patterns, speed up your searches, recognize you when you return to our Website and store information about your preferences.

### **HOW WE MAY USE YOUR INFORMATION**

To the extent permitted by applicable law, we may use information, including PII, that we collect:

- To contact you through email correspondence or by text message.
- To provide you with texts, emails or downloadable links with information related to your testing results.
- To present our Website and its contents to you in a fashion customized to match your preferences.
- To personalize your experience on our Website.
- To allow you to participate in interactive features on our Website.
- To send administrative information to you, for example, information regarding our Website and changes to our terms, conditions, features and policies.
- To carry out obligations and enforce our rights arising from any contract entered into between you and us.
- To pursue our legitimate interests.
- To comply with legal process.
- To respond to request from public and government authorities.
- To enforce our Terms and Conditions: <http://cdrmaguire.com/disclaimer/>

- To protect our operations or those of any of our affiliates.
- To protect our rights, privacy, safety or property, and/or that of our affiliates, you or others.
- To allow us to pursue available remedies or limit the damages that we sustain.
- For any other purpose with your consent.

If you are using our Website in connection with our HIPAA covered services, please refer to our HIPAA Notice of Privacy Practices, which describes how we use and disclose your protected health information, our legal duties with respect to your protected health information, and your rights with respect to your protected health information and how you may exercise them. In connection with HIPAA covered services, in the event of conflict between this Policy and our HIPAA Notice of Privacy Practices, our HIPAA Notice of Privacy Practices will prevail.

### **DISCLOSURE OF YOUR INFORMATION**

We may disclose aggregated information about our users, and information that does not identify any individual, without restriction.

To the extent permitted by applicable law, your PII may be disclosed:

- To identify you to anyone to whom you communicate on our Website.
- To our subsidiaries and affiliates for the purposes described in this Policy.
- To any third party in the event of any reorganization, merger, sale, joint venture, assignment, transfer or other disposition of any or all portion of our business, assets or equity interests, whether as a going concern or as part of bankruptcy, liquidation or similar proceeding.
- To comply with any court order, law or legal process, including to respond to any government or regulatory request.
- To enforce or apply our Terms and Conditions: <http://cdrmaguire.com/disclaimer/> and other agreements that we may have with you.
- If we believe disclosure is necessary or appropriate to protect the rights, property or safety of us or others.
- With your consent.
- For any other purpose disclosed by us when you provide the information.

We will not disclose or sell any PII to any unaffiliated third party for direct marketing purposes.

### **THIRD PARTY COLLECTION, USE, AND DISCLOSURE OF YOUR INFORMATION**

Our Website may contain links to various third party websites, such as links to [www.cdc.gov](http://www.cdc.gov) and [www.floridahealth.gov](http://www.floridahealth.gov). These third party websites may collect PII and other related information. This Policy does not address, and we are not responsible for, the privacy, information or other practices of any third party, including any third party operating any site to which our Website contains a link. The inclusion of a link on our Website or in any text message

we send you regarding your test results does not imply endorsement of the linked site by us or any of our subsidiaries or affiliates.

### **CHOICES AND ACCESS**

We strive to provide you with choices regarding our use and disclosure of PII. We have created mechanisms to provide you with the following control over your information, including your PII:

- You can set your browser to refuse all or some browser cookies or to alert you when cookies are being sent. To learn how you can manage your Flash cookie settings, please visit the Flash player settings page on Adobe's. If you disable or refuse cookies, please note that some parts of our Website may then be inaccessible or not function properly.
- If at any time you wish to stop receiving communication from us, please just let us know by contacting us using the contact information listed below (see **CONTACT INFORMATION**).

You can review and change your PII or other information by logging into our Website and visiting your account profile page. You may also review, correct, update, delete or otherwise limit our use of your PII or other information (such as behavioral tracking) by contacting us using the contact information listed below (see **CONTACT INFORMATION**). However, please note that we cannot delete your PII except by also deleting your user account and we may not accommodate a request to change information if we believe the change would violate any law or legal requirement or cause the information to be incorrect.

