Policy Context of IDEs

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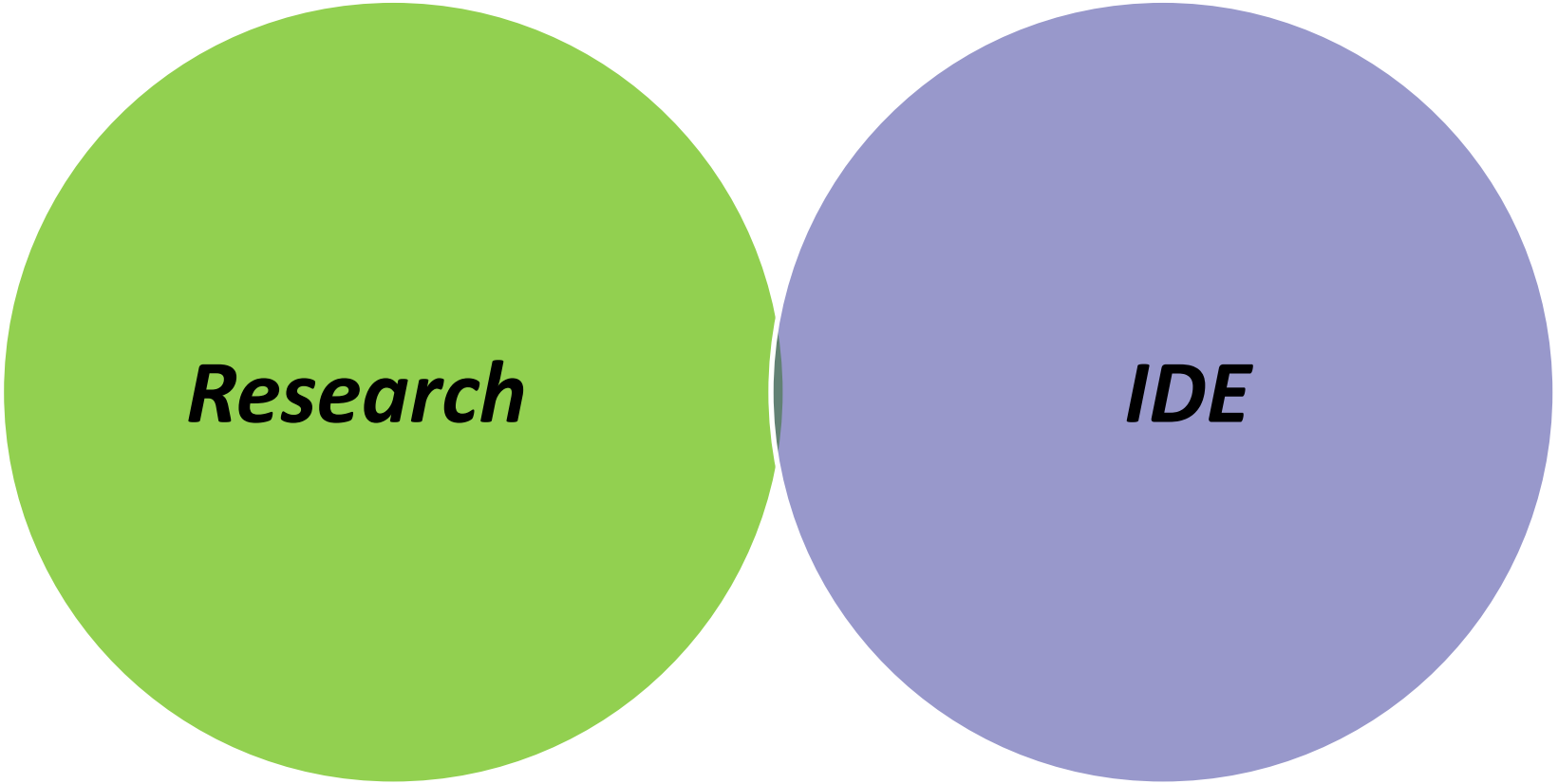
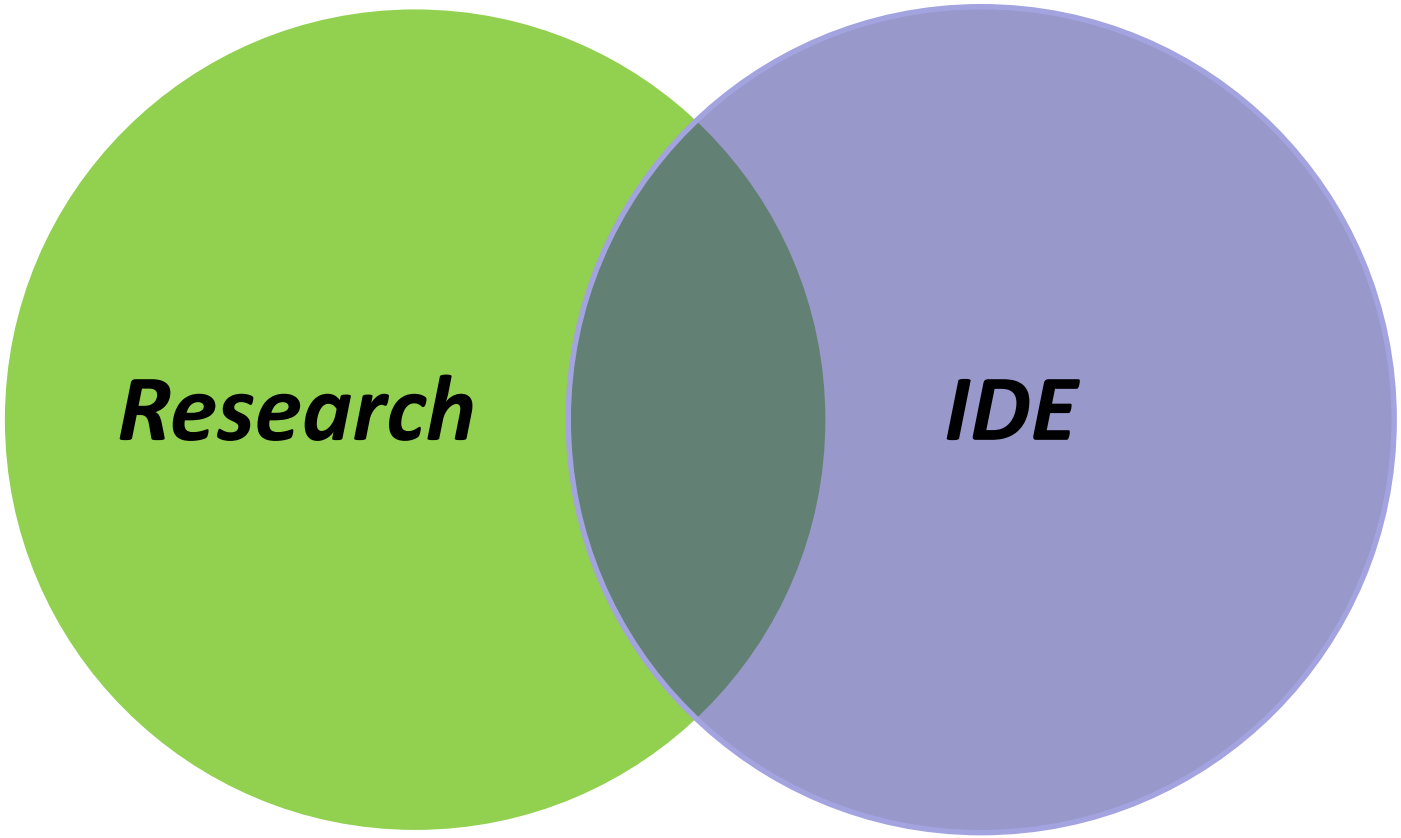
"Then"



