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IRB Issues and Translational Research

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Scholar Summary

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The function of an institutional review board (IRB) is to review, require modifications of, approve, or disapprove of research regarding the potential use of human subjects. An IRB will review informed consent processes, conduct continuing reviews of protocols, and maintain the authority to observe the given consent process and research. Furthermore, it is important to note that translational research is not a regulatory term, but rather a research term with varying definitions. One such definition from the NIH describes translational research as the "1) process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans, and 2) adoptions of best practices in the community". Notably, there are issues regarding human gene transfer, biospecimens, and genomics that are unique to translational-based research in the process of IRB review and approval. Specifically, the need to address/discuss topics including notification of new findings, commercial profit from specimens, return of specimens from biospecimen research, whether biospecimens will undergo whole-genome sequencing, and the need for additional review from the Institutional Biosafety Committee (IBC), Recombinant DNA Advisory Committee (RAC), or the Food and Drug Administration (FDA). In particular, special issues in gene transfer studies include the possibility of vector transmission, long-term follow up, requests for autopsies, and media coverage. Similarly, with regard to biospecimen repositories, common issues include approval of sample collection/distribution, informed consent of donor (how to explain, right to withdraw, future use/permissions, and risks/genetic issues). Indeed, because of these complex issues, protocols including repositories require significant advanced planning. Additionally, genomic considerations are dynamic and still evolving with the rapid pace of technology and availability of big data. Current issues include whether genomic data is considered protected health information (PHI) and specific risks regarding future insurability, employability, law enforcement access, stress/embarrassment, "group harm", return of results, and research beyond the initial description/consent. The NIH suggests that investigators should submit large-scale human genomic data to an NIH-designated data repository in a timely manner (i.e., GWAS, SNP arrays, sequencing, transcriptomes, etc.). Furthermore, institutions must certify that data submission meets laws, regulations, and institutional policies and must clearly delineate uses/exclusions dictated by participant consent. Conversely, the IRB must then verify that the data use is consistent with consent, that the de-identification plan meets NIH standards, and that the risks to individuals, families, and populations are sufficiently considered. These considerations include ensuring that genomic research is Clinical Laboratory Improvement Amendments (CLIA) certified and that there is a process for addressing incidental findings, variants of uncertain significance, and germline findings. In conclusion, translational research is similar to other forms of research from the perspective of the IRB, with the additions that the principal investigator may have further regulatory hurdles (such as the RAC, IBC, or FDA), that repositories require advanced planning, and that genomic-based research will likely force continued changes in these processes.