Balancing issues from the patient/parent perspective

Challenges and Opportunities in Using Newborn Screening Samples for Translational Research
Institute of Medicine
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President & CEO, Genetic Alliance
Founding Executive Director, PXE International

Transforming Health Through Genetics

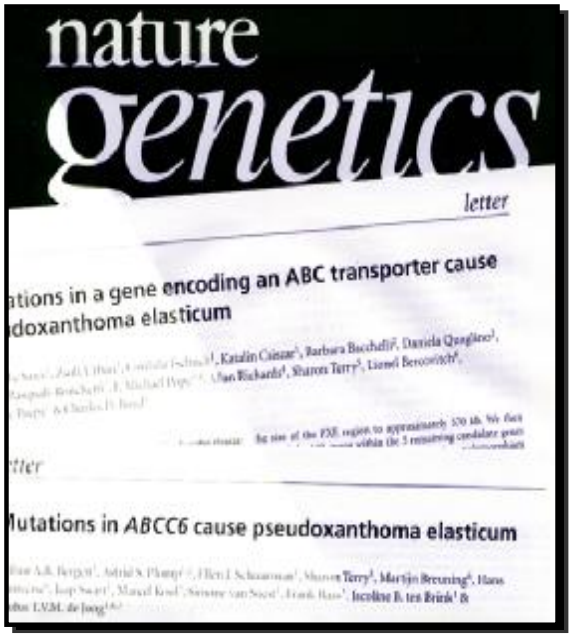
Network of 10,000 nonprofits, universities and companies

