

PRECISION  
for medicine

BIOSPECIMEN SOLUTIONS



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Tomorrows

# Study Participant Handbook for Blood & Specimen Collections

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PRECISION  
for medicine

Providing Specimen Solutions from Discovery to Diagnosis™

Phone: 774-265-1703    Email: [study@precisionformedicine.com](mailto:study@precisionformedicine.com)



## **BLOOD COLLECTION FREQUENTLY ASKED QUESTIONS FOR STUDY PARTICIPANTS**

### ***How do I become a participant in a Precision for Medicine blood or specimen collection study?***

If you are interested and choose to participate in one of our blood collection studies, or other specimen collections (*i.e.*, saliva, urine, etc.), you may do so by responding to one of our study announcements for a specific collection (*i.e.*, healthy participants, Lyme disease patients, etc.) or by registering with our confidential donor registry by filling-out a [Donor Contact Form](#) to receive email notifications when new studies open. When you contact us regarding a study, our study coordinators will answer any questions you may have about a study as well as ask you questions to determine your eligibility for a study. If you qualify for a study, our coordinators will schedule you for your study visit either at one of our study facilities located in Norton, MA or Fall River, MA, or you may schedule an in-home visit with our mobile phlebotomy staff, in which case our phlebotomists will meet you in your home to explain the study, obtain your consent to participate in the study, and perform the specimen collection in the comfort and privacy of your own home.

### ***I have been told I cannot donate blood, can I still participate in Precision for Medicine's blood collection studies?***

The blood collected for Precision for Medicine studies is not given to another patient (*i.e.*, it is not used to transfuse other patients who need blood) but is used exclusively for medical research. In many cases we are looking for patients with health conditions that may make them not eligible under the Food and Drug Administration (FDA) guidelines for blood donors but makes them eligible for our studies because our medical researchers are studying their specific disease or condition. To ensure patient safety, Precision for Medicine follows guidelines for safe collection of blood from patients with underlying medical conditions as established by the FDA, which has set limits for the total amount of blood that may be collected from patients under the treatment of a physician for a medical condition.

### ***Is the blood collection process safe?***

Blood collections occur in the same manner as when a patient's blood is drawn at his/her doctor's office or a clinical lab. Precision for Medicine uses only clean, sterile needles and medical grade materials for blood collections and follows FDA and American Association of Blood Banks (AABB) procedures and guidelines. All specimen collections are conducted under a clinical protocol that has been approved by an Independent Review Board (IRB), which is an independent committee of physicians, healthcare experts and community representatives who

ensure the study follows regulations for the protection of human subjects in research. Precision for Medicine clinical studies are conducted under the Department of Human Health and Service's Office of Human Research Protection (OHRP)-approved Federal Wide Assurance (00023836).

Phlebotomists will discuss with donors the common risks associated with blood collections (*i.e.*, bruising, fainting) at the time of obtaining informed consent.

***How much blood will be taken during a blood collection study?***

Each blood collection study has different amounts of blood that may be required during a single visit. You will be told in advance how much blood is required for a study about which you may be inquiring before we schedule you for a visit. On average, most Precision for Medicine collections require only 5 to 6 tablespoons of blood be collected. Healthy participants may qualify for whole pint collections (32 tablespoons), which we collect occasionally.

***If I choose to participate in a blood collection study, how many study visits do I have to make?***

Most Precision for Medicine studies only require a one-time visit to one of our facilities or a one-time in-home visit by our mobile phlebotomist. If a study requires more than one visit, donors will be told how many visits are needed before they consent to taking part in the study.

***How long will a study visit take?***

Most blood collection study visits last fewer than 30 minutes to complete. This time includes the phlebotomist explaining the study and answering any of your questions, obtaining informed consent, asking questions about your medical history, and collecting the specimen.

***If I decide to participate, how much am I compensated and when do I receive my study compensation?***

Study compensation varies from study to study (\$20 per visit up to \$100 per visit). Eligible study participants who are enrolled receive their compensation as soon as they complete the study. If a study requires more than one collection, a study participant will receive compensation at the end of each study visit. Participants may quit their participation at any time, and those who do will receive a portion of the compensation as described during the consent process.

***What if I need to reschedule or cancel my appointment?***

If you need to reschedule or cancel your appointment for any reason, please call or email one of our coordinators at **774-265-1701** or **774-265-1703** as soon as possible. You may also call and leave a voice message with the Precision for Medicine Clinical & Regulatory Department Director at **774- 265-1698**.

***Will Precision for Medicine require my medical information?***

For some collection studies in which we need to enroll patients with certain medical conditions, Precision for Medicine will ask you to provide a medical document (*i.e.*, a physician summary report, laboratory report, etc.) providing evidence of your medical diagnosis. Precision for Medicine will remove your name and any identifiers (*i.e.*, your medical record number, etc) from your medical record and any other data that we collect before sharing it with medical researchers.

