What is a Patient Registry?

- A patient registry is a collection of data on patients with a specific condition (or related conditions).
- RRP RRP Patient Registry: RRP Patient Registry is IRB reviewed, HIPAA/ GDPR compliant, continual in tracking the patient history from diagnosis until death.
- RRP RRP Patient Registry is a registry where the patients enter their data on a continuous basis and are asked to consent for the various uses of the registry. You control your consent.
- Unlike other patient registries, you enter your data, you own your consent, and the registry is governed by Sanford CoRDs, the RRPF and RRPF Scientific Advisors.
- “A potential game changer” a prominent RRP clinician and researcher regarding the RRPF RRP Patient Registry
RRPF RRP PATIENT REGISTRY BUILD TEAM

- The RRPF Board
- The RRP Task Force, Dr. Craig Derkay
- Dr. Simon Best, Johns Hopkins
- Dr. Clint Allen, NIH
- Sanford CoRDs
Purpose of the RRPF RRP Patient Registry

- Longitudinal study of RRP patients from diagnosis to death
- Locate patients and treatment centers across the world
- Clinical trial recruitment
- Work to develop Centers of Excellence for RRP Care
- Evaluate patient-reported outcomes
- Collect natural history of disease
- Drug Development
- Improve clinical care and establish evidence based medical practices
- Determine true risk of RRP complications, such as pulmonary spread and associated outcomes
- IRB Review/HIPAA and GDPR Compliant allows for global access for research/drug development
What is an IRB Review?

Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in (to secure approval), or disapprove research. This group review serves an important role in the protection of the rights and welfare of human research subjects. FDA

The purpose of IRB review is to assure, both in advance and by periodic review, that appropriate steps are taken to protect the rights and welfare of humans participating as subjects in the research. To accomplish this purpose, IRBs use a group process to review research protocols and related materials (e.g., informed consent documents and investigator brochures) to ensure protection of the rights and welfare of human subjects of research. FDA
Researcher/Clinician Access Application

This is a portion of the application that is required of all requests from researchers/clinicians. The IRB review process protects your information, and helps guarantee any data is only released for purposes with value. HIPAA and GDPR compliance is maintained at all times.
What is GDPR Compliance?

- GDPR: Under the GDPR, data is classified as personal. It clarifies that **online identifiers** and **location data** are all personal and must be protected as such. It is defined in the GDPR under Personal Data and Unique Identifiers.

- Countries under GDPR Compliance Rules: Austria, Belgium, Bulgaria, Croatia, Republic of Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom

- Online Identifiers: The regulation defines “personal” data as “any information relating to an identified or identifiable natural person (data subject); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.”

- The RRPF RRP Patient Registry, as administered by Sanford CoRDs, requires patient consent to enroll in the registry, and will require patient consent for any request that would require release of personal identifiers.
What is HIPAA?

- Health Insurance Portability and Accountability Act of 1996 (HIPAA) is the law enacted to **protect your privacy**, allow access to your medical records and designate who can speak on your behalf. This law was written for the consumer not the provider or institution.

- You own your data

- You consent to the release of any personal identifier, anytime it is requested. If you deny consent, the information is only given with random assigned registry number.

- HIPAA protects those who are in the United States
Why this registry matters.

IRB Review means researchers are able to access and use this information in research, drug development, off-label drug use approval process.

IRB Review means this information is more easily published in scientific publications.

IRB Review means data collected is of value to the FDA and CDC.
Steps to Enroll in the RRPF RRP Registry

Visit:
https://research.sanfordhealth.org/rare-disease-registry

1. Select Enroll
2. Any future visits will select Participant Portal

- Sanford CoRDs is the host of the RRPF RRP Patient Registry. As one of the premier research facilities, they are the host of several rare disease organization patient registries. You, the patient or caregiver, will first answer questions that are asked of every enrollee for every registry hosted by Sanford CoRDs. Once that section is completed, the RRP Patient Registry specific section will open.

- You are able to return to finish the registry entry process if you have to exit out.

- You will create a login specific to you. Please write this down. Duplicate accounts for a patient are not allowed.

- Questions related to technical issues while in the registry are to be addressed to: 1 (877) 658-9192
Initial Registry Page Diagnosis Entry

- Recurrent Respiratory Papilloma/Papillomatosis
- Laryngeal Papillomatosis
- Glottal Papillomatosis
- Pulmonary Recurrent Respiratory Papillomatosis
- Tracheal Papillomatosis

Enter your diagnosis as named in your clinic.
Sanford CoRDs-How they work with us.

Coordination of Rare Diseases at Sanford (CoRDS)

- Based at Sanford Research, a nonprofit research institution, CoRDS is a centralized international patient registry for all rare diseases.
- We coordinate the advancement of research into 7,000 rare diseases. Here's how:
  - We work with patient advocacy groups, individuals and researchers.
  - We capture health information from individuals with a rare diagnosis, undiagnosed patients, unaffected carriers or at-risk patients.
  - We connect researchers and patients and notify our participants of emerging clinical trials.
  - We make the registry accessible. Participants can enroll for free and researchers can access it for free.
Home Page For Login Update/Return

Once you have created your login, anytime you have to update/finish initial entry, you will need to select “Participant Portal” from the CoRDs homepage. It will bring you to this page.

https://cordsconnect.sanfordresearch.org/BayaPES/pp/participantLogin#
After you have created your account login/password and entered the CoRDs portion of the registration, you will enter the RRPF RRP Patient Registry.
Remission

For the purpose of the RRP registry, and under the guidance of the RRP Task Force and leading researchers, remission is no visible disease in the past 18 months, and/or no procedure to remove disease.

