Consent/Authorization Statement for Use and Disclosure of Protected Health Information:

Please read through this information carefully. This consent/authorization form describes the purpose, risks, and benefits of the Williams Syndrome Patient & Clinical Research Registry, referred to as the Registry, so that all individuals can make an informed choice about whether they would like to participate. If you have questions or concerns about the information on this consent/authorization form or your participation, please contact our Registry Coordinator at WSRegistry@partners.org or by phone at (617) 726-5318.

Registry Overview:
The purpose of the Registry is to connect families of individuals with Williams syndrome (WS) who are interested in learning more about potential research opportunities with the researchers performing these studies. The Registry accomplishes this by: 1) collecting basic health and developmental information (also called protected health information, or PHI) on individuals with WS from their parents or legal guardians; 2) collecting, organizing, and reviewing medical records; and 3) assisting researchers in finding persons listed in the Registry who would be eligible for their research and clinical studies. Recruitment for studies and clinical trials can sometimes take a long time, especially for rare diseases like WS. Having the Registry collect information from parents and from medical records is likely to speed up this process so that researchers can learn more about WS faster and get closer to finding better treatments.

Joining the Registry does not mean that you or the person with WS has to join any of the studies you are informed about. After you learn about a specific research or clinical study, you will be able to decide whether you want your child or legal dependent with WS to participate in the study. It is also important to point out that participation in the Registry does not guarantee you will qualify for, or be enrolled in, all available research or clinical studies.

Who Can Participate:
Any parent or legal guardian of a person with WS can sign up their child or legal dependent. The Registry only collects information about people diagnosed with WS.

If your child or legal dependent is 12 years of age or older, please explain the purpose, risks, and benefits of the Registry to him/her. Make sure that he or she is comfortable with and willing to join the Registry before you submit any health and developmental information to the Registry.

Registry Process:
1. Joining the Registry
If you choose to participate in the Registry after reading the information in this form, you will indicate both a) your family member with WS is in agreement with your decision (or is too young to understand), and b) that you agree to participate. You will then click the “Create Account” button, or for those completing a hardcopy form, sign below.

2. You Provide Information to the Registry
   a) The information you provided in the Registration form (such as your name, your child/legal dependent’s name, address, email address, or phone number) will be saved to the Registry.
   b) As a member of the Registry, you will be asked to provide some of your child/legal dependent’s health and development information (such as whether he/she has any heart or blood vessel problems, whether he/she has anxiety, etc.). You will do this by completing surveys such as the Williams Syndrome Health Survey.
   c) You will be able to fill out all surveys online and submit them electronically through a secure website. You also can request hardcopies from the Registry staff. If you answer online, you can save your work as you go and it will be submitted on the due date posted in the survey.
   d) You may also share records with the Registry or choose to authorize the Registry to obtain and review medical records from your family member with Williams syndrome. This is optional. You will be able to decide which records, if any, you choose to share with the Registry.

3. The Registry staff will Review the Information You Provide
The Registry staff will review your responses and may contact you if there are any questions about the information you entered.

4. The Registry Provides Researchers Relevant Information so They Can Study the Data and/or Determine who may Qualify for Their Study
In a way that does not reveal your identity, the Registry can provide selected medical and developmental information to researchers (using information that you have entered and/or that comes from medical records you have shared with the Registry). Some researchers may need no further involvement from you but others may be interested in recruiting subjects for research studies or clinical trials. If a researcher believes your child or legal dependent qualifies for his or her study, the researcher will provide a brief summary of their study and its goals, which you may view on the Registry.

5. You Decide Whether You Would Like to Hear More
The Registry will tell you about new studies looking for potential participants and you can read a summary of each on the Registry website. After you decide if you would like to learn more about a study, you can share your decision with the Registry.

If you indicate you want to hear more about a study, your name and contact information will be provided to the researcher. They will then contact you directly to give you more information about the study. Please note that agreeing for a researcher to contact you does not mean you have to join their study. You are only agreeing to learn more about
their study. The Registry will never release your contact information without your permission.

