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| **eMERGE Network: Manuscript Concept Sheet** | | |
| **Reference Number**  *(to be assigned by CC)* | NT332 | |
| **Submission Date** | January 27, 2019 | |
| **Project Title** | Network-wide lessons learned from the reporting of negative test results | |
| **Tentative Lead Investigator** *(first author)* | Richard Sharp, Mayo Clinic  Maureen Smith, Northwestern | |
| **Tentative Senior Author**  *(last author)* | Richard Sharp, Mayo Clinic  Maureen Smith, Northwestern | |
| **All Other Authors** | Wendy Chung, Columbia  Michelle Meyer, Cincinnati Children’s Hospital  Ingrid A. Holm, Boston Children’s Hospital  Others TBD | |
| **Sites Participating** | Invite representatives from all of the eMERGE sites that are reporting negative results:   * Cincinnati Children’s Hospital * Kaiser Permanente/University of Washington * Marshfield * Mayo Clinic * Vanderbilt * Meharry * Northwestern | |
| **Background / Significance** | Although the Outcomes Workgroup and each of the eMERGE sites have invested considerable energy into assessing best practices for reporting clinically actionable test results, less attention has been given to the methods that support patient understanding of a negative genomic test report. This study will draw on experiences across the eMERGE network, with the goal of creating a “lessons learned” paper that highlights the array of reporting methods employed, the challenges encountered in the reporting of negative test results, and makes recommendations for future research in this area. | |
| **Outline of Project** | 1. Establish a workgroup comprised of representatives from each eMERGE site that is reporting negative genomic test results.  2. Gather materials related to the reporting of negative test results, including letters sent to participants, FAQ documents, and other educational support tools.  3. Gather additional information re the process adopted at each site, focusing on challenges encountered, questions received from participants and clinical colleagues, strategies that might be improved in future initiatives, and self-assessments of the process used at each site.  4. Convene regular conference calls to synthesize these data into a network-wide statement on lessons learned regarding the reporting of negative test results.  5. Additional efforts may focus on the assessment of provider experiences counseling patients about negative test results, in partnership with ongoing studies of provider views regarding the impact of genomic test results (Holm R01 grant). | |
| **Desired Data - Common Variables\***  *(Available from the CC)* | Demographics  ICD9/10 codes  CPT codes  Phecodes  BMI | Common Variable Labs  Common Variable Meds  Other: Case/Control status on Phase I and Phase II phenotypes |
| **Other Desired Data *(Available from participating sites)*** | *Please specifically list out any data elements that participating sites would collect or extract from clinical or other sources for this project (i.e. not common variables above)*  None | |
| **Desired Genetic Data** | eMERGE I-III Merged set (HRC imputed, GWAS)  eMERGE PGx/PGRNseq data set  eMERGEseq data set (Phase III)  eMERGE Whole Genome sequencing data set  eMERGE Exome chip data set  eMERGE Whole Exome sequencing data set  Other (not listed above):  NONE | |
| **Does project pertain to an existing eMERGE Phenotype?** | Yes, if so please list  X No | |
| **Planned Statistical Analyses** | None, the project will be descriptive of practices across eMERGE sites. | |
| **Ethical Considerations** | None | |
| **Target Journal** | Genetics in Medicine; Journal of Medical Genetics; or similar. | |
| **Milestones**  *(This section should include the key dates for completion of project, including approval, project duration, draft completion, and submission.)* | Data collection phases of the project to be completed by April 30.  Manuscript submission to be completed by June 30, 2019. | |

**\*Common Variables available across all datasets:**

* Demographics: sex, year of birth, decade of birth, race, ethnicity
* Codes: (repeated values & age at event): ICD, CPT, Phecodes
* BMI: (repeated value & age at event) height, weight, BMI
* Labs: (lab name, repeated lab value & age at event) Serum total cholesterol, LDL, HDL, Triglycerides, Glucose fasting/non-fasting/unknown, & White Blood Cell count
* Medications: (medication name, repeated, & age at event) Cerivastatin sodium, Rosuvastatin, Simvastatin, Fluvastatin, Pravastatin, Lovastatin, Atorvastatin, & Pitavastatin
* Other: Case/Control status on Phase I and Phase II phenotype: only on GWAS dataset participants