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Project Name:

Regulation of International Direct-to-Participant Genomic Research

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Project Summary

New techniques for genomic research are being developed to take advantage of the ability to contact research participants directly, without utilizing physicians, hospitals, or biobanks. Researchers are now able to use the internet to recruit and enroll research participants in genomic studies by using an online application and consent process. Participants send their health records electronically and ship a sample of blood or saliva to the researchers. Although this process has been approved by IRBs for domestic studies, it is unclear whether this process is lawful for international research because of the diverse laws and policies of the countries where the participants reside.

This research will study the important, but complex, question of whether international direct-to-participant genomic research is lawful in a sample of 32 countries. It will also consider what steps are necessary to facilitate this efficient, diversity-enhancing research while still protecting the welfare of research participants.

The project has the following three aims:

Aim 1: Convene three expert working groups of researchers and IRB leaders to identify and prioritize the key issues for a standard questionnaire and template to distribute to the study's 32 international experts on country-specific laws and research ethics.

Aim 2: Distribute the questionnaires to the international experts, consult with and advise them as they prepare their responses to the questionnaires and summaries of country-specific legal and ethical issues, compile and analyze the responses, and draft conclusions and policy options.

Aim 3: Distribute the draft conclusions and policy options to the three expert working groups, international consultants, and advisory board members, and obtain their feedback; analyze the responses and use them to prepare a final draft; write and publish articles presenting the findings of the study; and disseminate the results in presentations to various groups of stakeholders.

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