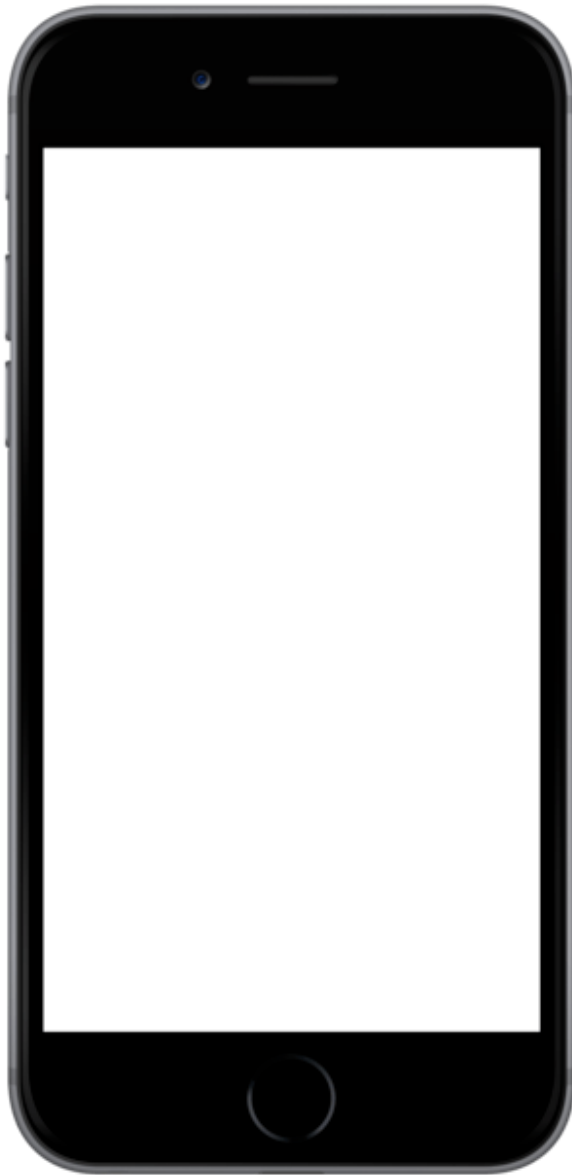




Face ID
Barometer
Three-axis gyro
Accelerometer
Proximity sensor
Ambient light sensor