Openness is our product and process

Shared infrastructure to transform health is our goal

PXE INTERNATIONAL

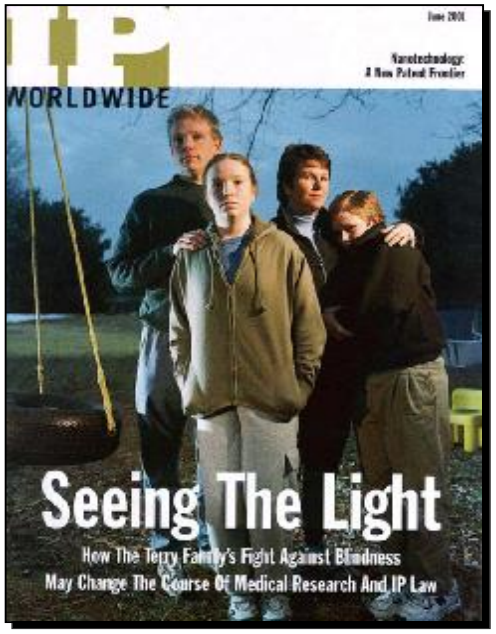
Gene Discovery



BioBank

Testing

Clinical Diagnostic Test Development via FDA & CLIA Regulatory Strategies



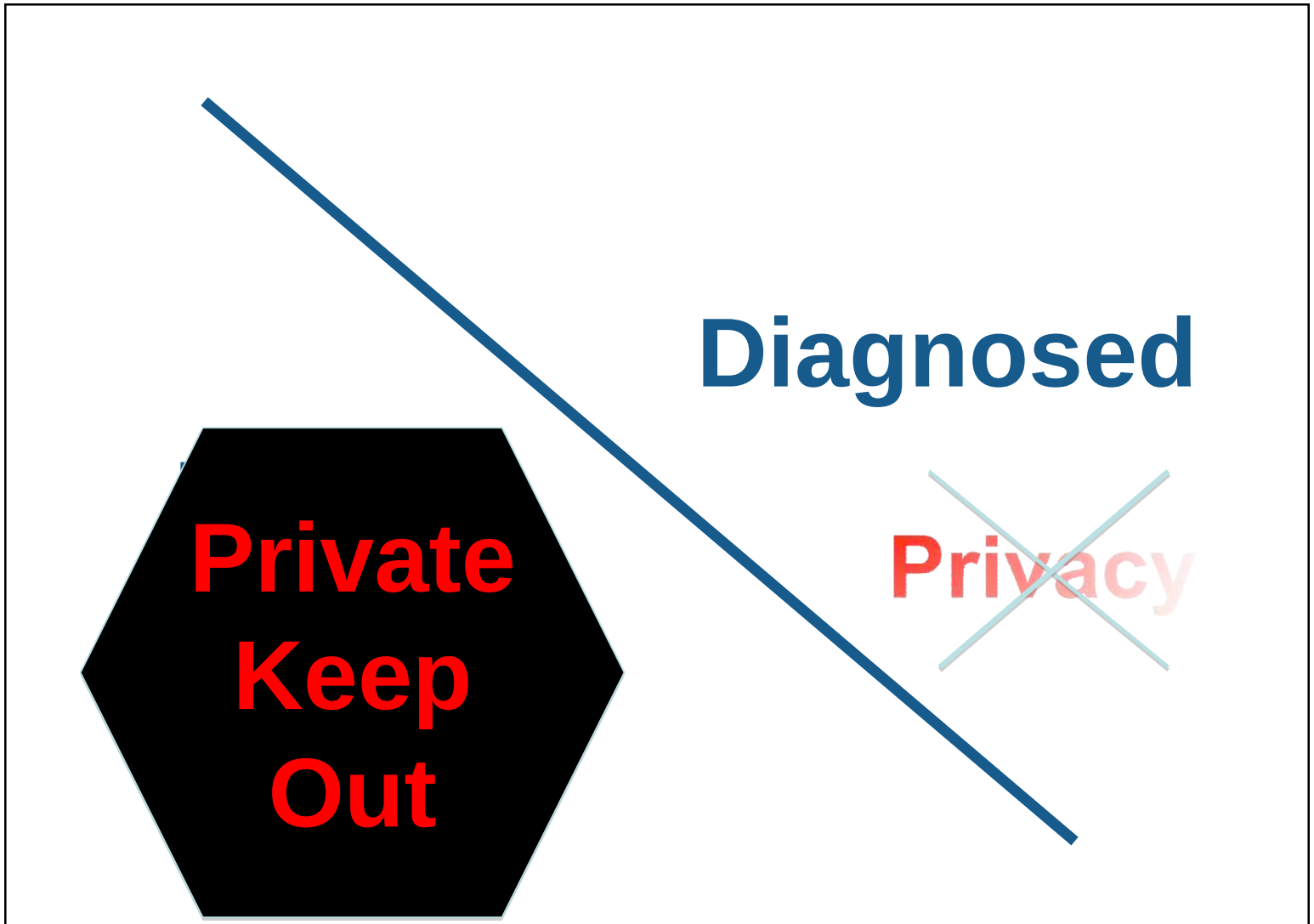
Patenting

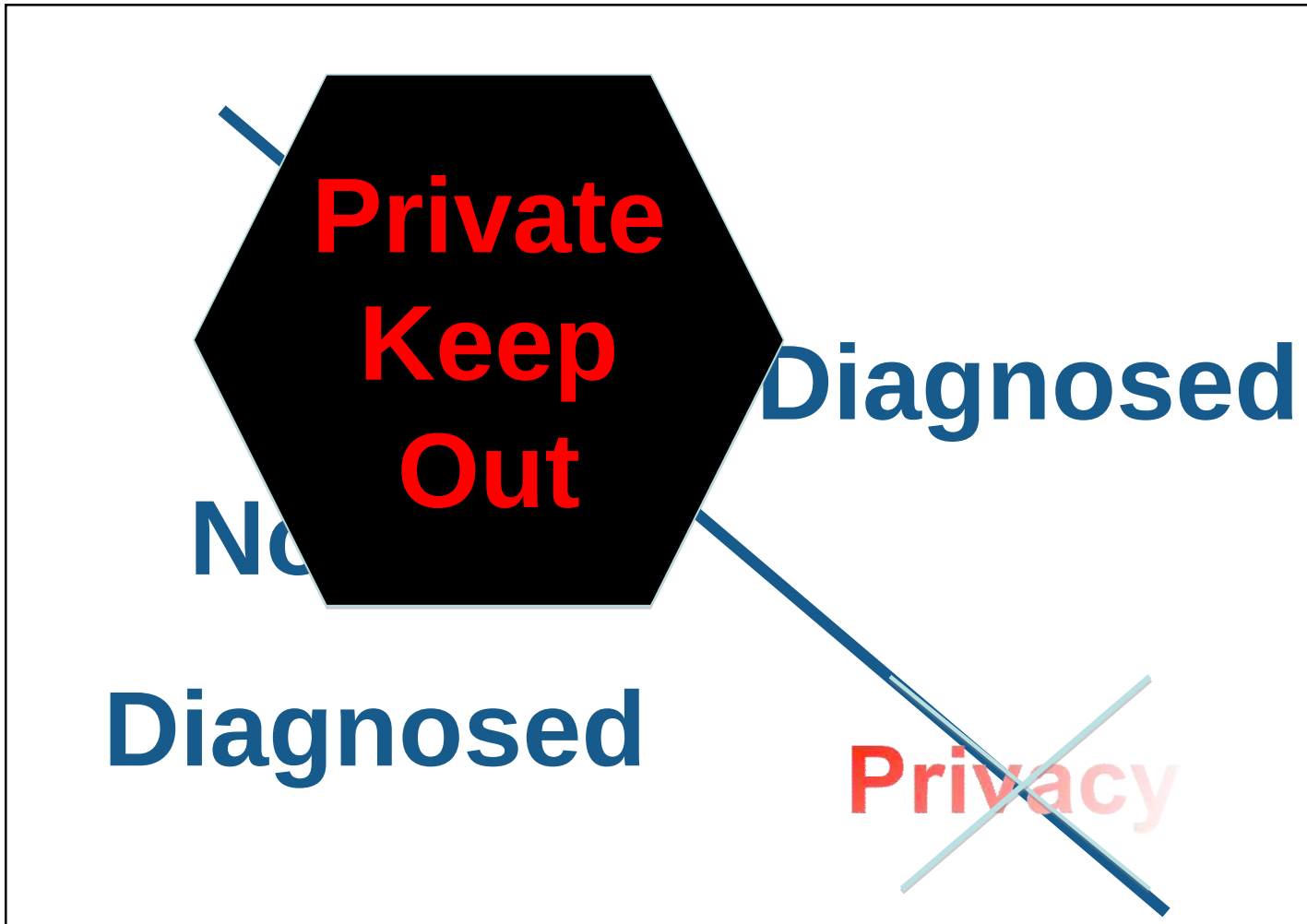
Licensing & Intellectual Property Management

