INDUSTRY I-PWG PHARMACOGENOMICS WORKING GROUP

Industry Pharmacogenomics Working Group (I-PWG) IRB/EC/REB

Survey regarding Return of Genomic Research Results

21 March 2021

General Questions

The I-PWG is conducting a global survey of Ethics Committees (ECs) – *also referred to as Independent Review Boards (IRBs), Independent Ethics Committees (IECs,) Ethical Review Boards (ERBs), and Research Ethics Boards (REBs)* – charged with the review and approval of research involving human subjects in accordance with applicable regulatory and other human research protection standards. Your responses to this survey will help the I-PWG evaluate global trends in this area and the ongoing debate regarding whether or not to return genomic research results. (The survey will take approximately 20 minutes to complete.)

* 1. Please enter your unique individual survey code that was provided to you.

* 2. What is your role within your organization? (select all that apply)

- [ ] IRB/EC/REB Chair
- [ ] Institutional Official
- [ ] Research Compliance Officer
- [ ] Human Research Protection Program (HRPP) Director
- [ ] General Counsel or other Office of General Counsel Attorney
- [ ] Faculty member
- [ ] Other (please specify)

* 3. What degrees do you hold? (select all that apply)

- [ ] Bachelor's degree
- [ ] Medical Degree (MD, DO, DDS, DVM, etc.)
- [ ] PhD or other doctorate degree
- [ ] Master's degree
- [ ] Law degree (LLB or JD)
- [ ] Other (please specify)

* 4. What is your area of expertise? (select all that apply)

- [ ] Law
- [ ] Ethics
- [ ] Medicine
- [ ] Nursing
- [ ] Other (please specify)
- [ ] Genetics
- [ ] Public Health
- [ ] Social Sciences
- [ ] Liberal Arts
- [ ] Regulatory Affairs
- [ ] Research Compliance

* 5. What type of organization do you work for or are you affiliated with? (select all that apply)

- [ ] Hospital
- [ ] University
- [ ] Health System
- [ ] Other (please specify)
- [ ] Independent Commercial IRB/EC/REB
- [ ] Independent Nonprofit IRB/EC/REB
- [ ] National IRB/EC/REB
- [ ] Regional IRB/EC/REB

* 6. In what country is your organization located? (select all that apply)

- [ ] Afghanistan
- [ ] Albania
- [ ] Algeria
- [ ] Andorra
- [ ] Angola
- [ ] Antigua and Barbuda
- [ ] Argentina
- [ ] Armenia
- [ ] Australia
- [ ] Austria
- [ ] Azerbaijan
- [ ] Bahamas
- [ ] Bahrain
- [ ] Ghana
- [ ] Greece
- [ ] Grenada
- [ ] Guatemala
- [ ] Guinea
- [ ] Guinea Bissau
- [ ] Guyana
- [ ] Haiti
- [ ] Holy See
- [ ] Honduras
- [ ] Hungary
- [ ] Iceland
- [ ] India
- [ ] Panama
- [ ] Papua New Guinea
- [ ] Paraguay
- [ ] Peru
- [ ] Philippines
- [ ] Poland
- [ ] Portugal
- [ ] Qatar
- [ ] Republic of Korea
- [ ] Republic of Moldova
- [ ] Romania
- [ ] Russian Federation
- [ ] Rwanda