If you delete User Contributions, copies of your User Contributions may remain viewable in archived pages, or may have been copied or stored by other Website users.

### **SECURITY**

When users submit sensitive information via our Website, their information is protected both online and offline. Prevention of unauthorized access or disclosure of data is of the utmost importance. Physical, administrative and technical procedures are employed to safeguard all collected information.

All data transactions occurring over a public network (i.e. the Internet) are encrypted using SSL technology. Specific certifier details can be inspected in your browser during a secure session (see browser-specific help for details).

Access to PII and data by our employees is limited to those persons or agents of CDR that have a specific business purpose for maintaining and processing such PII. These individuals are made aware of their responsibilities to protect the security of that PII and also uphold the principles of confidentiality and integrity. This process protects such individual's credentials and the information such individual may access.

The safety and security of information also depends on you. Where we have given you (or where you have chosen) a password for access to certain parts of our Website, you are

responsible for keeping this password confidential. Please do not share your password with anyone. Sharing of account passwords is considered an acceptable use violation and may result in loss of access to our Website.

Unfortunately, new vulnerabilities arise in the realm of technology every day. Although we strive to protect your information, circumstances beyond our control may compromise that goal. As with any website, please be conscious of the data you share. If you are not comfortable providing any information, it is your right to withhold it. IN NO EVENT SHALL WE BE LIABLE FOR ANY DAMAGES (WHETHER CONSEQUENTIAL, DIRECT, INCIDENTAL, INDIRECT, PUNITIVE, SPECIAL OR OTHERWISE) ARISING OUT OF, OR IN ANY WAY CONNECTED WITH, A THIRD PARTY'S UNAUTHORIZED ACCESS TO YOUR INFORMATION, REGARDLESS OF WHETHER SUCH DAMAGES ARE BASED ON CONTRACT, STRICT LIABILITY, TORT OR OTHER THEORIES OF LIABILITY, AND ALSO REGARDLESS OF WHETHER WE ARE GIVEN ACTUAL OR CONSTRUCTIVE NOTICE THAT DAMAGES WERE POSSIBLE, EXCEPT AS PROVIDED UNDER APPLICABLE LAWS.

#### **INDEMNITY**

As a condition to accessing or using our Website, you agree to indemnify and hold harmless CDR, its subsidiaries and affiliates and its and their respective directors, shareholders, officers, employees and agents against any and all liabilities, expenses (including, without limitation, attorney's fees and court costs) and damages arising out of or otherwise in connection with third party claims resulting from or otherwise in connection with your access to or use of our Website, including, without limitation, any claims alleging facts that, if true, would constitute a breach of the terms and conditions stated in this Policy.

#### **RETENTION PERIOD**

We may retain your PII for the period necessary to fulfill the purposes outlined in this Policy, unless a longer retention period is required or allowed by law or to otherwise fulfill a legal obligation.

#### **CHANGES TO OUR PRIVACY POLICY**

If we decide to change this Policy, we will post any changes we make on this page with a notice that this Policy has been updated on the home page of our Website. Any changes to this Policy will become effective when we post the revised Policy on our Website. The effective date for this Policy is identified at the top of this page. You are responsible for periodically visiting our Website and this Policy to check for any changes. Your use of our Website following these changes means that you accept the revised Policy.

#### **CHILDREN**

Our Website is not intended for children (as defined by local law) other than for the purposes of providing test results a child has taken. We do not knowingly collect PII from children outside

of information provided to properly identify the child and any medical tests performed. In the event that we learn that we have collected PII from a child, we will delete such PII as soon as possible except as required to properly deliver and provide test results. If you believe we might have any PII from or about a child, then please contact us using the contact information listed below (see **CONTACT INFORMATION**). Visit the Federal Trade Commission website for more information about the Children's Online Privacy Protection Act.

