

## Data Request Form

A primary goal of the FOP Registry is to provide medical and demographic data to interested researchers. Please refer to our Fee Schedule in Table 1 and then complete the FOP Registry Data Request Form below and remit to [info@fopregistry.org](mailto:info@fopregistry.org). After we receive your request, we will contact you with any follow up questions and an estimated date of completion.

### Contact Information

<b>Name of Requester:</b>	
<b>Institution:</b>	
<b>Phone No.:</b>	
<b>Email Address:</b>	

### Purpose of Request

- ☐ General FOP information / education  
☐ Support clinical research / study design  
☐ Publication (meeting abstract, manuscript, etc.)\*  
 Please provide the name of the Meeting/Congress or intended Journal: \_\_\_\_\_  
☐ Other: \_\_\_\_\_

\*The FOP Registry team will provide aggregate data and tables for analysis. Data requests for aggregate Registry data to support a publication must follow the FOP Registry Publication Guidelines which includes sharing draft abstracts and manuscripts with the Registry Publication Committee. Publications including Clementia-Ipsen's Natural History Study will require review by the NHS Publications Committee.

The requestor agrees to only use this data for the purposes outlined in this request form. Furthermore, the requestor agrees to not share the data with third parties, other than to publish the data, without written approval from the IFOPA.  
NOTE: Physicians are free to publish data on patients from their institutions at any time.

**Date of Request:**

**Date the Data Request Report is Needed\*\*:**

\*\*Please allow at least four (4) weeks for delivery.

**Requestor E-signature:**

## Data Request Form

*Please provide as much information as you can about your request to guide statistical analysis\*\*\*.*

<b>Research question/ Hypothesis:</b>	
<b>Registry data elements</b> (See Table 2)	
<b>Patient cohort(s)</b> (e.g. identified by age, gender, FOP clinical symptoms, etc.)	
<b>Other information</b>	

\*\*\*Depending on requestor's institution/organization and the amount of time required to complete the request, the IFOPA may need to charge a fee to support the statistical analysis. See Table 1 for the fee schedule. Additional data requests not included on this form will result in additional fees.

**Table 1**  
**Fee Schedule**

	< 2 hours IFOPA personnel time	2-8 Hours IFOPA personnel time	≥ 8 hours IFOPA personnel time
<b>Medical Advisory Board Member</b>	No Charge	No Charge	Rate of \$60/hour
<b>Hospital / Academic / Non-Profit Institution</b>	No Charge	Rate of \$60/hour	Rate of \$150/hour
<b>Pharmaceutical/ For Profit Organization*</b>	No Charge	Rate of \$300/hour	Rate of \$500/hour

\*Pharmaceutical organizations sponsoring the FOP Registry with financial support are exempt from the above fees. Data requests for Medical Advisory Board publications are exempt from the above fees.

## Data Request Form

**Table 2**  
**FOP Registry Patient Portal**  
**Summary of Data Elements**

Domain	Demographics and Diagnosis	Medical Care	FOP Signs	Quality of Life Surveys	Withdrawal
<b>Enrollment (Baseline)</b>	Race FOP type Date of first FOP symptoms Date of FOP diagnosis Diagnosis method (tests) MD specialty – first FOP symptoms MD specialty – all diagnosis attempts Incorrect Diagnosis (Y/N) • Type MD specialty – correct diagnosis Use website or on-line info?	Number of MD visits for physical health – past 12 months Number of MD visits for emotional health – past 12 months Number of hospital admissions – past 12 months • Reason(s) for hospital admission Number of dental care visits – past 12 months • Reason(s) for dental care Past clinical trial subject? • Y/N Donate bio-specimen?	Flare-up Event <ul style="list-style-type: none"> <li>• Location</li> <li>• Description of symptoms</li> <li>• Start date</li> <li>• End date</li> <li>• Outcome</li> </ul> Extra Bone Growth <ul style="list-style-type: none"> <li>• Location</li> <li>• Mobility status</li> <li>• Preceded by injury, etc.? (Y/N)</li> <li>• Preceded by flare-up? (Y/N)</li> </ul> No history of HO, but locked joint <ul style="list-style-type: none"> <li>• Y/N</li> <li>• Location</li> </ul>	FOP-PFQ Global Health Scale Aids, Assistive Devices, Adaptations	Date of withdrawal Reason for withdrawal If deceased: <ul style="list-style-type: none"> <li>• Date of death</li> <li>• Cause of death</li> </ul> Lost to follow-up