***How does Precision for Medicine protect my privacy and confidentiality?***

Precision for Medicine will never share your personal identifying information with a third party. All private health information (PHI) provided to Precision for Medicine is kept confidential and coded, so no one can identify you or connect you with your medical information. No samples we share with medical researchers contain any information that can

directly identify you. For further information on how Precision for Medicine protects your privacy and confidentiality, please refer to [Precision for Medicine's Privacy Statement](#) included in this information packet.

***How does Precision for Medicine use my blood and other specimens?***

Precision for Medicine provides your blood and other specimens to medical researchers throughout the world who are developing new drugs or diagnostic tests for earlier diagnosis and/or better management of various diseases. Over the past 19 years, with the assistance of our valued study participants and collaborating clinical research investigators throughout the world, Precision for Medicine has made direct contributions to medical research and healthcare including:

- advancements in the safety of the world's blood supply;
- improvements in the early diagnoses of Breast, Colorectal and other cancers;
- enhancements to technologies for the monitoring of Hepatitis and HIV patients;
- simplified methods for the detection of Sexually Transmitted Diseases;
- development of novel point-of-care testing devices for acute coronary events; and
- FDA marketing approval of Kalydeco, a genetic mutation-specific drug that halts the progression of cystic fibrosis in patients ages 2 years and older.

***Will I receive any test results from my blood specimen?***

In most cases, you will not receive any test results from your donated specimen unless we tell you in advance that we are sending the specimen for specific testing to a clinical diagnostic laboratory (*i.e.*, for Lyme disease, infectious diseases, etc.). You will be notified before you provide informed consent if your sample will be tested by a diagnostic laboratory. Most samples collected under our studies are used in the development of new tests that have not yet been approved by the FDA as a diagnostic test and therefore, no information on specific test results will be available to you.

***Will I be given information on which specific research my specimen is being used?***

Precision for Medicine works with medical researchers from both federally grant funded and private pharmaceutical and biotechnological companies; the latter of which prevents us from disclosing proprietary information regarding the specific nature of the research. Until a drug or diagnostic test developed by a private corporation receives marketing approval from the FDA or a foreign regulatory body, we are unable to disclose specifics for any research conducted. All we can say regarding the collection is how your whole blood sample is being processed (*i.e.*, to serum and/or plasma) and that it is being used to discern biomarkers that may be linked (in case of patient samples) or not linked (in the case of healthy donor samples) with a certain disease.

Once a drug or diagnostic test is approved, we are allowed to provide greater specifics, such as in the case of our contribution to the development of Kalydeco, a genetic mutation-specific drug that halts the progression of cystic fibrosis in patients ages 2 years and older. Precision for Medicine does share updates on the advances to which we contribute with donors on one of our Facebook pages (<https://www.facebook.com/PrecisionforMedicineinMA/>), but it may take many years from the time of biospecimen donation to the point of regulatory clearance/approval for the specific product allowing us to share this information.



## Precision for Medicine Privacy Statement

Your privacy is important to Precision for Medicine. This privacy statement provides information about the personal information that Precision for Medicine collects, and the ways in which Precision for Medicine uses that personal information. If you contact us in response to this advertisement and select to register yourself in our research database, Precision for Medicine will ask you to voluntarily provide personal data (*e.g.*, name, address, email, telephone number, etc.) in order that we may notify you of opportunities to volunteer for our research studies. Precision for Medicine will not disclose your personal information to any third-party. We use reasonable security procedures to protect against unauthorized or unlawful access, processing, disclosure, alteration, destruction or accidental loss of your personal data. We collect, process and maintain your personal data in accordance with the practices described in this Privacy Notice and applicable local legal and regulatory requirements. We limit access to and use of your personal data to authorized persons. When your personal data is no longer needed, we will securely destroy your personal data. If you choose to register with our research database, you may update your personal information at any time or you may instruct us to remove your information at any time by contacting Precision for Medicine at:

Email: ***study@Precision for Medicine.com***

Telephone: ***(774) 265-1698***

Questions about this privacy policy or Precision for Medicine's treatment of your personal information may also be directed to the contacts listed above. Precision for Medicine may update this privacy policy from time to time by posting a new version.

# **DONOR CONTACT FORM**

By completing the information and signing below, I hereby give permission to be contacted for potential participation in future clinical research studies at Precision for Medicine, LLC.

