

ASHG Policy Luncheon: Genomics Research and the FDA

NHGRI: Raising Awareness Regarding FDA's Investigational Device Exemption

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NHGRI: Division of Policy, Communications, and Education (DPCE)

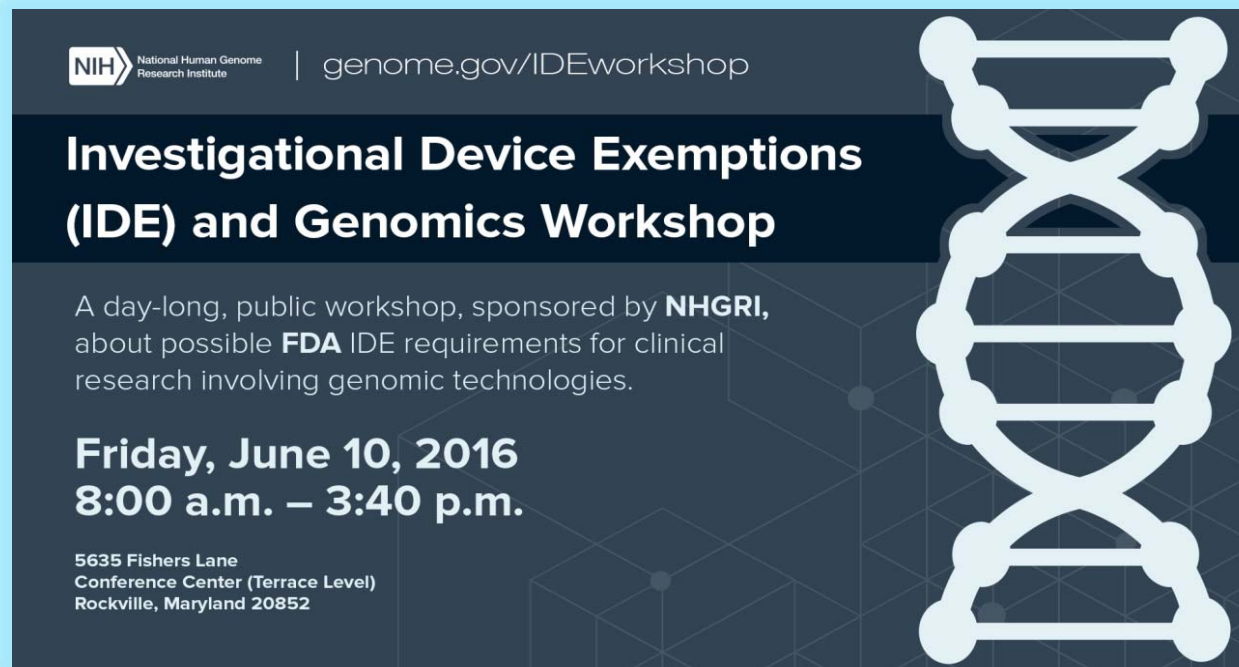


Our Mission

NHGRI Mission: NHGRI supports the development of resources and technology that will accelerate genome research and its application to human health.

DPCE Mission: To promote the integration and utilization of genomic knowledge to advance human health and society.

NHGRI IDE and Genomics Workshop



The poster features a dark blue background with a light blue DNA double helix graphic on the right side. The text is in white and light blue. At the top left is the NIH logo and the text 'National Human Genome Research Institute'. To the right of the logo is the URL 'genome.gov/IDEworkshop'. Below this is the main title 'Investigational Device Exemptions (IDE) and Genomics Workshop'. Underneath the title is a paragraph describing the workshop as a day-long public event sponsored by NHGRI, focusing on FDA IDE requirements for clinical research involving genomics. The date and time are listed as Friday, June 10, 2016, from 8:00 a.m. to 3:40 p.m. The address is 5635 Fishers Lane, Conference Center (Terrace Level), Rockville, Maryland 20852.

NIH National Human Genome Research Institute | genome.gov/IDEworkshop

Investigational Device Exemptions (IDE) and Genomics Workshop

A day-long, public workshop, sponsored by **NHGRI**, about possible **FDA** IDE requirements for clinical research involving genomic technologies.

Friday, June 10, 2016
8:00 a.m. – 3:40 p.m.

5635 Fishers Lane
Conference Center (Terrace Level)
Rockville, Maryland 20852

Meeting report and video available
at genome.gov

Points to Consider Regarding FDA's Investigational Device Exemption

The screenshot shows the NIH National Human Genome Research Institute website. At the top left is the NIH logo. To its right is the text 'National Human Genome Research Institute'. Further right is a search bar with the text 'Search Genome.gov' and a magnifying glass icon. Below the search bar are social media icons for Facebook, Twitter, and YouTube, and a link for 'Español'. A navigation menu below the header includes links for 'Research Funding', 'Research at NHGRI', 'Health', 'Education', 'Issues', 'Newsroom', 'Careers', and 'About'. The main content area is titled 'Regulation of Genetic Tests' and features the main heading: 'Points to Consider Regarding the Food and Drug Administration's Investigational Device Exemption Regulations in the Context of Genomics Research'. Below the heading, it says 'Updated: July 27, 2017'. A list of links includes: Overview, Does the IDE regulation apply to my study?, Does my study pose nonsignificant risk (NSR) or significant risk (SR) to participants?, What do I do if my study is a nonsignificant risk (NSR)?, What do I do if my study is a significant risk (SR)?, and Glossary. A disclaimer box at the bottom states: 'Disclaimer: The content of this resource is not intended to provide official guidance from the National Human Genome Research Institute (NHGRI) or from the Food and Drug Administration (FDA). This resource reflects information presented at NHGRI's "Investigational Device Exemptions (IDE) and Genomics Workshop," held in June 2016, and is also informed by the experience of NHGRI grantees complying with the Investigational Device Exemption regulation.'

Also available at genome.gov