

## **Generating Advancements in Longitudinal Analysis in X & Y variations (GALAXY) Registry Data Request and Use Policy**

### **OVERVIEW**

This document provides guidance for requesting data from the GALAXY Registry. The goal is to establish an international, multicenter, prospective, longitudinal clinical data registry to improve clinical outcomes in individuals with X&Y chromosome variations, including but not limited to, Klinefelter syndrome (XXY), Double Y (XYY/Jacob's syndrome), Trisomy X (XXX) and XXYY syndrome.

### **GALAXY DATA SYSTEM**

GALAXY data include all registry, questionnaire, and biobank data for individuals with an X&Y chromosome variation participating in GALAXY. Registry data include demographic information, diagnostic information, medications, vital sign parameters, laboratory values, and select patient reported data. Data are entered into a secure online application, Research Electronic Data Capture (REDCap), housed at the University of Colorado. Contact GALAXY@ucdenver.edu for specific data elements.

### **NATURE OF DATA PROVIDED**

Requests for a subset of de-identified data (for which the applicant wishes to do their own analysis) or summary statistics should be expected to be fulfilled in a timely fashion. Requests for more complex analyses will be considered, but timely fulfillment may not be possible depending on available resources. Requests for data containing personally identifying information will not be fulfilled.

For studies proposing using GALAXY to contact and recruit participants, the proposed process to contact potentially eligible individuals must be made through the GALAXY coordinating center.

### **DATA REQUESTS**

#### *Requests for Data Access from Non-GALAXY Registry Member Investigators/Individuals*

Requests for GALAXY Registry data access from non-member investigators and/or individuals will not be considered without written verification of sponsorship by an investigator who is a member of the GALAXY consortium. It is expected that the sponsor will work closely with the investigators and/or individuals for use of data to ensure they remain within the goals of the GALAXY Registry.

#### *Submitting a Request*

Investigators may submit data requests using the template attached. Requests should be no longer than 3 pages.

### *Approval of Requests*

Data use requests will be reviewed by the Steering Committee within one month of submission. The committee will consider the applicability and priority of the study question, the ability of the study team to appropriately use the data, the workload and feasibility for the GALAXY study team, and the impact of this study on the X & Y chromosome variation community. Priority for requests will be given to teams actively contributing data to the registry. If you plan to publish or present results, you will be expected to follow the GALAXY Publication Policy.

A request may be approved, invited to resubmit, or rejected. If you are invited to resubmit, the committee will provide specific feedback or requests for additional information on the project.

## TEMPLATE FOR PROPOSAL FOR DATA USE

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#### A. Requestor Information

Requestor name: \_\_\_\_\_

Project team lead: \_\_\_\_\_

Requestor's contact information (include institution, mailing address, email address, phone #):  
\_\_\_\_\_

GALAXY Sponsor (if requestor is not part of the GALAXY consortium): \_\_\_\_\_

Is this request associated with a funded project or grant proposal:  Yes  No

If yes, provide the name of the project/proposal and details on the funding source(s) and grant number(s) if applicable: \_\_\_\_\_

Main purpose of this request (check one):

- Analysis of data for peer-reviewed publication
- Analysis of data for presentation
- Recruitment of individuals/families into a new research project
- Summary statistics for use in proposal or report
- Other (please specify):

If for presentation or publication, requester must agree to the publication policy.

#### B. Specific Aims

*State the goal(s) of the proposed project and hypotheses/research questions you aim to answer using GALAXY data.*

#### C. Background and significance

*Describe the impact of the proposed project for patients with X&Y variations. Identify gaps in the literature and how this project will fill them. Describe how the proposed project focuses on questions that affect outcomes of interest to patients/families.*

#### D. Study design and analytic plan

*Describe the methodologic/statistical approach including a conceptual model or theory that anchors the background/significance of the project and informs the study design.*

##### D.1 Variables

*Describe the key variables and relationships being tested, including a list of variables needed from the registry.*

Dependent Variables: *List the variables that are the main outcomes of interest and state which items in the GALAXY data dictionary will provide information on these outcomes. Include form name and item number.*

Independent Variables and Covariates: *List all other variables that are necessary for the analysis, including demographic information. Include form name and item number and format of data if applicable.*

## **D.2 Statistical Analysis**

*Describe a priori plans for data analysis that correspond to the project's aims. Provide the sample size and power, if applicable. If using a sub-set of registry participants, list inclusion and exclusion criteria.*

## **E. Community engagement**

*Describe the plan to engage patients and stakeholders meaningfully in the project. Describe what stakeholders will be engaged, at what stages of the project they will be engaged, and what level of engagement they will have. If you have multiple stakeholder groups involved, describe the role of each in the project.*

*Every project should have some level of community engagement. If you need assistance putting this into action or generating ideas, the GALAXY Steering Committee can help.*

## **F. Dissemination**

*Describe how you will make project findings available to: the GALAXY Steering Committee, GALAXY registry participants and their families, patients with X&Y chromosome variations and their families broadly, and clinicians working with X&Y chromosome variation patients. All results will be posted on the GALAXY website.*

## **G. Project team**

*Describe the team's capacity to accomplish the goals set forth in this project, including each team member's expertise in relation to the proposed project. Include proposed authors for any publication or presentation is to come from this request.*

## **H. Timeline**

*Describe the timeline for completion of your project.*

## **I. References**

*List the source material cited in this proposal using an accepted and consistent citation style.*