Return of Results Researcher Questionnaire (FORGE and CPCGC)
Code number (for reminder purposes) _____

This is a voluntary, confidential questionnaire to explore the attitudes of researchers to the return of INDIVIDUAL research results to participants in cancer genomics research.

THIS SURVEY TAKES ABOUT 30 MINUTES TO COMPLETE.

For the purposes of this questionnaire, we are seeking your thoughts and experience related to genomic variation or sequencing studies, using Genome Wide Association studies, SNP analysis, whole-genome sequencing, and other genomic techniques. We are NOT seeking information on returning results from gene therapy studies or clinical exams. Please only complete the survey once.

Definitions

Incidental results: Findings that are not the primary objective of the study (for example finding mutations in the cystic fibrosis gene in a genome wide study of breast cancer patients).

Core condition results: Findings directly related to the primary objective (for example finding of mutations in a leukemia gene in a genome wide study of leukemia patients).

Right: That which is just, morally good, legal, proper or fitting.

Analytic validity: how accurately/reliably the result describes the finding of interest

Clinical utility: results that can be acted upon to intervene in the health of the participant

Validated results: results that have both analytic validity and clinical utility

I. INFORMATION/ OPINION QUESTIONS

1. Genomic researchers have a responsibility to examine the genomic data set they create beyond the core condition under study for findings that would have health/clinical relevance to the individual research subject? (Please circle only one answer)

a. Strongly Agree
b. Agree
c. Disagree
d. Strongly Disagree

2. Genomic researchers, in general, have a responsibility to communicate findings of an incidental result of potential clinical significance for AN INDIVIDUAL (e.g., communicate finding to relevant authority or oversight committee or to a clinician)? (Please circle only one answer)

a. Strongly Agree
b. Agree
c. Disagree
d. Strongly Disagree

3. What right do you feel a participant has to get analytically validated results of genetic research regarding the core condition under study? (Please circle only one answer)

a. Participants have a right to get results in almost all circumstances
b. Participants have a right to get results in the majority of circumstances
c. Participants have a right to get results in a minority of circumstances
d. Participants have no right to get results.

4. **What right do you feel a participant has to get analytically validated results of genetic research that uncovers potentially clinically relevant incidental findings unrelated to the core condition under study? (Please circle only one answer)**

a. Participants have a right to get results in almost all circumstances
b. Participants have a right to get results in the majority of circumstances
c. Participants have a right to get results in a minority of circumstances
d. Participants have no right to get results.

5. What participant sample should be used to test for analytic validity? (Please circle only one answer)**

a. The SAME sample
b. A SECOND sample

6. Which of the following must be done to confirm analytical validity prior to return of a result to a participant? (Please circle all that apply)

The sample is tested for analytic validity by:

a. The same lab that originally found the result, using the same technology
b. The same lab that originally found the result using an alternate technology
c. Another researcher's laboratory, using the same technology.
d. Another researcher's laboratory, using an alternate technology
e. A certified clinical laboratory, e.g., lab approved to conduct clinical tests for medical decision making
f. Other, please specify:
_____

7. Should research participants have access to any of the following? (Please circle all that apply)

a. Raw data, not interpreted (e.g., actual DNA sequence data or mRNA expression pattern)
b. Interpretation of raw data: presence or absence of a mutation or polymorphism (e.g., having a mutation in the BRCA1 gene or a CYP2D6*4 genotype)
c. Interpretation of raw data: association of the mutation or genotype with risk of disease development or response to therapy
d. Participants should not have access to any research results
e. Participants should have access to the conclusions of a study (for example, gene X causes disease Y)
f. Other_____,