Human Clinical Trials

Drug Screening & Development Approaches

Therapeutics
--Small Molecules
--Nonsense mutants

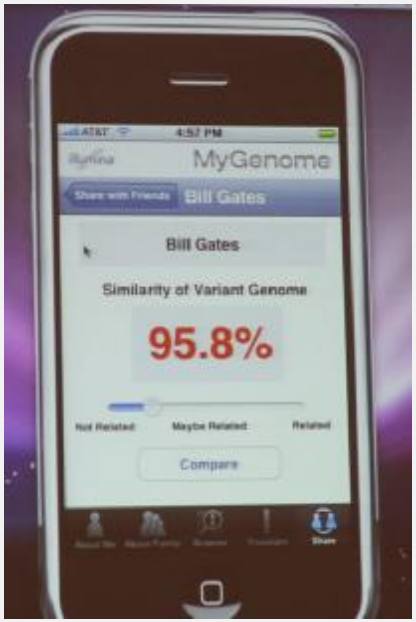




The Equation?

benefits for the ‘sick’ population

risks for the general population



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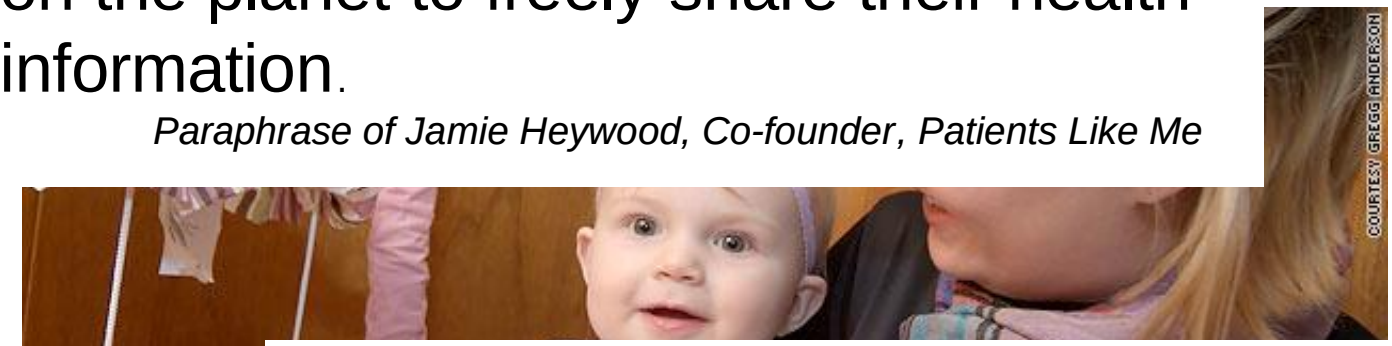
It is the moral imperative of every person on the planet to freely share their health information.

Paraphrase of Jamie Heywood, Co-founder, Patients Like Me



"We were appalled when we found out. Why do they need to store my baby's DNA indefinitely? Something on there could affect her ability to get a job later on, or get health insurance."

Karen Brown, Nurse, new mother, Florida

Multiple Other Studies Corroborate the Interest of Patients/Parents in Participating in Research – if they have control…

- 75% of Americans think their health care provider should use electronic health records, but 60% say they are not confident they will remain confidential (42% say that potential risks out weigh benefit).
- More than 700 cancer therapies clog the research pipeline partially because under 5% of patients enter clinical trials.
- 30% of people decline to participate due to "concern their personal information would not be kept private and confidential".
- 57% of people would permit their PHI to be used for research *only if* various privacy-oriented conditions are met (38% requiring notice and express case-by-case consent).

Data sources: Harris/Westin survey results, IOM, NCI.

