

OHF Registry Proposals

Applicants can submit more than one application during a cycle.

Application

An application for the OHF Registry Initiative must include:

- 1) **Award Project Period:** Maximum 2 Years - If the grant is completed within 1 year, additional funds may be available on a competitive basis for registry maintenance to sites that achieve predefined benchmarks (i.e. patient enrollment targets). Include a detailed budget justification for specific elements included.
- 2) **Award Budget** - The total costs (direct and indirect) for a project awarded will not exceed \$60,000 for the entire project period. A maximum of 10% of overall budget can be allotted for indirect costs.
- 3) **Page Limitation** – Maximum of 10 Pages total, not including resources
- 4) **Applicant Biosketch** – (click on Biosketch link to download)
- 5) **Research Project Plan** – Must be single spaced
 - a. **Specific Aims** (1 Page Maximum) -Describe the specific aims of the registry-based project.
 - b. **Background and Preliminary Data** (3 Page Maximum) - Describe your experience in the research area of the hyperoxalurias, including access to patient cohorts and previous research. Include any additional background or data as needed to support a proposed clinical study.
 - c. **Research Strategy** (5 Page Maximum)
 - i. Describe the research section in enough detail so the scientific merit can be judged on the basis of the written proposal. Begin with a short section that clearly states how that project responds to the OHF Registry RFA.
 - ii. Applicants are required to submit registry-based research projects that can characterize and more completely define the genetic hyperoxalurias and the course/consequences of these conditions. Data supporting the patient enrollment numbers is recommended. The study design and objectives should take into consideration what information regarding this rare disease population would be needed in order to pursue clinical trials in PH.
 - iii. Describe in detail how patients will be recruited; how the database will be built and maintained; how data will be obtained from patients and entered into the data-base; describe the security of the database and how it will be maintained; describe how the identity of the participants will be protected. Describe the proposed research question.

- iv. Describe in detail the governance structure of the database: Who will have access to the data? What processes will exist for access to the data? How will publications and authorship be adjudicated? **NOTE: The proposal should include a list of core data elements that will be available for collaborative outcome studies coordinated by the OHF.**
- v. A plan must include provisions for rigorous data management and quality assurance. These monitoring activities are distinct from the requirement for study review and approval by an Institutional Review Board (IRB).

6) Other

- a. **Resource Sharing Plan** (1/2 Page Maximum) - All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.
- b. **Human Subjects Protections** (1/2 Page Maximum) - Provide a general description of a monitoring plan to establish the overall framework for data and safety monitoring.

7) References

Document Formatting

Additionally, the proposal must follow NIH guidelines including the following formatting guidelines:

- Use Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of at least 11-points. A Symbol font may be used to insert special characters.
- Type density, including characters and spaces, must be no more than 15 characters per inch. Type may be no more than six lines per inch. Use standard paper size (8 1/2" x 11). Use at least one-half inch margins (top, bottom, left, and right) for all pages. No information should appear in the margins.

Submitting Your Application

Applications will be accepted in Microsoft Word or PDF formats only. Completed applications should be sent to grantapp@ohf.org. File name should be in the following format: Date of Submission (Month, Day, Year), Last Name, First Name, and Proposal Number.

For example: 06302015 Hollander, Kim Registry Proposal 1
07312015 Hollander, Kim Registry Proposal 2

Notification of Award

Applicants will receive a notification email from the Oxalosis & Hyperoxaluria Foundation within 3 months of applying.

Contact

Please contact the Oxalosis and Hyperoxaluria Foundation with any questions at grantapp@ohf.org.