**eMERGE Network Proposal for Analysis**

Project/Manuscript Concept Sheet

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| **Submission Date** | 10/10/2019 |
| **Project Title** | **Participants perceived clinical and personal utility of receiving positive genomic results in eMERGE III** |
| **Tentative Lead Investigator (first author)** | Ingrid Holm |
| **Tentative Senior Author (last author)** | TBD |
| **All other authors**  | Melanie Myers (CCHMC), John Connolly (CHOP), Margaret Harr (CHOP), Heather Hain (CHOP), Melissa Heller (CHOP), Julia Wynn (Columbia), Hila Milo Rasouly (Columbia), Alanna Rahm (Geisinger), Janet Williams (Geisinger), Kurt Christensen (Harvard), David Veenstra (KPW/UW), Richard Sharp (Mayo), Sharon Aufox (NW), Christin Hoell (NW), Maureen Smith (NW), Ellen Clayton (Vanderbilt), Brittany City (Vanderbilt – CC)Members of the ROR-ELSI Participant Survey subgroup |
| **Sites Involved** | All eMERGE III clinical sites |
| **Background / Significance** | Most eMERGE III sites conducted baseline participant surveys, and all sites conducted post-disclosure surveys of participants receiving positive genomic results to understand the impact of return of genomic information to participants. The Participant survey subgroup has harmonized survey questions across sites to allow for comparing how the impact differs among participants across a variety of health care settings and prior clinical conditions. Responses are being collected locally in REDCap, and the responses to the questions common to all sites will be downloaded into a REDCap database at the CC.One of the major questions is the clinical and personal utility of receiving positive on participants. Do participants find results useful? Do they adhere to HCP recommendations? Do they make changes in response to the results? |
| **Outline of Project** | We will analyze data from participants with positive results on the 6-12 month post-disclosure participant surveys at all sites. Participant’s perceived clinical and personal utility of positive results will be assessed using the following outcomes:* If the HCP makes a recommendation, does the participant adhere to the recommendation/s (referral to specialist, testing, procedures)?
* Do participants make lifestyle changes in response to results (e.g., healthier diet, sleep, stop smoking)
* Do participants make life changes in response to results (e.g., change job, move, buy insurance, etc.)

Analyses will be conducted to determine if clinical or personal utility (above) is associated with the following predictors:* Perceived usefulness of result
* Psychological impact (FACToR-12)
* Result related to indication for sequencing or unrelated to known conditions
* Participants who already knew of their result before they were disclosed (from Outcomes form)
* Decisional regret
* Privacy/confidentiality concerns (HINTS)
* Sharing with family members
* Gender
* Age
* Condition
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| **Desired****Variables (essential for analysis****indicated by \*)** | All participant survey questions common to all sites Race, ethnicity, age, other demographic variables, diagnoses |
| **Desired data** | Answers to the survey questions. |
| **Planned Statistical Analyses** | TBD to address the hypotheses |
| **Ethical considerations** | This survey assesses the risks and benefits of return of uncertain genomic information to participants. |
| **Target Journal** | TBD |
| **Milestones\*\*** | 1. Formulate data analysis plan – 10/2019
2. Data collection completed at all sites – 10/2019
3. Data analysis completed – 1/2020
4. Draft manuscript – 3/2020
5. Finalize manuscript – 4/2020
6. Submission to journal – 5/2020
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**\*\*** This section should include: Timeline for completion of project, including approval, project duration, first and second draft of the paper and submission.