- [ ] Bangladesh
- [ ] Barbados
- [ ] Belarus
- [ ] Belgium
- [ ] Belize
- [ ] Benin
- [ ] Bhutan
- [ ] Bolivia (Plurinational State of)
- [ ] Bosnia and Herzegovina
- [ ] Botswana
- [ ] Brazil
- [ ] Brunei Darussalam
- [ ] Bulgaria
- [ ] Burkina Faso
- [ ] Burundi
- [ ] Cabo Verde
- [ ] Cambodia
- [ ] Cameroon
- [ ] Canada
- [ ] Central African Republic
- [ ] Chad
- [ ] Chile
- [ ] China
- [ ] Colombia
- [ ] Comoros
- [ ] Congo
- [ ] Costa Rica
- [ ] Côte D'Ivoire
- [ ] Croatia
- [ ] Cuba
- [ ] Cyprus
- [ ] Czech Republic
- [ ] Democratic People's Republic of Korea
- [ ] Democratic Republic of the Congo
- [ ] Indonesia
- [ ] Iran (Islamic Republic of)
- [ ] Iraq
- [ ] Ireland
- [ ] Israel
- [ ] Italy
- [ ] Jamaica
- [ ] Japan
- [ ] Jordan
- [ ] Kazakhstan
- [ ] Kenya
- [ ] Kiribati
- [ ] Kuwait
- [ ] Kyrgyzstan
- [ ] Lao People’s Democratic Republic
- [ ] Latvia
- [ ] Lebanon
- [ ] Lesotho
- [ ] Liberia
- [ ] Libya
- [ ] Liechtenstein
- [ ] Lithuania
- [ ] Luxembourg
- [ ] Madagascar
- [ ] Malawi
- [ ] Malaysia
- [ ] Maldives
- [ ] Mali
- [ ] Malta
- [ ] Marshall Islands
- [ ] Mauritania
- [ ] Mauritius
- [ ] Mexico
- [ ] Micronesia (Federated States of)
- [ ] Monaco
- [ ] Saint Kitts and Nevis
- [ ] Saint Lucia
- [ ] Saint Vincent and the Grenadines
- [ ] Samoa
- [ ] San Marino
- [ ] Sao Tome and Principe
- [ ] Saudi Arabia
- [ ] Senegal
- [ ] Serbia
- [ ] Seychelles
- [ ] Sierra Leone
- [ ] Singapore
- [ ] Slovakia
- [ ] Slovenia
- [ ] Solomon Islands
- [ ] Somalia
- [ ] South Africa
- [ ] South Sudan
- [ ] Spain
- [ ] Sri Lanka
- [ ] State of Palestine
- [ ] Sudan
- [ ] Suriname
- [ ] Swaziland
- [ ] Sweden
- [ ] Switzerland
- [ ] Syrian Arab Republic
- [ ] Tajikistan
- [ ] Thailand
- [ ] The former Yugoslav Republic of Macedonia
- [ ] Timor-Leste
- [ ] Togo
- [ ] Tonga
- [ ] Trinidad and Tobago

- [ ] Denmark
- [ ] Djibouti
- [ ] Dominica
- [ ] Dominican Republic
- [ ] Ecuador
- [ ] Egypt
- [ ] El Salvador
- [ ] Equatorial Guinea
- [ ] Eritrea
- [ ] Estonia
- [ ] Ethiopia
- [ ] Fiji
- [ ] Finland
- [ ] France
- [ ] Gabon
- [ ] Gambia
- [ ] Georgia
- [ ] Germany
- [ ] Mongolia
- [ ] Montenegro
- [ ] Morocco
- [ ] Mozambique
- [ ] Myanmar
- [ ] Namibia
- [ ] Nauru
- [ ] Nepal
- [ ] Netherlands
- [ ] New Zealand
- [ ] Nicaragua
- [ ] Niger
- [ ] Nigeria
- [ ] Norway
- [ ] Oman
- [ ] Pakistan
- [ ] Palau
- [ ] Tunisia
- [ ] Turkey
- [ ] Turkmenistan
- [ ] Tuvalu
- [ ] Uganda
- [ ] Ukraine
- [ ] United Arab Emirates
- [ ] United Kingdom of Great Britain and Northern Ireland
- [ ] United Republic of Tanzania
- [ ] United States of America
- [ ] Uruguay
- [ ] Uzbekistan
- [ ] Vanuatu
- [ ] Venezuela (Bolivarian Republic of)
- [ ] Vietnam
- [ ] Yemen
- [ ] Zambia
- [ ] Zimbabwe

* 7. Does your IRB/EC/REB have an agreed upon position regarding the return of genomic research results?

- ( ) Yes
- ( ) No

Comment

* 8. If your IRB/EC/REB does not have an agreed upon position regarding the return of genomic research results, please indicate why. (select all that apply)

- [ ] We have not considered this issue
- [ ] Our experience is too limited to develop a standard position
- [ ] We are waiting to see how regulations evolve in this area
- [ ] N/A - Our IRB/EC/REB has an agreed upon position
- [ ] We handle these issues on a case-by-case basis
- [ ] Other (please specify)

* 9. If your IRB/EC/REB has an agreed upon position, how recently did your IRB/EC/REB determine its position regarding the return of genomic research results?

- ◯ Less than 3 Months ago
- ◯ 3 - 6 months ago
- ◯ Greater than 6 months ago
- ◯ N/A - Our IRB/EC/REB does not have an agreed upon position

Comment

10. Does your IRB/EC/REB allow for the return of individual genomic research results?

- ◯ Yes, it generally allows for the return of results
- ◯ Yes, it generally supports returning results but only in limited circumstances
- ◯ No, our IRB/EC/REB does not allow the return of results under any circumstances

Comment

* 11. Does your IRB/EC/REB plan to change its current position regarding the return of individual genomic research results?