"Now"



Recommendations from *Evolution of Translational Omics: Lessons Learned and the Path Forward* (Institute of Medicine, 2012)

- FDA [should] communicate the IDE requirements for use of omics-based tests in clinical trials to the Office of Human Research Protections (OHRP), IRBs, and other relevant institutional leadership.

- The committee encourages FDA to organize forums with members of the scientific community and have an open and publicly accessible dialogue…This will provide test developers with some insight into FDA's thinking and potential next steps.

Special Challenges for Academic Researchers

- No prior interaction with FDA
- No prior experience with IDE regulation
- Lack of adequate regulatory support
- Time-limited nature of NIH-funded research

Purpose of this Workshop

- Understanding the IDE regulation will allow you to be prepared.

- Planning ahead will make the process much easier. Having to figure out the IDE regulation after a research project has begun can be disruptive.

- Identifying barriers to meeting IDE requirements is important to FDA.

IDE Regulation (21 CFR 812)

- "…purpose…is to encourage, **to the extent consistent with the protection of public health and safety and with ethical standards,** the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose."
- An IDE is a **regulatory submission** that permits clinical investigation of devices/IVDs.
- An approved IDE permits a device to be shipped lawfully for the purpose of conducting investigations of the device **without complying with other requirements** of the Food, Drug, and Cosmetic Act (Act) that would apply to devices in commercial distribution.
- Focused on risk
- Delegated responsibilities

IDE approval aims to ensure that:

- Risks are outweighed by anticipated benefits to subjects and importance of knowledge to be gained.
- Informed consent is adequate.
- Investigational device plausibly is effective.