8. What types of *individual genomic research results* do you feel should be offered to participants, if any? (Please circle all that apply)

a. A validated genomic result that has clinical utility for the individual research subject

b. A different diagnosis that is validated and obtained through the course of research (e.g., genomic results from a patient with lymphoblastic leukemia suggests instead myeloid leukemia)

c. A validated genomic research result obtained through the course of research that currently IS available as a clinical test (e.g. BRCA1 mutation identified during the course of gene sequencing in a breast cancer study)

d. A validated genomic research result obtained through the course of research that currently IS NOT available as a clinical test (e.g., a new polymorphism associated with response to chemotherapy)

e. A validated genomic research result obtained through the course of research, but not related to the aims of the research study (e.g. BRCA1 mutation identified during the course of research on diabetes)

f. I do not think any genomic research results should be offered to participants

g. Other, please specify:
_____

9. What threshold measure should be used to determine if analytically valid incidental findings of genomic research should be offered to participants? (Please circle all that apply)

a. The results should be offered based on exceeding a minimum absolute risk (for example more than >50% with the incidental genetic finding will develop the condition will develop breast cancer if the BRC1 gene is found)
b. The results should be offered based on exceeding a minimum relative risk (for example an incidental genetic finding gives a RR of >3 for a condition to develop).
c. The results should be offered based on the severity of the condition predicted by the incidental genetic finding (for example the finding confers a condition with a high risk of death)
d. Incidental findings should not be offered.
e. Results should be offered only if they are variants that meet a list of genes to be disclosed determined prior to the study commencing
f. Other (please specify) _____

10. What do you believe are the best ways to deal with analytically valid genomic results that may have uncertain impacts upon participants? (Please circle only one answer)

a. The researcher should decide whether or not to give back the results
b. The researcher and the participant should decide together.
c. All results should be returned to participants, even if the meaning is uncertain.
d. An independent committee made up of members of the public and scientists should decide if the results should be offered to research participants.
e. The researcher should return results to the consulting physician/medical geneticist for them to decide
f. Other _____

11. Should a participant be able to challenge a decision by a researcher or independent committee not to give genetic results back to participants? (Please circle only one answer)

a. Yes
b. No

12. Should formal genetic counselling be offered prior <u>to a sample being taken</u> to do genetic research? (Please circle only one answer)

a. Almost always
b. Frequently
c. Infrequently
d. Almost never

13. Should formal genetic counselling be offered prior <u>to research results being returned</u> to participants or their families? (Please circle only one answer)

a. Almost always
b. Frequently
c. Infrequently
d. Almost never

14. Consider a situation in which a participant in a research study was discovered to have a gene that causes a serious condition (either the core condition under study or an incidental finding). As a result, a sibling is at risk for the same condition. (Please check one box per row).

	Very Strong rights	Strong rights	Few rights	No right
a. What rights do you think the sibling has to be informed about the risk that they might carry a gene that causes a serious condition ***that has NO effective treatment or prevention***?				
b. What right do you think the sibling has to be informed about the risk that they might carry a gene that causes a serious condition ***that has effective treatment or prevention***?				

15. Sometimes a child or adult with a genetic condition dies before the results of the genetic research testing is available. Consider the situation in which the consent form does not address what should happen in the event of the death of the participant. What do you feel should happen with this research information? (Please circle all that apply)

a. The research results should not be given to any member of the family
b. The research results should be offered to the parents or next of kin
c. The research results should be offered to the brothers or sisters, if they are old enough to understand the results
d. The research results should be published in the medical literature only.
e. Other_____

16. a. Tissues samples from a child may be stored for many years after consent. What should be done if the patient is now over 18 years of age but cannot be found to confirm consent for continuing storage and research? (Please circle all that apply)

a. The tissue should be destroyed
b. The tissue should not be used for new research purposes
c. The tissue should be used for original research purposes
d. The tissue should be used for whatever research purpose it may be needed
e. The parents should be contacted, if possible, to ask their wishes.
f. Other, please describe:_____

16. b. Genetic data/information from a child may be stored for many years after consent. What should be done if the patient is now over 18 years of age but cannot be found to confirm consent for continuing usage? (Please circle all that apply)

a. The genetic data should be destroyed
b. The genetic data should not be used for new research purposes
c. The genetic data should be used for original research purposes
d. The genetic data should be used for whatever research purpose it may be needed
e. The parents should be contacted, if possible, to ask their wishes.
f. Other, please describe: _____

II. EXPERIENCE QUESTIONS

17. In conducting genomic research have you ever found some health or clinical information that you felt might be important for the research subject to know? (Please circle only one answer)

a. Yes
b. No (If no, please skip to question 20).