- ○ Yes, we currently do not allow the return of results but we plan to transition to allowing this to occur
- ○ Yes, we currently allow the return of results and we plan to transition to allowing the return of significantly more results than we currently do
- ○ Yes, we currently allow the return of results but we plan to transition to allowing the return of significantly fewer results than we currently do
- ○ Other (please specify)
- ○ Yes, we currently allow the return of results but we plan to transition to not allowing the return of results
- ○ No, we do not plan to change our policy regarding the return of results
- ○ N/A - My IRB/EC/REB has no agreed upon policy regarding the return of results, but plans to develop one
- ○ N/A - My IRB/EC/REB has no agreed upon policy regarding the return of results and does not plan to develop one

* 12. If your IRB/EC/REB allows for the return of individual genomic research results, why did your IRB/EC/REB make that decision? (select all that apply)

- ☐ To be responsive to study participants' desire to receive their results
- ☐ To allow the results to be incorporated into the management of the study participant's health
- ☐ Other (please specify)
- ☐ To fulfill study participants' right to receive data generated from their biological samples
- ☐ To fulfill legal or regulatory obligations to return the results
- ☐ N/A - My IRB/EC/REB does not support the return of individual genomic research results

* 13. If your IRB/EC/REB does not allow for the return of individual genomic research results in some or all cases, why did the IRB/EC/REB make that decision? (select all that apply)

- [ ] Providing results would compromise the integrity of the clinical trial
- [ ] Most study participants are not interested in receiving them
- [ ] Some results are not interpretable at the individual level
- [ ] Some results are not useful for clinical decision-making
- [ ] There is not an industry standard to return results
- [ ] Liability concerns
- [ ] Results are not generated in a CLIA-certified (or equivalent) laboratory setting
- [ ] Logistical hurdles
- [ ] Resource limitations
- [ ] Site investigators are not comfortable conveying results to study participants
- [ ] To avoid promoting therapeutic misconception (study participants may conflate the purpose of research with that of clinical care)
- [ ] N/A - My IRB/EC/REB allows for the return of individual genomic research results
- [ ] Other (please specify)

* 14. Which parties influenced your IRB/EC/REB's decision regarding whether or not to return individual genomic research results? (select all that apply)

- [ ] Study sponsor
- [ ] Site investigator
- [ ] Institutional leadership
- [ ] IRB/EC/REB members
- [ ] Stakeholders such as patient advocacy groups
- [ ] 3rd party laboratory generating the result
- [ ] 3rd party genetic counselor not affiliated with the sponsor, analysis lab, or site investigator
- [ ] Information based on literature
- [ ] Industry/institutional practice
- [ ] Other (please specify)

* 15. Which of the following influenced your IRB/EC/REB's position regarding the return of individual genomic research results? (select all that apply)

- [ ] 2017 ICH-E18, which was also adopted by the U.S. Food and Drug Administration (FDA)
- [ ] U.S. Food and Drug (FDA) Regulations
- [ ] 2018 revised Common Rule (45 CFR 46, Subpart A - *U.S. Federal Policy for the Protection of Human Subjects*)
- [ ] 2018 Food and Drug Administration (FDA) guidance on the revised Common Rule
- [ ] 2018 European Union General Data Protection Regulation (GDPR)
- [ ] U.S. Centers for Medicare and Medicaid Services (CMS) Requirements
- [ ] Health Insurance Portability and Accountability Act (HIPAA)
- [ ] IRB/EC/REB Policy
- [ ] Organizational Policy
- [ ] None
- [ ] Other (please specify)

* 16. What factors does your IRB/EC/REB consider when making study specific decisions regarding whether to allow the return of individual genomic research results? (select all that apply)

- [ ] Whether the results are appropriate for clinical decision-making
- [ ] Whether the results are those that are the focus of the research being tested
- [ ] Other (please specify)
- [ ] Whether there are legal, regulatory, or other standards that require the return of individual results
- [ ] Whether the study participant initiated a request for the results
- [ ] N/A - My IRB/EC/REB does not support the return of individual genomic research results

* 17. If your IRB/EC/REB allows for the return of individual genomic research results, from what types of studies will your IRB/EC/REB allow results to be returned? (select all that apply)

- [ ] All types of research
- [ ] Rare diseases (https://rarediseases.info.nih.gov/diseases/pages/31/faqs-about-rare-diseases)
- [ ] Oncology
- [ ] N/A
- [ ] Other subset of diseases (please specify)

* 18. If your IRB/EC/REB allows for the return of individual genomic research results, is your position different for research involving adults versus pediatric?