FDA review

- Interactive
  - Many conversations between FDA and sponsor
  - Presubmission allow conversations before submissions
- Case-by-case review – what is actually required depends on a number of factors
  - Can be specific to intended use, technology, study design, etc.
  - Tailored to the way that different risks can be mitigated
- Different focus than peer review
  - Evaluates safety
  - Includes ethics
  - Analytical validation – detailed review that can include evaluation of line data

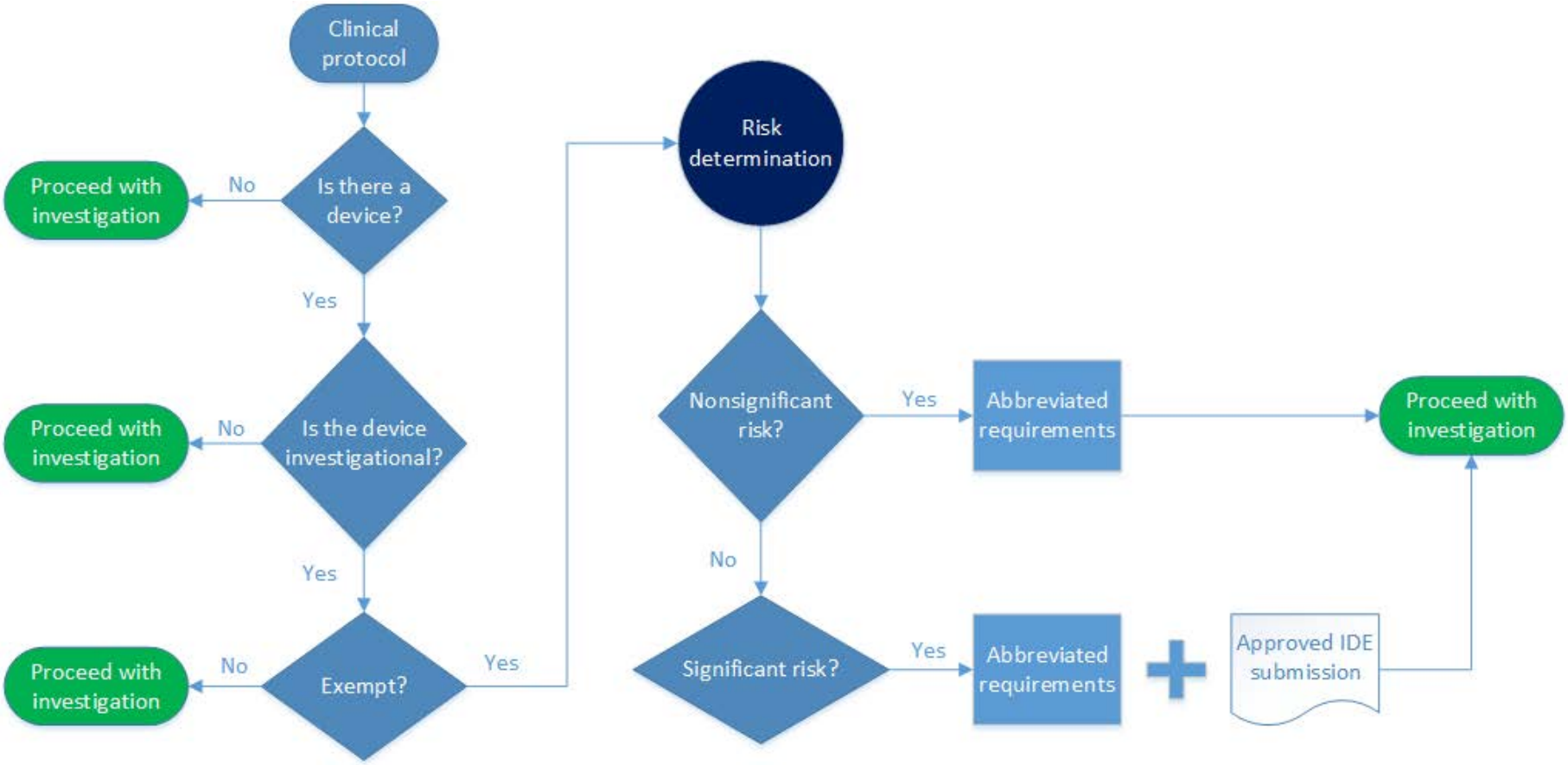
Most IVD studies are exempt from the IDE regulation.

- Example: Use of archived, de-identified specimens is usually exempt from the IDE regulation

Office of In Vitro Diagnostics and Radiological Health

DIHD	Division of Immunology and Hematological Devices
DMGP	Division of Molecular Genetics and Pathology
DMD	Division of Microbiology Devices
DCTD	Division of Chemistry and Toxicology Devices
DRH	Division of Radiological Health
DMQS	Division of Mammography Quality Standards

Overview


Clinical protocol
Is there a device?
No
Proceed with investigation
Yes
Is the device investigational?
No
Proceed with investigation
Yes
Exempt?
No
Proceed with investigation
Yes
Risk determination
Nonsignificant risk?
Yes
Abbreviated requirements
Proceed with investigation
No
Significant risk?
Yes
Abbreviated requirements
Approved IDE submission