CMS-P
Pluse Oximeter



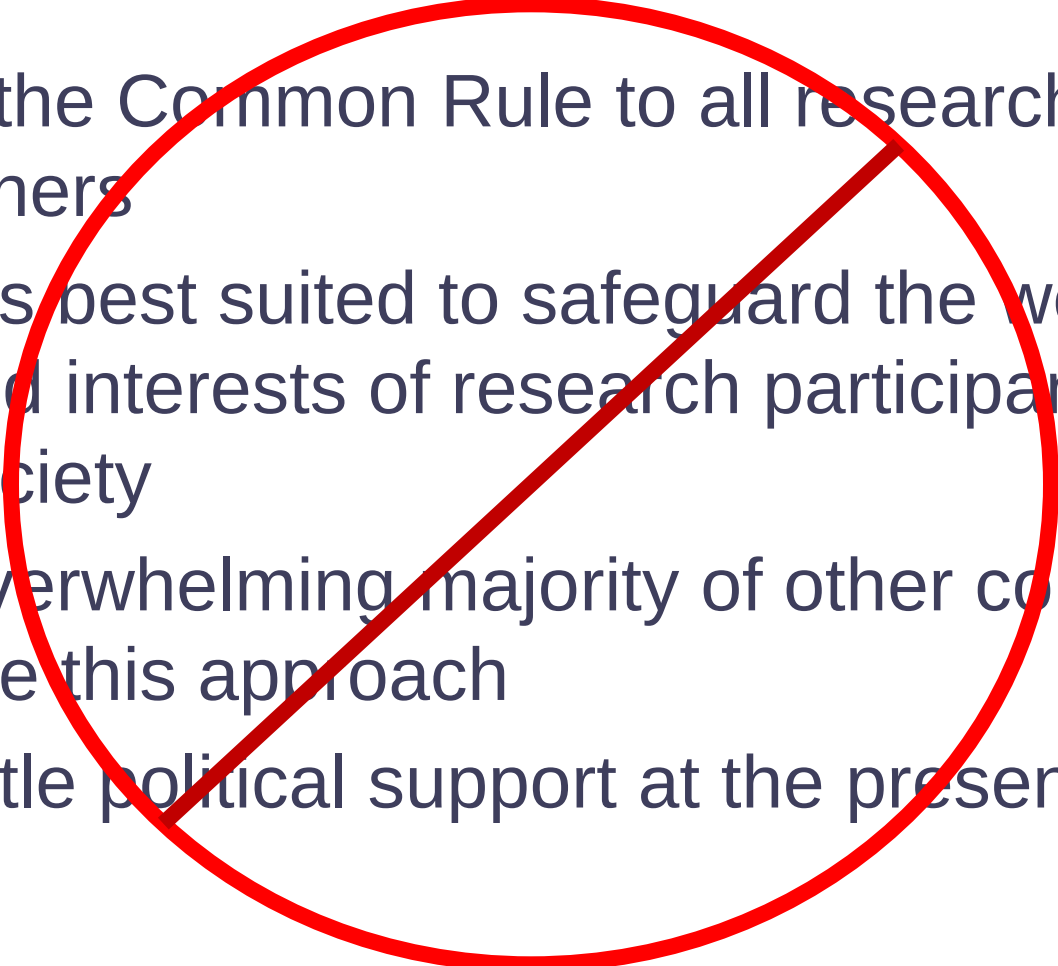


Question: How do you persuade independent-minded individuals and entities to do what you think is right when they have no legal obligation to do so and they think it's unnecessary?

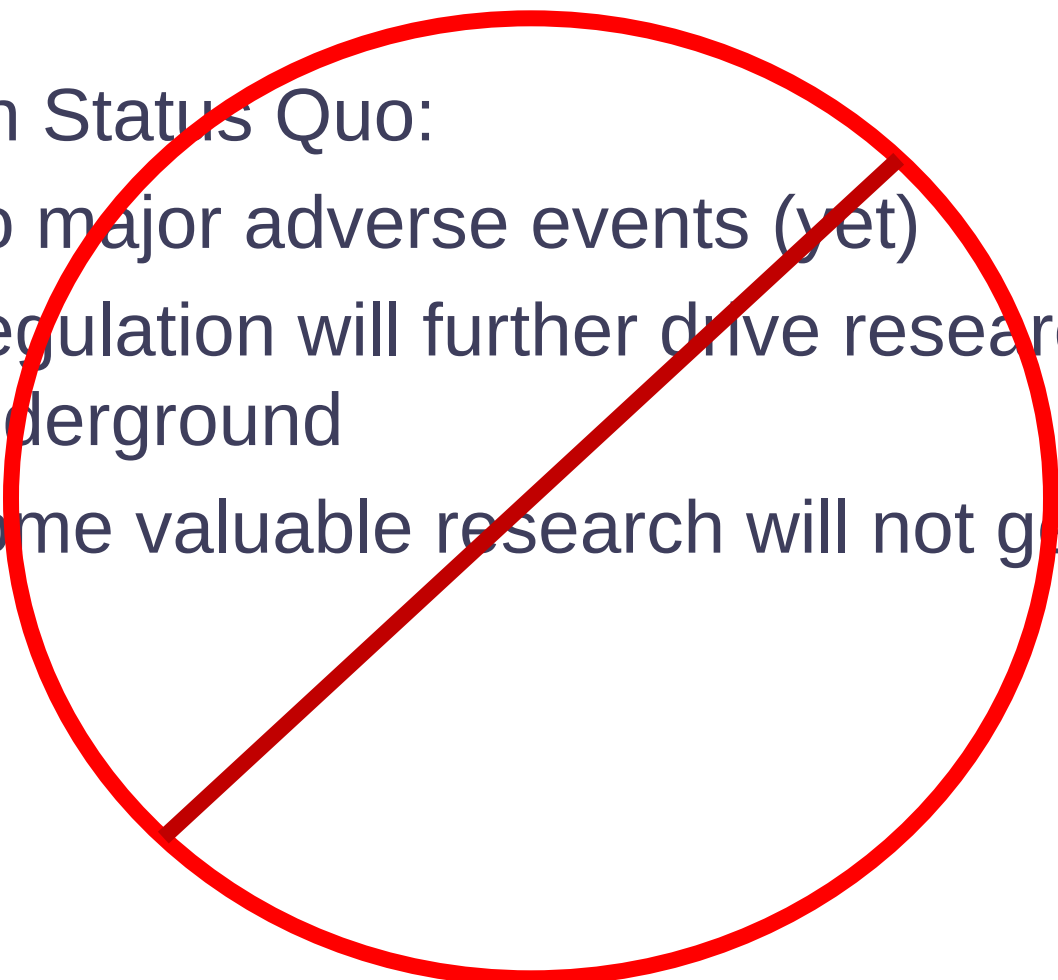
Research Methodology

- Qualitative interviews with thought leaders:
 - App and device developers
 - Researchers using mobile devices
 - Patient and research participant advocates
 - Regulatory and policy professionals
- Working group meetings to hear from stakeholders
- JLME Special Issue – March 2020
- Policy and App Developer workshops to disseminate

Options for Preventing Harms from Unregulated Health Research Using Mobile Devices