- ( ) Yes
- ( ) No
- ( ) It depends on the nature of the study
- ( ) N/A
- ( ) Other (please specify)

* 19. If your IRB/EC/REB allows for the return of individual genomic research results, what types of information may be returned? (select all that apply)

- [ ] American College of Medical Genetics (ACMG) gene variants that are the focus of the test
- [ ] ACMG gene variants that are included in the assay but are not the focus of the test
- [ ] Selected non-ACMG variants that are the focus of the test
- [ ] Selected non-ACMG variants that are included in the assay but are not the focus of the test
- [ ] All genomic data generated as part of a given test
- [ ] N/A
- [ ] Other (please specify)

* 20. If your IRB/EC/REB allows for the return of individual genomic research results, what types of results may be returned to study participants? (select all that apply)

- [ ] Raw sequence or genotype data
- [ ] Predicted phenotype data
- [ ] Variant call files
- [ ] N/A
- [ ] Other (please specify)

* 21. If your IRB/EC/REB allows for the return of individual genomic research results, what types of labs may be used for studies in which individual genomic research results may be returned? (select all that apply)

- [ ] CLIA-certified Lab
- [ ] Only Lab results from FDA approved assays
- [ ] N/A
- [ ] Non-CLIA certified lab that is qualified/validated as an alternative to CLIA
- [ ] Only Lab results from investigational assays
- [ ] Research Only Lab
- [ ] All of the above
- [ ] Other (please specify)

* 22. If your IRB/EC/REB allows for the return of individual genomic research results, does your IRB/EC/REB require genetic counseling if individual genomic research results are returned to study participants?

- ( ) Yes, always
- ( ) Sometimes, but only in the case of ACMG variants
- ( ) Sometimes, and not just for ACMG variants
- ( ) Never
- ( ) N/A

Comment

* 23. Which of the following methods of genetic counseling does your IRB/EC/REB allow if individual genomic research results are returned? (select all that apply)

- [ ] Genetic counselor who is part of the clinical trial team at the research site
- [ ] 3rd party genetic counseling service outside the research institute
- [ ] N/A
- [ ] Genetic counselor at the research institute who is not a member of the clinical trial team
- [ ] Online genetic counseling tool
- [ ] Other (please specify)

* 24. If your IRB/EC/REB requires genetic counseling, does the IRB/EC/REB require the counseling to be paid for by the study?

- ( ) Yes
- ( ) No
- ( ) N/A

Comment

* 25. What process does your IRB/EC/REB allow for returning individual genomic research results? (select all that apply)

- [ ] Study sponsor → Site investigator → Study participant
- [ ] Study sponsor → Site investigator → Genetic counselor → Study participant
- [ ] Study sponsor → Site investigator → Study participant's Primary Care Provider → Study participant
- [ ] Study sponsor → Study participant
- [ ] Study sponsor → Genetic counselor → Study participant
- [ ] Study sponsor → Study participant's Primary Care Provider → Study participant
- [ ] 3rd party analysis lab → Site investigator → Study participant
- [ ] 3rd party analysis lab → Genetic counselor → Study participant
- [ ] 3rd party analysis lab → Study participant's Primary Care Provider → Study participant
- [ ] Study participant executes self-service access via a portal
- [ ] N/A
- [ ] Other (please specify)

* 26. Regardless of whether or not individual genomic research results will be returned, does your IRB/EC/REB require information regarding individual results return to be included in the study protocol?

- ( ) Yes, always
- ( ) Yes, sometimes
- ( ) No, never

Comment

* 27. Which of the following are required by the IRB/EC/REB in the study protocol if individual genomic research results will be returned? (select all that apply)

- [ ] Whether study participants will receive individual results of tests performed on their biological samples
- [ ] When return of results will occur in relation to the lifecycle of the study
- [ ] What information will be shared
- [ ] How the results will be communicated
- [ ] Under what circumstances will results be communicated
- [ ] What the risks and benefits of receiving the results are
- [ ] Whether the results will go to the study participant's primary care provider or into their medical record
- [ ] What support and/or services will be provided
- [ ] Whether there will be re-contact in the future (e.g. if new tests are performed after the study is over or if the interpretation of a previous test result changes)
- [ ] N/A - My IRB/EC/REB does not require any of the above in the protocol
- [ ] N/A - My IRB/EC/REB does not require information to be added in the protocol
- [ ] Other

* 28. Which of the following influenced your IRB/EC/REB's policy regarding discussing the return of individual genomic research results in the study protocol? (select all that apply)