### **CONTACT INFORMATION**

If you have any questions, comments or concerns about this Policy or other privacy-related matters, then you may contact us in the following ways:

Mailing Address: PO Box 771750, Miami, FL 33177

Email Address: [info@cdrmaguire.com](mailto:info@cdrmaguire.com)

Phone Number: 786-235-8534

## **HIPAA NOTICE OF PRIVACY PRACTICES**

### **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.**

#### **NOTICE OF PRIVACY PRACTICES**

CDR Maguire, Inc. and its affiliates (collectively referred to as “CDR,” “we,” “our” and “us”) are committed to protecting the privacy of your identifiable health information. This information is known as “protected health information” or “PHI.” PHI includes, without limitation, information that CDR has created or received about your past, present or future health or condition, the provision of healthcare to you or the payment of this healthcare.

Please read this HIPAA Notice of Privacy Practices (this “**Notice**”) carefully to understand our policies and practices regarding your PHI and how we may use or disclose it.

#### **OUR RESPONSIBILITIES**

CDR is required by law to maintain the privacy of your PHI. We are also required to provide you with this Notice of our legal duties and privacy practices upon request. This Notice describes our legal duties, privacy practices and your patient rights as determined by the Health Insurance Portability and Accountability Act of 1996 (“**HIPAA**”). We are required to follow the terms of this Notice currently in effect. We are required to notify affected individuals in the event of a breach involving unsecured PHI. PHI is stored electronically and is subject to electronic disclosure.

#### **HOW WE MAY USE OR DISCLOSE YOUR PHI**

We use and/or disclose your PHI for treatment, payment or healthcare operations purposes and for other purposes permitted or required by law. Not every use or disclosure is listed in this Notice, but all of our uses and disclosures of your PHI will fall into one of the categories listed below.

We will obtain your written authorization to use or disclose your PHI for any purpose not covered by one of the categories listed below. Subject to applicable law, we will not use or disclose your PHI for marketing purposes or sell your PHI, unless you have signed an authorization. You may revoke any authorization you sign at any time. If you revoke your authorization, we will no longer use or disclose your PHI for the reasons stated in your authorization except to the extent we have already taken action based on your authorization.

The law permits us to use and disclose your PHI for the following purposes:

**Treatment:** CDR discloses your PHI, including, without limitation, your COVID-19 test results, to authorized healthcare professionals who need access to your test results and/or PHI for treatment purposes, including but not limited to, the provision, coordination or management of your health care.

**Payment:** CDR will use and disclose your PHI for purposes of billing and payment. For example, we may disclose your PHI to health plans or other payers to determine whether you are enrolled

with the payer or eligible for health benefits or to obtain payment for our services. If you are insured under another person's health insurance policy (for example, parent, spouse, domestic partner or a former spouse), we may also send invoices to the subscriber whose policy covers your health services.

**Healthcare Operations:** CDR may use and disclose your PHI for activities necessary to support our healthcare operations, such as performing quality checks on our testing, internal audits or arranging for legal services.

**Other Uses and Disclosures of Your PHI that Do Not Require Authorization:** We are also allowed or required to share your PHI, without your authorization, in certain situations or when certain conditions have been met.

**Business Associates:** CDR may provide your PHI to other companies or individuals that need the information to provide services to us. These other entities, known as "business associates," are required to maintain the privacy and security of PHI. For example, we may provide information to companies that assist us with billing for our services. We may also use an outside collection agency to obtain payment when necessary.

**As Required by Law:** CDR may use and disclose PHI as required by law.

**Law Enforcement Activities and Legal Proceedings:** CDR may use and disclose your PHI if necessary, to prevent or lessen a serious threat to your health and safety or that of another person. We may also provide PHI to law enforcement officials as may be required by law. We may also disclose PHI to appropriate agencies if we reasonably believe an individual to be a victim of abuse, neglect or domestic violence. We may disclose your PHI as required to comply with a court or administrative order. We may disclose your PHI in response to a subpoena, discovery request or other legal process in the course of a judicial or administrative proceeding, but only if efforts have been made to tell you about the request or to obtain an order of protection for the requested information.