1. Extend the Common Rule to all research and researchers
 - It is best suited to safeguard the welfare and interests of research participants and society
 - Overwhelming majority of other countries use this approach
 - Little political support at the present time
- 

2. Maintain Status Quo:

- No major adverse events (yet)
 - Regulation will further drive research underground
 - Some valuable research will not get done
- 

Answer:

1. Establish outer boundaries
2. Provide education and assistance
3. Appeal to their self-interest and sense of decency



CONN: CONNECTICUT
MASS: MASSACHUSETTS
NH: NEW HAMPSHIRE
RI: RHODE ISLAND
VT: VERMONT





FDA

**U.S. Department of Health and Human Services
Food and Drug Administration**

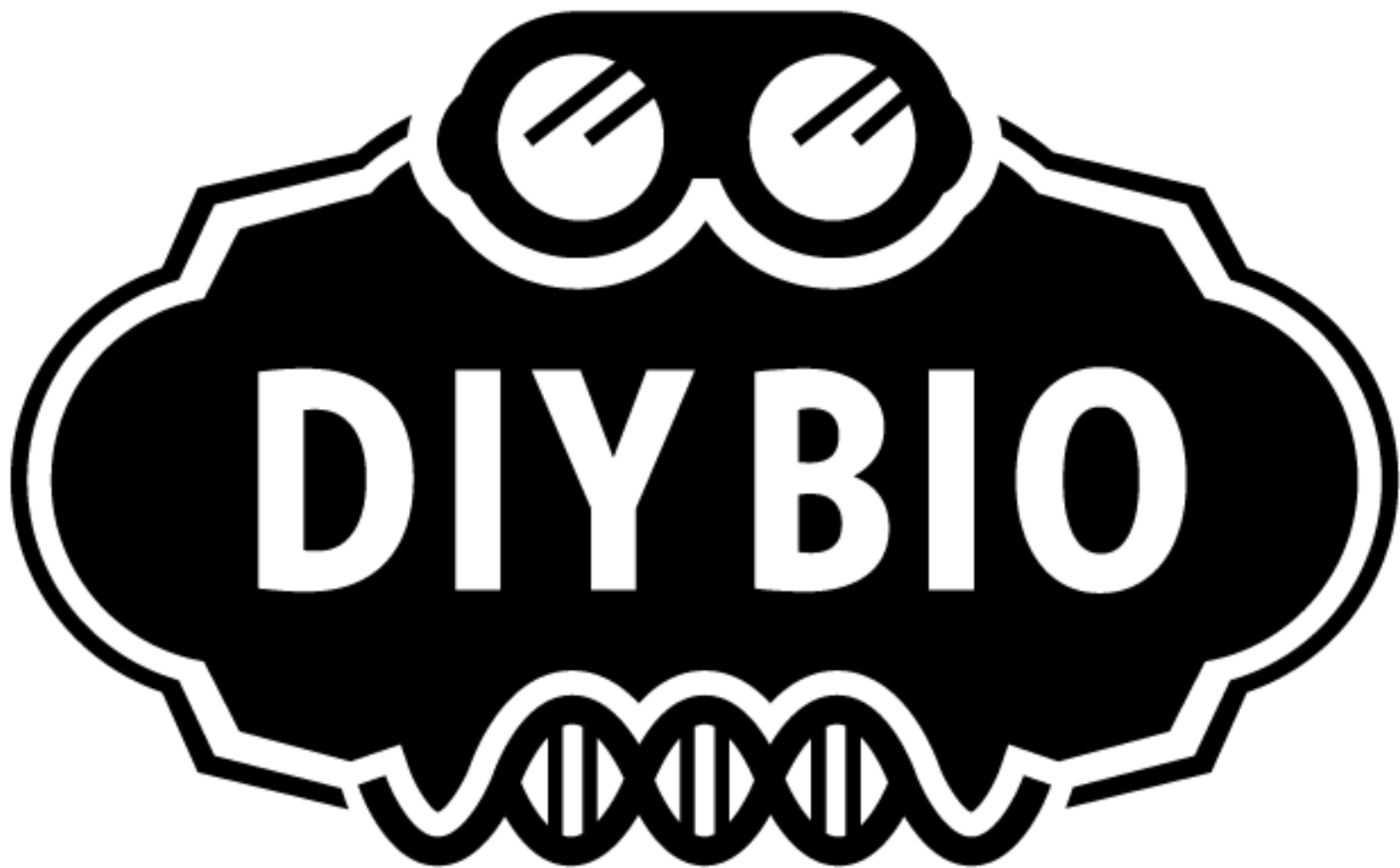






CDC

**CENTERS FOR DISEASETM
CONTROL AND PREVENTION**



Download the summary article

<http://bit.ly/MobileELSI>

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