- [ ] 2017 ICH-E18, which was also adopted by the U.S. Food and Drug Administration (FDA)
- [ ] U.S. Food and Drug (FDA) Regulations
- [ ] 2018 revised Common Rule (45 CFR 46, Subpart A - U.S. Federal Policy for the Protection of Human Subjects)
- [ ] 2018 Food and Drug Administration (FDA) guidance on the revised Common Rule
- [ ] 2018 European Union General Data Protection Regulation (GDPR)
- [ ] U.S. Centers for Medicare and Medicaid Services (CMS) Requirements
- [ ] Health Insurance Portability and Accountability Act (HIPAA)
- [ ] IRB/EC/REB Policy
- [ ] Organizational Policy
- [ ] None
- [ ] Other (please specify)

* 29. Regardless of whether or not individual genomic research results will be returned, does your IRB/EC/REB require information regarding individual results return to be included in the study consent form?

- ◯ Yes, always
- ◯ Yes, sometimes
- ◯ No, never

Comment

* 30. Which of the following are required by the IRB/EC/REB in the study consent form? (select all that apply)

- ☐ Whether study participants will receive individual results of tests performed on their biological samples
- ☐ When return of results will occur in relation to the lifecycle of the study
- ☐ What information will be shared
- ☐ How the results will be communicated
- ☐ Under what circumstances will results be communicated
- ☐ What the risks and benefits of receiving the results are
- ☐ Whether the results will go to the study participant's primary care provider or into their medical record
- ☐ What support and/or services will be provided
- ☐ Whether there will be re-contact in the future (e.g. if new tests are performed after the study is over or if the interpretation of a previous test result changes)
- ☐ N/A - My IRB/EC/REB does not require any of the above in the study consent form
- ☐ Other topics (please specify)

* 31. Which of the following influenced your IRB/EC/REB's policy regarding discussing the return of individual genomic research results in the study consent form? (select all that apply)

- [ ] 2017 ICH-E18, which was also adopted by FDA
- [ ] FDA Regulations
- [ ] 2018 revised Common Rule
- [ ] 2018 FDA guidance on revised Common Rule
- [ ] 2018 EU General Data Protection Regulation (GDPR)
- [ ] U.S. Centers for Medicare and Medicaid Services (CMS) Requirements
- [ ] Health Insurance Portability and Accountability Act (HIPAA)
- [ ] IRB/EC/REB Policy
- [ ] Organizational Policy
- [ ] None
- [ ] Other (please specify)

* 32. Has your IRB/EC/REB encountered challenges in complying with any laws, regulations, guidelines, or standards regarding returning individual genomic research results?

- ( ) Yes
- ( ) No
- ( ) N/A

Comment

* 33. If your IRB/EC/REB encountered challenges in complying with any laws, regulations, guidelines, or standards regarding returning individual genomic research results, please select those your IRB/EC/REB have had challenges with. (select all that apply)

- [ ] 2017 ICH-E18, which was also adopted by FDA
- [ ] FDA Regulations
- [ ] 2018 revised Common Rule
- [ ] 2018 FDA guidance on revised Common Rule
- [ ] 2018 EU General Data Protection Regulation (GDPR)
- [ ] U.S. Centers for Medicare and Medicaid Services (CMS) Requirements
- [ ] Health Insurance Portability and Accountability Act (HIPAA)
- [ ] No, we have not encountered any challenges with these regulations/guidances
- [ ] N/A
- [ ] Other (please specify)

* 34. If you selected any of the options referenced in **Question 33,** please provide further information to explain the challenge(s) in the space provided.

* 35. Which of the following has your IRB/EC/REB been effective in applying in order to be compliant with the return of genomic research results requirements? (select all that apply)

- [ ] 2017 ICH-E18, which was also adopted by FDA
- [ ] FDA Regulations
- [ ] 2018 revised Common Rule
- [ ] 2018 FDA guidance on revised Common Rule
- [ ] 2018 EU General Data Protection Regulation
- [ ] U.S. Centers for Medicare and Medicaid Services (CMS) Requirements
- [ ] Health Insurance Portability and Accountability Act (HIPAA)
- [ ] No, we have not taken measures to comply with any of these regulations/guidances in relation to returning individual genomic research results.
- [ ] N/A
- [ ] Other (please specify)

* 36. If you selected any of the options listed in **Question 35** please provide further information to explain your answer in the space provided.

37. If you have written policies, procedures, guidelines, etc. that your IRB/EC/REB follows regarding the return of genomic research results, and you are able to share them, please upload them below.

Please upload relevant documents here.

Choose File Choose File No file chosen

* 38. Do you have additional comments that you think would be useful to include in this survey? If YES, please include your comments in the space provided.

- ◯ Yes
- ◯ No

Comment