translational research

**PRACTICAL GUIDELINES FOR ETHICAL AND POLICY ISSUES THAT ARISE FROM THE CLINICAL APPLICATION OF WHOLE GENOME SEQUENCING IN CANCER PATIENTS**

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**Aim:** Our group utilizes whole genome sequencing (WGS) to identify candidate driver pathways to guide personalized treatment decisions in oncology. There is debate as to whether research grade genomic results should be provided to subjects and if so, what process should be used. We developed a working model based on respect for autonomy, non-maleficence, beneficence and justice. This model aims to address the challenges associated with reporting individual research results (IRR), incidental findings (IF) and access to raw, research grade genomic data.

**Methods:** We created an ethics sub-committee, comprised of a bioethicist, a genetic counselor, bioinformaticians, genomic pathologists, and medical oncologists to review existing recommendations and guidelines on reporting WGS results.

**Results:** The key element of this model is informed consent. 1) In the consent forms, the subjects are given the choice to be informed or not of both IRR and IF. 2) In case of IF, only clinically actionable genetic variants will be reported after validation by clinically approved testing and referred to genetic counseling. 3) Requests for release of the research grade raw data generated by WGS will be reviewed on a case by case basis. The data released will consist of raw base calls and not contain custom analysis or biological inferences. The reliability and validity of the data will be communicated to the participants prior to data release. 4) Subjects will be informed that due to the personalized nature of genomic information, it is not possible to guarantee anonymity of the data. 5) The project will only be responsible for reporting IFs for the duration of the research project. 6) If the data are shared with other research organizations and IFs are identified, these researchers would not be responsible for communicating these data back to the subject or their physician. 7) Disclosure of IRR or IF to deceased subjects’ relatives should follow the same working model developed for this program.

**Conclusions:** WGS provides a wealth of research information, some of which can impact treatment decision-making. It is certain that IF and difficult questions regarding access to research grade data will arise in any study involving genome sequencing. We created an ethical guideline to ensure that the information is used and reported in an appropriate and responsible manner.

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