**Disclosure to Others Involved in Your Care:** CDR may disclose relevant PHI to a family member, friend or anyone else you designate in order for that person to be involved in your care or payment related to your care.

**Research:** Under certain circumstances, we may disclose your PHI for research purposes.

**Disaster Relief Efforts:** CDR may disclose PHI to those assisting in disaster relief efforts so that others can be notified about your condition, status and location.

**Other Uses and Disclosures:** As permitted by HIPAA, CDR may also disclose your PHI to:

- Public Health Authorities;
- The Food and Drug Administration;
- Health Oversight Agencies;
- Military Command Authorities;
- National Security and Intelligence Organizations;

- Correctional Institutions;
- Organ and Tissue Donation Organizations;
- Coroners, Medical Examiners and Funeral Directors; and
- Workers Compensations Agents.

### **STATE LAW**

For all of the above purposes, when state law is more restrictive than federal law, we are required to following the more restrictive state law.

### **RIGHT TO INSPECT AND COPY**

You have the right to inspect and obtain a copy of your PHI that we maintain about you. If you request a copy of your PHI, we may charge a fee for the costs of copying, mailing or other supplies associated with your request. We may deny your request to inspect and copy in certain limited circumstances. If you are denied access to inspect and copy, then you may request that the denial be reviewed.

### **AMENDING YOUR PHI**

You may request amendments to your PHI by making a written request. However, we may deny the request in some cases (such as if we determine the PHI is accurate). If we deny your request to change your PHI, we will provide you with a written explanation of the reason(s) for the denial and additional information regarding further actions that you may take.

### **ACCOUNTING OF DISCLOSURES**

You have the right to receive a list of certain disclosures of your PHI made by CDR in the past six years from the date of your written request. Under the law, this does not include disclosures made for purposes of treatment, payment or healthcare operations or certain other purposes.

### **REQUEST RESTRICTIONS**

You may request that we agree to restrictions on certain uses and disclosures of your PHI. We are not required to agree to your request, except for requests to limit disclosures to your health plan for purposes of payment or healthcare operations when you have paid us for the item or service covered by the request out-of-pocket and in full and when the uses or disclosures are not required by law.

### **REQUEST CONFIDENTIAL COMMUNICATIONS**

You have the right to request that we send your PHI by alternative means or to an alternative address, and we will accommodate your reasonable requests.

### **COPY OF THIS NOTICE**

You have the right to obtain a paper copy of this Notice upon request.

**HOW TO EXERCISE YOUR RIGHTS**

You may write or send an email to us with your specific request. CDR will consider your request and provide you with a response.

**COMPLAINTS AND QUESTIONS**

If you believe your privacy rights have been violated, you have the right to file a complaint with us. You also have the right to file a complaint with the Secretary of the U.S. Department of Health and Human Services, Office for Civil Rights. CDR will not retaliate against any individual for filing a complaint. To file a complaint with us, or should you have any questions about this Notice, then you may contact us by writing us a letter to PO Box 771750, Miami, FL 33177.

**CHANGES TO THIS NOTICE**

We reserve the right to amend the terms of this Notice to reflect changes in our privacy practices, and to make the new terms and practices applicable to all PHI that we maintain about you, including, without limitation, PHI created or received prior to the effective date of the Notice revision. Our Notice is displayed on our website and a copy is available upon request.

### **Consent for CDR Maguire to Contact**

I understand that CDR Maguire or an affiliate may contact me to offer me additional services and information including but not limited to clinical services, voluntary participation in research studies (subject to my written, informed consent), or participation in genomics research (subject to my written, informed consent). I understand I am under no obligation to participate, and I am voluntarily furnishing my phone number and/or email address for such purposes or for other purposes in connection with CDR Maguire or its affiliates' business.