## Data Request Form

Domain	Demographics and Diagnosis	Medical Care	FOP Signs	Quality of Life Surveys	Withdrawal
	<ul style="list-style-type: none"> <li>Y/N</li> </ul> Family members with FOP? <ul style="list-style-type: none"> <li>Y/N</li> </ul>	<ul style="list-style-type: none"> <li>Y/N</li> <li>Type of bio-specimen</li> </ul>	FOP symptoms <ul style="list-style-type: none"> <li>Date of first symptoms</li> <li>Brains and nerves</li> <li>Ears</li> <li>Skin</li> <li>Stomach and digestion</li> <li>Lungs and breathing</li> <li>Heart, arteries, and veins</li> <li>Kidneys and urinary system</li> <li>Glands and hormones</li> <li>Sleep</li> </ul>		
<b>Follow-Up (Every 6 months)</b>		Number of MD visits for physical health – since last report  Number of MD visits for emotional health – since last report  Number of hospital admissions – since last report	Flare-up Event <ul style="list-style-type: none"> <li>Location</li> <li>Description of symptoms</li> <li>Start date</li> <li>End date</li> <li>Outcome</li> </ul> Extra Bone Growth <ul style="list-style-type: none"> <li>Location</li> <li>Mobility status</li> </ul>	FOP-PFQ  Global Health Scale  Aids, Assistive Devices, Adaptations	

## Data Request Form

Domain	Demographics and Diagnosis	Medical Care	FOP Signs	Quality of Life Surveys	Withdrawal
		<ul style="list-style-type: none"> <li>Reason(s) for hospital admission</li> </ul> <p>Number of dental care visits – since last report</p> <ul style="list-style-type: none"> <li>Reason(s) for dental care</li> </ul> <p>Past clinical trial subject since last report?</p> <ul style="list-style-type: none"> <li>Y/N</li> </ul> <p>Donate bio-specimen since last report?</p> <ul style="list-style-type: none"> <li>Y/N</li> <li>Type of bio-specimen</li> </ul>	<ul style="list-style-type: none"> <li>Preceded by injury, etc.? (Y/N)</li> <li>Preceded by flare-up? (Y/N)</li> </ul> <p>No history of HO, but locked joint</p> <ul style="list-style-type: none"> <li>Y/N</li> <li>Location</li> </ul> <p>FOP symptoms</p> <ul style="list-style-type: none"> <li>New or continuing</li> <li>If new, start date</li> <li>Brains and nerves</li> <li>Ears</li> <li>Skin</li> <li>Stomach and digestion</li> <li>Lungs and breathing</li> <li>Heart, arteries, and veins</li> <li>Kidneys and urinary system</li> <li>Glands and hormones</li> <li>Sleep</li> </ul>		

## Data Request Form

**Table 3.A**  
**FOP Registry Patient Portal**  
**Natural History Study**  
**Summary of Data Elements**  
**Screening visit**

Domain	Demographics	Features Diagnosis and Family History	Prior and Concomitant Medications	Quality of Life Surveys	ECG Test Details	FOP Medical History
<b>Screening</b>	Date of Birth Age Sex	Age at first Flare-Up Location of first Flare-Up FOP Diagnosis date Diagnosis made by Clinical Symptoms: Y/N Diagnosis made by Genotyping: Y/N Diagnosis made by imaging: Y/N <ul style="list-style-type: none"> <li>Radiographs</li> <li>CT Scans</li> <li>MRI</li> <li>Dexa Scans</li> <li>Other</li> </ul> Performed biopsies: Y/N Any misdiagnoses before proper diagnoses: Y/N <ul style="list-style-type: none"> <li>Juvenile Fibromatosis</li> </ul>	Medications Medication response Start Date Stop Date	FOP-PFQ Global Health Scale Aids, Assistive Devices, Adaptations Joint Involvement Scale	Date Time ECG Test/Name Position of Subject Result or finding in original units Character result/finding in std format	Body Region Medical condition/event Event Present Severity Scale