Problems

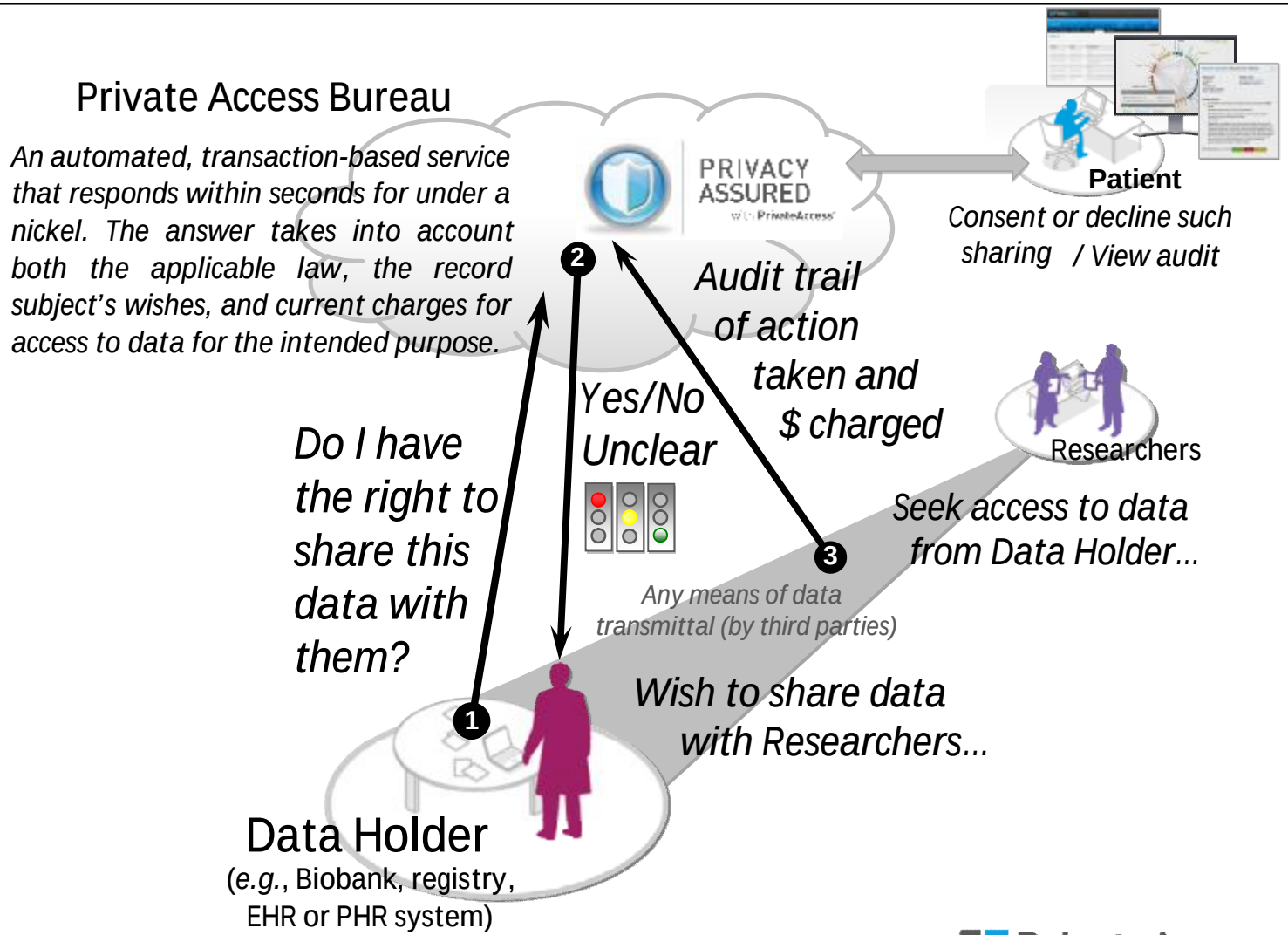
- Context is critical, and messy
  - All information is not created equal, and where it lives, and who it might see it later, is important
  - Samples from children
- Misinformation/confusion
  - DNA?
  - Identifiable?
  - GINA protections
- TRUST is hard to measure, to regulate, to codify, AND it is essential

Translational Research

- Difficult and expensive
- Well annotated samples essential
- There is dying going on – NOW
- What do we trade? Is my one dying child worth the privacy risks of others?
- Should my privacy protection preferences delay translational research for even more X years?
- What are our responsibilities as a people?

Private Access Bureau

An automated, transaction-based service that responds within seconds for under a nickel. The answer takes into account both the applicable law, the record subject's wishes, and current charges for access to data for the intended purpose.



PrivateAccess
Creating an environment of trust™

It isn't easy

Any system must consider:

- Trust
- Transparency
- Context
- Value

Communities of trust are core to the necessary systems

Collaborators

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