## NOTICE OF PRIVACY PRACTICES

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PLEASE REVIEW IT CAREFULLY.

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### USES AND DISCLOSURES OF YOUR PROTECTED HEALTH INFORMATION

Protected health information includes demographic and medical information that concerns the past, present, or future physical or mental health of an individual. Demographic information could include your name, address, telephone number, social security number and any other means of identifying you as a specific person. Protected health information contains specific information that identifies a person or can be used to identify a person.

Protected health information is health information created or received by a health care provider, health plan, employer, or health care clearinghouse. The Department of Health can act as each of the above business types. This medical information is used by the Department of Health in many ways while performing normal business activities.

Your protected health information may be used or disclosed by the Department of Health for purposes of treatment, payment, and health care operations. *Health care professionals use medical information in the clinics or hospital to take care of you. Your protected health information may be shared, with or without your consent, with another health care provider for purposes of your treatment. The Department of Health may use or disclose your health information for case management and services. The Department of Health clinic or hospital may send the medical information to insurance companies, Medicaid, or community agencies to pay for the services provided you.*

Your information may be used by certain department personnel to improve the department's health care operations. The department also may send you appointment reminders, information about treatment options or other health-related benefits and services.

Some protected health information can be disclosed without your written authorization as allowed by law. Those circumstances include:

- Reporting abuse of children, adults, or disabled persons.
- Investigations related to a missing child.
- Internal investigations and audits by the department's divisions, bureaus, and offices.
- Investigations and audits by the state's Inspector General and Auditor General, and the legislature's Office of Program Policy Analysis and Government Accountability.
- Public health purposes, including vital statistics, disease reporting, public health surveillance, investigations, interventions, and regulation of health professionals.
- District medical examiner investigations;
- Research approved by the department.
- Court orders, warrants, or subpoenas;
- Law enforcement purposes, administrative investigations, and judicial and administrative proceedings.

Other uses and disclosures of your protected health information by the department will require your written authorization. These uses and disclosures may be for marketing and for research purposes, certain uses and disclosure of psychotherapist notes, and the sale of protected health information resulting in remuneration to the Department of Health.

This authorization will have an expiration date that can be revoked by you in writing.

## INDIVIDUAL RIGHTS

You have the right to request the Department of Health to restrict the use and disclosure of your protected health information to carry out treatment, payment, or health care operations. You may also limit disclosures to individuals involved with your care. The department is not required to agree to any restriction.

You have the right to be assured that your information will be kept confidential. The Department of Health will make contact with you in the manner and at the address or phone number you select. You may be asked to put your request in writing. If you are responsible to pay for services, you may provide an address other than your residence where you can receive mail and where we may contact you.

You have the right to inspect and receive a copy of your protected health information that is maintained by the Department of Health within 30 days of the Department's receipt of your request to obtain a copy of your protected health information. You must complete the Department's Authorization to Disclosure Confidential Information form and submit the request to the county health department or Children's Medical Services office. If there are delays in getting you the information, you will be told the reason for the delay and the anticipated date when you will receive your information.

Your inspection of information will be supervised at an appointed time and place. You may be denied access as specified by law.

If you choose to receive a copy of your protected health information, you have the right to receive the information in the form or format you request. If the Department cannot produce it in that form or format, it will give you the information in a readable hard copy form or another form or format that you and the Department agree to.

The Department cannot give you access to psychotherapy notes or certain information being used in a legal proceeding. Records are maintained for specified periods of time in accordance with the law. If your request covers information beyond that time the Department is required to keep the record, the information may no longer be available.

If access is denied, you have the right to request a review by a licensed health care professional who was not involved in the decision to deny access. This licensed health care professional will be designated by the department.