18. If yes, how often has this happened?
(Please circle only one answer)

a. 1-2 times
b. 3-5 times
c. Greater than 5 times

19. How often were the findings unrelated or incidental to the aims or scope of your study?
(Please circle only one answer)

a. Almost always
b. Frequently
c. Infrequently
d. Almost never

20. How often has an individual research result from one of your genomic studies been returned to a clinician or research subject? (Please circle only one answer)

a. Not sure
b. Never happened
c. 1-2 times
d. 3-5 times
e. Greater than 5 times

III. INSTITUTIONAL PRACTICES

21. Does your research ethics board require researchers to offer to return individual genetic research results to participants? (Please circle only one answer)

a. Never
b. Sometimes
c. Always
d. I don't know

22 Does your research ethics board recommend a process of how to return individual genomic research results to participants? (Please circle only one answer)

a. Yes
b. No
c. I don't know
d. Our policy is not to return any individual results from research studies

23. At your institution, who is involved in making the decision to return or not return individual research results? (Please circle all that apply):

a. Genomic Researcher
b. Research ethics committee
c. Treating physician
d. Genetic counsellor
e. Other relevant experts (e.g., clinical or research experts)
f. Patient or research subject
g. Patient representative/advocate
h. Don't know
i. Other, please specify: _____

24. How are individual genomic results returned at your institution? (Please circle all that apply)

a. Researcher contacts the research subject
b. Researcher contacts the treating physician
c. Ethics committee contacts the research subject
d. Ethics committee contacts the treating physician
e. A clinical professional (e.g., genetic counsellor) contacts the research subject
f. The treating physician contacts the research subject
g. Don't know
h. Individual genomic results are not returned
i. Other, please describe: _____

25. For what length of time should a researcher be responsible for the return of individual genomic research results? (Please circle all that apply)

a. The length of the project period
b. Until manuscript publication
c. Ten years
d. The length of time the database is available for use or access
e. Indefinitely
f. Don't know
g. Other, please specify: _____

26. Please consider the scenario in which children who participated in genomic research are now adults capable of fully informed consent. What responsibility, if any, do you feel that researchers have to ensure that genomic results with potential clinical utility are eventually offered to these participants? (Please circle only one answer)

a. Full responsibility
b. Shared responsibility (with parents)
c. Shared responsibility (with physician)
d. No responsibility
e. Other, please specify_____

IV. RESPONDENT DEMOGRAPHICS

27. With which consortium are you affiliated? (Please circle only one answer)

a. FORGE
b. CPCGC
c. Both

28. Please describe your role(s) in the research process (Please circle all that apply):

a. Genomic researcher
b. Clinician, non geneticist
c. Medical geneticist
d. Other, please specify: _____

29. How many years have you been in practice: (Please circle only one answer)

a. less than 1 year
b. 1 to 5 years
c. 6 to 10 years
d. 11 to -20 years
e. more than 20 years

30. How comfortable are you in discussing the results of genetic research with research participants? (Please circle only one answer)

a. Very comfortable
b. Comfortable
c. Uncomfortable
d. Very Uncomfortable

31. What is your age in years? (Please circle only one answer)

a. 21-40
b. 41-55
c. older than 55

32. In which country did you receive your most senior training? (Please circle only one answer)

a. Canada
b. USA
c. Europe
d. Indo-Asia
e. Other, please specify: _____

Please add any additional comments that you would wish to make here.

Some of these questions were derived in part and with permission from the Return of Results Survey that was developed by Lynn Dressler and the Ethics and Policy Working Group of the International Cancer Genome Consortium.

Returning genetic research results to research participants – CPCGC/FORGE Researcher questionnaire

This page will be detached from the questionnaire to maintain your confidentiality.

If you would like to receive a copy of the results of this study please indicate here:

- o No, I don't need a copy.

- o Yes, I would like a copy. Send the results to (name and address):

_____
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