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

Address: \_\_\_\_\_

\_\_\_\_\_

Email: \_\_\_\_\_

Phone: \_\_\_\_\_

Date of Birth: \_\_\_\_\_

Ethnicity: \_\_\_\_\_

Gender: \_\_\_\_\_

Current Medical Conditions: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Current Medications: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Do you authorize Precision for Medicine, LLC to send you text message reminders before your appointment? (Please initial next to your choice)

YES, I would like text message reminders: \_\_\_\_\_ at this number: \_\_\_\_\_

NO, send me reminders via email: \_\_\_\_\_

Subject's Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

(Please return this form to Precision for Medicine, LLC at: [mailto:study@Precision for Medicine.com](mailto:study@PrecisionforMedicine.com))

## Directions to Precision for Medicine (Norton Collection Center)

### Points North traveling Route 93 South to 24 South to 495 North:

Take 93 South to Exit 4 (MA-24 S towards Brockton )  
Take exit 14B to merge onto I-495 N toward Worcester  
Take exit 9 toward Bay St/Taunton/Easton  
Turn left onto Bay St (signs for Taunton/Industrial Park Rd)  
Proceed with "From Bay St." directions below.

### Route 95 North or South to 495 South:

Head North (from Providence) or South (from Canton) on Route I-95.  
Take Exit 6A off of I-95 to merge onto I-495 S toward Cape Cod.  
Take exit 9 for Bay St toward Taunton/Easton  
Turn slight right onto Bay St.  
Proceed with "From Bay St." directions below.

### From Points South (Fall River):

Take MA-24 N to exit 14B (I-495 N toward N Worcester).  
Take exit 9 off of I-495 N toward Bay St/Taunton/Easton.  
Turn left onto Bay St (signs for Taunton/Industrial Park Rd).  
Proceed with "From Bay St." directions below.

### **From Bay St:**

Turn right onto **Industrial Park Rd.**  
Take the **second right** onto **Joseph I. Quinn Drive** which is the turn before the Holiday Inn entrance. If you pass the Holiday Inn on Industrial Park Road, you have gone too far.  
Proceed left around the curve to continue on N Boundary Rd/S Washington St .  
Proceed past the "Entering Norton" sign and the Extended Stay America Hotel (on right).  
Turn **left** onto **Commerce Way** (first left after Extended Stay America Hotel).  
Take **first left** off of Commerce Way to **enter the facility parking lot**, then take an immediate left and follow the road in front of the building complex.  
Proceed past the Precision for Medicine facility (Building 10C), which is the last building on the right, and turn right into the side parking lot.

**The Precision for Medicine Clinical Laboratory entrance is at the rear of the building to the right of "Outlaw Group" entrance . Please ring bell for admittance.**

10 Commerce Way, Norton, MA 02766  
phone: 508.285.7877      fax: 774.265.1679  
internet: [www.PrecisionforMedicine.com](http://www.PrecisionforMedicine.com)

## Directions to Precision for Medicine (Fall River Collection Center)

### From Points North (Assonet, Dighton, Berkley) traveling 24 South:

Take MA-24 S toward Fall River.

Keep right to take MA-79 S via EXIT 7 toward N Fall River/Somerset.

Keep left to remain on MA-79/ MA-138 S toward Tiverton, RI.

At the fourth traffic light, turn left onto Columbia St.

At the second traffic light, turn left onto South Main St.

161 S MAIN ST is on the left, across the street from the Fall River District Courthouse (second floor above the Taphouse Grille Restaurant).

### From Points West (Somerset, Swansea, Providence, RI) traveling Route I-195 East

Take I-195 E toward Fall River.

Keep right to take MA-79/MA-138 S toward Tiverton, RI.

At the traffic light at the end of the off-ramp, turn left onto MA-138/MA-79 N/Western Fall River Expy.

Continue straight ahead onto the Broadway Extender to the set of traffic lights.

At the traffic light turn left onto Columbia St.

At the second traffic light, turn left onto South Main St.

161 S MAIN ST is on the left, across the street from the Fall River District Courthouse (second floor above the Taphouse Grille Restaurant).

### From Points East (Westport, North Dartmouth, New Bedford) traveling Route I-195 West

Follow I-195 W and take exit 6-7 for MA-81 S/Pleasant St/Plymouth Ave.

Keep left at the fork to continue on Exit 6, follow signs for Pleasant Street

Keep right at the fork to stay on Exit 6, follow signs for Pleasant St

Turn right onto Pleasant St.

Turn left onto 7th St.

Turn left onto Bedford St

Turn left onto S Main St.

161 S MAIN ST is on the right, across the street from the Fall River District Courthouse (second floor above the Taphouse Grille Restaurant).

**The Precision for Medicine Collection Facility's Entrance is the second door to the left of the Taphouse Grille Restaurant entrance. Please ring the Precision for Medicine doorbell for entry.**

**Parking:** Metered street parking is available along South Main St. Paid parking garages are located on Third St. and Pearl St.

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