## Data Request Form

		<ul style="list-style-type: none"> <li>• Lymphedema</li> <li>• Soft Tissue Sarcoma</li> <li>• Other</li> </ul> <p>Family history of FOP</p> <ul style="list-style-type: none"> <li>• Inherited from</li> <li>• Other Family Members with FOP symptoms</li> <li>• Family member diagnosed by genotyping</li> <li>• Family member diagnosed by biopsy</li> </ul>				
--	--	----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--	--	--	--

### Screening Visit Data Elements Continued

Domain	Physical Exam	Pulmonary Function Test	Previous Flare Ups	Reproductive Female	Surgical Procedures	Vital Signs
<b>Screening</b>	Body System Result of PE Abnormalities	Date Test Name Result	Flare Ups in last 12 months Ever had Flare-Up Location of Last Flare-Up Start/Stop Date of Flare Ups Flare Up Ongoing	Menses: Y/N Date of first menses Ever Pregnant: Y/N Pregnancies Number of live births Complications during pregnancy:	Date of procedure Location Type of procedure Type of anesthesia Required endotracheal intubation: Y/N Complications	Date Test: Height Weight Blood Pressure Heart Rate Oral Temperature Respiration Rate

## Data Request Form

			Flare-Up Symptoms Flare-Up resulted in Bone Formation Flare-up resulted in restricted movement	<ul style="list-style-type: none"> <li>• Flare-Ups</li> <li>• Breathing difficulties</li> <li>• Phlebitis</li> <li>• Other</li> <li>• Complications for child born</li> </ul>	Experienced Flare-Ups: Y/N Experience loss of any movement: Y/N Experience flare-up at distal location: Y/N Flare up resulted in bone formation at location distal from surgery: Y/N	
--	--	--	------------------------------------------------------------------------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	--



**Table 3.B**  
**FOP Registry Patient Portal**  
**Natural History Study**  
**Summary of Data Elements**  
**Follow-Up Visits**

Domain	Clinical Event	Current Flare Up Patient Reported	Prior and Concomitant Medications	12-lead ECG	Quality of Life Surveys
<b>Month 12, 24, 36</b>	Category <ul style="list-style-type: none"> <li>• Ear</li> <li>• Cardiopulmonary</li> <li>• Endocrine/Metabolic</li> <li>• Gastrointestinal</li> <li>• Genitourinary/Reproductive</li> <li>• Musculoskeletal</li> <li>• Neurologic</li> <li>• Psychiatric</li> </ul> Medical Condition/Event Event Present	Date of Flare-Up onset  Location of Flare-up  Flare-up symptoms <ul style="list-style-type: none"> <li>• Swelling</li> <li>• Pain</li> <li>• Redness</li> <li>• Warmth</li> <li>• Stiffness</li> <li>• Decreased range of motion</li> <li>• Fever</li> <li>• Lethargy</li> <li>• Loss of appetite</li> <li>• Change in mood or behavior</li> <li>• Other</li> </ul>	Medications  Medication response  Start Date  Stop Date	Date of Assessment  Time of Assessment  Overall Interpretation <ul style="list-style-type: none"> <li>• Abnormal, not clinically significant</li> <li>• Normal</li> </ul> ECG Test/Name  Position of Subject  Result or finding in original units	FOP-PFQ  Global Health Scale  Aids, Assistive Devices, Adaptations  Joint Involvement Scale

## Data Request Form

### Follow Up Visit Data Elements Continued

Domain	Laboratory Assessment	Pulmonary Function Test	Vital Signs
<b>Month 12, 24, 36</b>	Date of collection Blood/Urine Lab/Examination name Result or finding Reference range	Date Test Name Result	Date Test: Height Weight Blood Pressure Heart Rate Oral Temperature Respiration Rate