

**Implementing Genomics In Practice (IGNITE) Pharmacogenetics Interest Group
Collaborative Agreement
April 3, 2015**

Background

A number of institutions (the “pharmacogenetics interest group”) have implemented pharmacogenetic testing into clinical practice. Some of these groups are funded through the Implementing Genomics In Practice (IGNITE) Network, and the remainder are IGNITE network affiliates. There is an interest among these groups in working together to collect and share data relevant to pharmacogenetics implementation. This creates an opportunity to combine data in order to create a sample of sufficient size to identify important outcomes or metrics from pharmacogenetic testing or prescription trends relevant to pharmacogenomics. IGNITE Network scientists are interested in data dissemination, and so embark upon this collaboration in data aggregation with the assumption that de-identified aggregated data will be deposited into an IGNITE database for use in future publications.

Collaborative Agreement

1. IGNITE Pharmacogenetics interest group “member” will be defined as an institution or group of investigators within an institution participating in the effort. This AGREEMENT can be signed by one designate of the institution. They will indicate other participating members from their institution, and will ensure that all participants from their institution abide by the principles set forth in this AGREEMENT.
2. It is expected that there will be two types of groups who join this IGNITE Interest Group. First are those who have implemented pharmacogenetic testing for the topic of interest and have data to contribute to the collaboration. These members will have full access to the compiled aggregate data, and will be authors on resulting papers. The other type of member will be those who are in the process of implementing and wish to learn from the experiences of others, and may in the future have data to contribute to later efforts. These members will be able to fully participate in conference calls and discussions but will not have access to the data if they do not contribute data, and will not be expected to be authors on resulting papers where they did not contribute data. Exceptions may be made for individuals who bring specific expertise to the analysis of the data.
3. In order to be a member of the pharmacogenetic interest group, a group must agree to share data on outcomes, metrics, or prescribing trends related to pharmacogenetic testing. If they do not currently have data available, they will agree to share such data when they become available, and if a relevant project is in progress.
4. The IGNITE Network will allocate resources to accept the member’s relevant data, and curate the data using standards for phenotype files.

5. Pharmacogenetics interest group members will designate points of contact for IGNITE Network staff to work with on each individual data set. These contacts should be very familiar with the details of the data sets, or have easy access to those who do.
6. IGNITE Network staff will put the data into standard phenotype data templates, and will work with each member to carefully document the details and meaning of each measurement. This is a critical activity for resolving subtle differences in the data sets. The result will be a phenotype file suitable for submission to a preview site (i.e., site for member access to data prior to publication).
7. The phenotype and genotype submissions will remain on a preview site until publication of the data. Genotypes and phenotypes will be linked, and all display functionality of the IGNITE network will be available for the data. Only pharmacogenetics interest group members who have submitted data will have access to the complete data set and agree to use these data only as a basis for conversation with the originators. Pharmacogenetics interest group members with access to the data agree that viewing these data is associated with responsibility for not publishing or disclosing it without approval of the pharmacogenetics interest group members.
8. Pharmacogenetics interest group members are free to write papers based on their own data before, during, and after the activities association with this agreement and interest group.
9. Pharmacogenetics interest group members may not write papers based on the data of others, except with explicit permission of those who collected the data. Members may suggest a manuscript idea to the interest group that utilizes the compiled data and a decision will be made to move forward as a group.
10. Investigators with specialized expertise in analyzing the data, but who have not contributed data, can only enter the pharmacogenetics interest group as registered collaborators with one of the data-submission groups (or the IGNITE Network). These collaborators must agree to terms of this AGREEMENT and be considered a member of whichever consortium site sponsors them.
11. Access to the pharmacogenetics interest group data sets and draft publications is limited to pharmacogenetics interest group members that have contributed data, registered collaborators, and members of the IGNITE Network team (members of the IGNITE curation and science staff who also agree to the AGREEMENT). Those with major contributions to the respective cohorts will be expected to have lead roles in resulting manuscripts, and will have major roles (if they desire) in the analysis approach that is undertaken. Authors of pharmacogenetics interest group publications will include all data contributors, data analysts, data curators, and writing group members who have participated in the pharmacogenetics interest group. Authors may be listed on the byline of the published paper or within appendices, as dictated by both contribution and the journal publishing the paper. It is expected that at least one author from each member group will be represented on the byline of the published paper as allowed by the publishing journal. The general rule for authorship order will be lead authors at the beginning and end, usually by level of contribution, and all other co-authors will be listed alphabetically in the middle. It is anticipated that there will be one designated leader of a specific project and the ultimate decision

about author order at the beginning and end will reside with him/her, after consultation with these leading authors.

12. With publication and release of the data on the public site, the IGNITE Network and the pharmacogenetics interest group will engage in appropriate dissemination, announcements, and emphasis of the availability of this exciting data set to the community.

13. Data to be posted to public databases will require an investigator outside of the IGNITE pharmacogenetics interest group to apply for access to the individual level data. The members of the pharmacogenetics interest group contributing data will establish the rules for accessing the individual level data by an outside investigator. If other data aggregation efforts arise from the pharmacogenetics interest group, the pharmacogenetics interest group members will similarly work to define the rules for access to those data. These data will be made available to other investigators after the publication of the relevant data.

Name _____

Affiliation _____

Signature line _____

Date _____