You have the right to correct your protected health information. Your request to correct your protected health information must be in writing and provide a reason to support your requested correction. The Department of Health may deny your request, in whole or part, if it finds the protected health information:

- Was not created by the department.
- Is not protected health information.
- Is by law not available for your inspection.
- Is accurate and complete.

If your correction is accepted, the department will make the correction and tell you and others who need to know about the correction. If your request is denied, you may send a letter detailing the reason you disagree with the

decision. The department may respond to your letter in writing. You also may file a complaint, as described below in the section titled Complaints.

You have the right to receive a summary of certain disclosures the Department of Health may have made of your protected health information. This summary does not include:

- Disclosures made to you.
- Disclosures to individuals involved with your care.
- Disclosures authorized by you.
- Disclosures made to carry out treatment, payment, and health care operations.
- Disclosures for public health.
- Disclosures to health professional regulatory purposes.
- Disclosures to report abuse of children, adults, or disabled.
- Disclosures prior to April 14, 2003.

This summary does include disclosures made for:

- Purposes of research, other than those you authorized in writing.
- Responses to court orders, subpoenas, or warrants.

You may request a summary for not more than a 6 year period from the date of your request.

If you received this Notice of Privacy Practices electronically, you have the right to a paper copy upon request.

The Department of Health may mail or call you with health care appointment reminders.

## DEPARTMENT OF HEALTH DUTIES

The Department of Health is required by law to maintain the privacy of your protected health information. This Notice of Privacy Practices tells you how your protected health information may be used and how the department keeps your information private and confidential. This notice explains the legal duties and practices relating to your protected health information. The department has the responsibility to notify you following a breach of your unsecured protected health information.

As part of the department's legal duties this Notice of Privacy Practices must be given to you. The department is required to follow the terms of the Notice of Privacy Practices currently in effect.

The Department of Health may change the terms of its notice. The change, if made, will be effective for all protected health information that it maintains. New or revised notices of privacy practices will be posted on the Department of Health website at <http://www.floridahealth.gov/about-the-department-of-health/about-us/patient-rights-and-safety/hipaa/index.html> and will be available by email and at all Department of Health buildings. Also available are additional documents that further explain your rights to inspect and copy and amend your protected health information.

## COMPLAINTS

If you believe your privacy health rights have been violated, you may file a complaint with the: Department of Health's Inspector General at 4052 Bald Cypress Way, BIN A03/ Tallahassee, FL 32399-1704/ telephone 850-245-4141 and with the Secretary of the U.S. Department of Health and Human Services at 200 Independence Avenue, S.W./ Washington, D.C. 20201/ telephone 202-619-0257 or toll free 877-696-6775.

The complaint must be in writing, describe the acts or omissions that you believe violate your privacy rights, and be filed within 180 days of when you knew or should have known that the act or omission occurred. The Department of Health will not retaliate against you for filing a complaint.

### FOR FURTHER INFORMATION

Requests for further information about the matters covered by this notice may be directed to the person who gave you the notice, to the director or administrator of the Department of Health facility where you received the notice, or to the Department of Health's Inspector General at 4052 Bald Cypress Way, BIN A03/ Tallahassee, FL 32399-1704/ telephone 850-245-4141.

### EFFECTIVE DATE

This Notice of Privacy Practices is effective beginning July 1, 2013, and shall be in effect until a new Notice of Privacy Practices is approved and posted.

### REFERENCES

"Standards for the Privacy of Individually Identifiable Health Information; Final Rule." 45 CFR Parts 160 through 164. *Federal Register* 65, no. 250 (December 28, 2000).

"Standards for the Privacy of Individually Identifiable Health Information; Final Rule" 45 CFR Part 160 through 164. *Federal Register*, Volume 67 (August 14, 2002).

HHS, Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information and Nondiscrimination Act; Other Modifications to the HIPAA Rules, 78 Fed. Reg. 5566 (Jan. 25, 2013).