<table>
<thead>
<tr>
<th>Question</th>
<th>Choices</th>
</tr>
</thead>
<tbody>
<tr>
<td>19. If the participant is currently in remission (no procedure or visible disease in the past 18 months), when was the approximate date of last papilloma removal? (mm/yyyy)</td>
<td>□ Yes □ No □ Don't know</td>
</tr>
<tr>
<td>20. If the participant is currently in remission (no procedure or visible disease in the past 18 months), when was the approximate date of last visual check? (mm/yyyy)</td>
<td>□ Yes □ No □ Don't know</td>
</tr>
<tr>
<td>21. If the participant is currently in remission (no procedure or visible disease in the past 18 months), what was the age at remission onset? ___________ years</td>
<td>□ Yes □ No □ Don't know</td>
</tr>
<tr>
<td>22. If the participant currently does not have active papilloma growth, was partial or complete remission associated with the onset of puberty?</td>
<td>□ Yes □ No □ Unknown □ N/A</td>
</tr>
</tbody>
</table>
Pulmonary RRP

For the purpose of the RRPF RRP Patient Registry, pulmonary RRP does include any disease under “distal spread.”

If you do not select any of the disease sites associated with pulmonary RRP, the Pulmonary section will not open up to you.

<table>
<thead>
<tr>
<th>Pulmonary Involvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>37. Has there been a diagnosis of distal spread of the RRP (trachea, bronchus, carina, lungs)?</td>
</tr>
<tr>
<td>□ Yes □ No □ Don’t know</td>
</tr>
<tr>
<td>If papillomas extend to the trachea, bronchus, carina or lungs please answer questions 38-39.</td>
</tr>
<tr>
<td>38. Are papillomas in the bronchial tubes?</td>
</tr>
<tr>
<td>□ Yes □ No □ Don’t know</td>
</tr>
<tr>
<td>39. Are papillomas in the lung tissue?</td>
</tr>
<tr>
<td>□ Yes □ No □ Don’t know</td>
</tr>
<tr>
<td>40. Indicate which lobes, if any, where the pulmonary papilloma is located:</td>
</tr>
<tr>
<td>□ Right Upper □ Left Middle</td>
</tr>
<tr>
<td>□ Right Middle □ Left Lower</td>
</tr>
<tr>
<td>□ Right Lower □ Don’t know</td>
</tr>
<tr>
<td>□ Left Upper</td>
</tr>
<tr>
<td>41. How was pulmonary involvement diagnosed? (select all that apply):</td>
</tr>
</tbody>
</table>
Surgical History/In-Office History

- The section on surgical history, and/or in-office procedure history asks for you to enter as much data as you can for your disease history. Once you cannot remember, you are instructed to stop entering dates. Each date will be completed before entering the next date.
- **ENTER MOST CURRENT PROCEDURE FIRST**
- Q59-Q67 for each procedure date.
- **SURGICAL HISTORY INCLUDES IN-OFFICE PROCEDURES**
68. Has the participant used adjuvant therapy (outside of the OR room), to include pharmaceutical and/or supplements?

- [ ] Yes
- [ ] No

69. If the participant has used, or is using, and adjuvant therapy, please indicate which therapies and dosage information if known, start/end dates, improvement in disease (Y/N). If still receiving treatment/therapy, do not select an end date.

<table>
<thead>
<tr>
<th>Adjuvant Therapy</th>
<th>Dosage/Frequency</th>
<th>Start Date (DD/MM/YEAR)</th>
<th>End Date (DD/MM/YEAR)</th>
<th>Improvement</th>
</tr>
</thead>
<tbody>
<tr>
<td>DIM</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indole-3-Carbin (I3C)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Interferon</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cidofovir</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Artemisinin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MMR</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Gardasil Vaccine</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avastin (by injection during procedure)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Avastin (Via IV)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

70. If the participant answered yes to Avastin (via IV) above, verify the treatment was via IV (Systemic). Please enter all dates for Avastin infusions (working from most current to first dose, returning to add new dates as infusions occur). (If No, skip to question 80).

- [ ] Yes
- [ ] No

71. Name of hospital where administered:

72. Name of Medical Oncologist:
What Is Required In Updates?

- Your login that you created at the time of initial registration.
- Lost or unable to remember login? Contact Registry Host:
  1 (877) 658-9192
- Once you have completed the initial registry registration, you will only need to update dates of new procedures/treatments/diagnosis/outcomes.
RRPF RRP PATIENT REGISTRY HELP

If you are in the RRPF RRP Patient Registry, and you have questions regarding how to answer a particular question or section, or you have questions regarding how/when to update, you can reach out to any of the RRPF Board listed below:

Bill Stern: bills@rrpf.org
Marcelle Stiff: marcelles@rrpf.org
Kim McClellan: kimmc@rrpf.org

You will be contacted yearly by the Registry Host to update your account. You can update surgery dates, treatments, infusions at any time. The RRPF will reach out periodically as well. You are also welcome to share the registration link with any RRP Patient or Caregiver or Clinician. Only one registration account per patient, and the registry platform will prevent dual registrations.