**Follow-Up Surveys & Medical Record Requests:**
It is important that the Registry contain accurate information. Because of this, you will be asked on a periodic basis to complete another, shorter, WS Health Survey about your child/legal dependent’s health and/or development. In addition to collecting updated information, the periodic follow-up survey may contain a few new questions, as well. When it is time to complete a new survey, you will get an email (or letter) asking you to go to the website, login, and complete the new survey. Additionally, you will be asked to sign an updated medical record release form each year. You are also welcome to visit the Registry website to view and update your contact information at any time.

**Use of Information:**
If you agree to participate, you are allowing the Registry to collect and use your child or legal guardian’s Protected Health Information (PHI) for the following purposes:

1. Facilitate research studies with the data and medical records you provide. Your information will only be shared after identifying information (such as your family member’s name, date of birth, etc) are removed unless you give us permission to share identifiable information.

2. Tell you about research studies and/or clinical trials for which your child or legal dependent with WS may qualify

3. Help researchers find persons with WS who could participate in their research studies or clinical trials

The Registry only gives out PHI and contact information to researchers with studies approved by the Registry.

No medical recommendations will be made by Registry Staff based on the information you share or review of the records provided. The Registry will also not be able to return medical records for clinical purposes.

**Risks:**
You are being asked to allow the Registry to share some of the personal information you provided about you and your child or legal dependent with qualified researchers. As with all electronic communication and databases, there is a small chance that private information about your child or legal dependent could be stolen or viewed by someone outside of the Registry. Registry Staff are doing all they can to prevent this.

- The Registry website and database are secure and encrypted to keep your contact information and questionnaire answers private. It uses HTTPS (Hypertext Transfer Protocol over Secure Socket Layer, or HTTP over SSL) encryption to ensure that your information is as securely protected during transmission as possible.
• All paper forms you mail to the Registry are kept in a locked room in a secure building.

• All medical records will be kept in a locked room in a secure building until scanned into a password protected computer. After scanning, the paper copy of the medical record will be destroyed unless the scanned version is not readable.

• Researchers using the database will not have access to names or contact information until you give permission.

Some of the questions in the WS Health Survey are about sensitive health and developmental issues in your child or legal dependent with WS. Though the Registry hopes you will answer all questions, you do not have to answer anything that makes you uncomfortable. Additionally, sharing medical records is optional and you can decide which records, if any, to share.

Benefits:
Those who participate in the Registry may not receive any direct benefit, but the Registry will:

• Promote access to studies that will increase knowledge and potentially test new therapies in individuals with WS.

• Help families by quickly and effortlessly letting you learn about studies of potential interest.

• Directly connect you with researchers to make it easier for you to participate in studies of your choosing.

• Serve as a “clearinghouse” for research information (meaning you only have to answer certain questions or share medical records for research purposes in one place)

• Create a powerful data set for research from the information you share and the records you provide

• Help researchers identify study participants faster (which in turn could speed up efforts to develop new therapies for individuals with WS).

• Make it easier to get study findings back to families, under the auspices of the Williams Syndrome Association.

• Better define the changes that occur in persons with WS over time, by comparing information collected in the follow-up surveys and obtained from medical records.
Confidentiality:
The staff of the Registry and the Massachusetts General Hospital understands that health and development information about your family member with WS is personal, and is committed to protecting the privacy of that information.

When you submit your and your child/legal dependent’s information to the Registry, it will be stored and maintained in a database on a private server, and can only be accessed on a password-protected computer. Only the Registry coordinators and administrators will have access to the database. Researchers wanting to use information in the Registry will not be given direct access to the database. Only certain information will be provided to researchers: a de-identified, limited data set and/or the information they use to decide whether your child or legal dependent qualifies for their study, and then, with your permission, the information they use to contact you.

Protection of privacy:

As part of joining the Registry, you will be providing identifiable information about your child/legal dependent’s health. In the rest of this section, we refer to this information simply as “health information.” In general, under federal law, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use, and share your health information and why they may need to do so.

Who may see, use, and share your identifiable health information and why they may need to do so:

- Partners research staff involved in the Registry
- The people or groups hired by the Registry to help in its development or implementation
- A group that oversees the data (study information) and safety of the Registry
- The Partners ethics board that oversees patient registries and the Partners research quality improvement programs
- People from organizations that provide independent accreditation and oversight of hospitals and projects such as the Registry
- People or groups that we hire to do work for us, such as programmers, data storage companies, insurers, and lawyers
- Federal and state agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health, and other US or foreign government bodies that oversee or review patient registries and research)
- Public health and safety authorities (for example, if we learn information that could mean harm to you or others, we may need to report this, as required by law)
Some people or groups who get your health information might not have to follow the same privacy rules that we follow. We share your health information only when we must, and we ask anyone who receives it from us to protect your privacy. However, once your information is shared outside Partners, we cannot promise that it will remain private.

Because the Registry has been developed to promote research in an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your health information.

You have the right to see and get a copy of your health information that you’ve provided to the Registry. To ask for this information, please contact Registry Staff.

Financial Disclosures:
The Williams Syndrome Association pays for the costs associated with creating, maintaining, and managing the Registry. Additional support comes from the Massachusetts General Hospital.

Voluntary Participation:
Your participation in the Registry is completely voluntary. You have a right not to agree to this consent/authorization and thereby not participate in the Registry or allow us to use your health information to connect you with researchers interested in studying WS. If you choose not to participate in the Registry, your child or legal dependent with WS’s health care, payment for health care, or health care benefits will not be affected. Also, you can still participate in activities, programs, and projects through the Williams Syndrome Association (WSA) even if you decide not to participate in the Registry.

If you choose to participate in the Registry, you must agree to the terms of this consent/authorization form and acknowledge your acceptance by checking you agree to participate below.

Withdraw:
You can withdraw your name and your child or legal dependent’s name and personal health & development information from the Registry at any time. You can do this by completing the Withdrawal form located on the Registry website. By completing the Withdrawal form and mailing it back to the Registry staff, you understand your withdrawal will apply only to use of the data in Registry after the date that the withdrawal is confirmed by the Registry staff. This includes your right to withdraw your permission for us to use or share your health information with qualified researchers seeking to recruit subjects for their research studies. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others.

Questions?
If you have questions about this consent/authorization form please contact the Registry coordinator (at WSRegistry@partners.org) before you agree to and create an account. By checking the three boxes below and creating an account, or by signing below, you indicate that you have had the chance to ask questions about this consent/authorization.
If you would like to speak with someone not directly related with this research project, please call the Human Research Office at: 617-424-4100. You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Once you have read all of the information in this consent form and if you are interested in joining the Registry, indicate this by checking the three boxes below. Please tell us that the family member you are registering has WS, your family member with WS is in agreement with your decision (or is too young to understand), and that you agree to participate. Then click the “Create Account” button (or sign below). Please do not enroll your child/legal dependent into the Registry if they state that they do not wish to join.

If you create a new account, you are agreeing to participate in the Registry and to the terms presented above. After you click the “Create Account” button, you will be asked to verify your email address and then will be able to log on to your home page. From there you can view any study opportunities or surveys available to you. If you are completing a hardcopy of this form, Registry Staff will contact you with additional account details. Please keep a copy of this consent for your records. You may review the document/print it once you long on to your account or by contacting Registry Staff for a copy.

**Checking all three items below indicates you agree with them, and that you are choosing to join the Registry.**

- The family member I am registering has Williams syndrome (WS)
- My family member with WS agrees with my decision to participate (or is too young to understand). I am making this decision on his/her behalf.
- I agree to participate

Online Click:  [Create Account]

Offline Sign Below:

______________________________________________
Signature of Parent/Legal Guardian

______________________________________________
Date