COMP 918: Research Administration for Scientists

Volume 1: Research Funding, Grantsmanship, and Research Ethics

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Computer Science Department, UNC-Chapel Hill

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These materials were prepared for the "Research Administration for Scientists" course by Timothy L. Quigg, Lecturer and Associate Chair for Administration, Finance and Entrepreneurship, Computer Science Department, UNC-Chapel Hill. They are published in four volumes: Volume 1 – Research Funding, Grantsmanship, and Research Ethics, Volume 2 – Sponsored Research Agreement Types, Budgeting, FAR, and OMB Circulars A-21 and A-110, Volume 3 – Management in the Academic and Scientific Enterprise, and Volume 4 – Intellectual Property: Patents, Copyrights, Trademarks and Trade Secrets.

Tim created and taught this course each year from 2001-2013. More than 600 graduate students, post-docs, faculty and staff from over 40 UNC-Chapel Hill departments have taken the course, many for credit and many others as auditors. In 2009, the Computer Science Graduate Student Association honored Tim with the Excellence in Teaching Award for his work with this course!

COMP 918: Research Administration for Scientists

History of Research Funding in U.S. Universities

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Before WWII, most university research was funded by external non-profit charities or from internal university funds.

However, the Federal Government was heavily involved in funding one area of university research.

What area was it? **Agriculture!**

- Morrill Act of 1862: Land-Grant Colleges
- Hatch Act of 1887: Agricultural Experiment Stations
- Morrill Act of 1890: Land-Grant Colleges
- Smith-Lever Act of 1914: Cooperative Extension Service

The Morrill Act of 1862

The Act, named for its primary sponsor Representative Justin Smith Morrill of Vermont, provided each state with 30,000 acres of federal land for each of its congressional representatives. The land was to be sold and the proceeds used to establish a Land-Grant College!

Cornell University ($5.50/acre)
University of Kentucky (50¢/acre)

Quite a range!

The law defined Land Grant Colleges as institutions

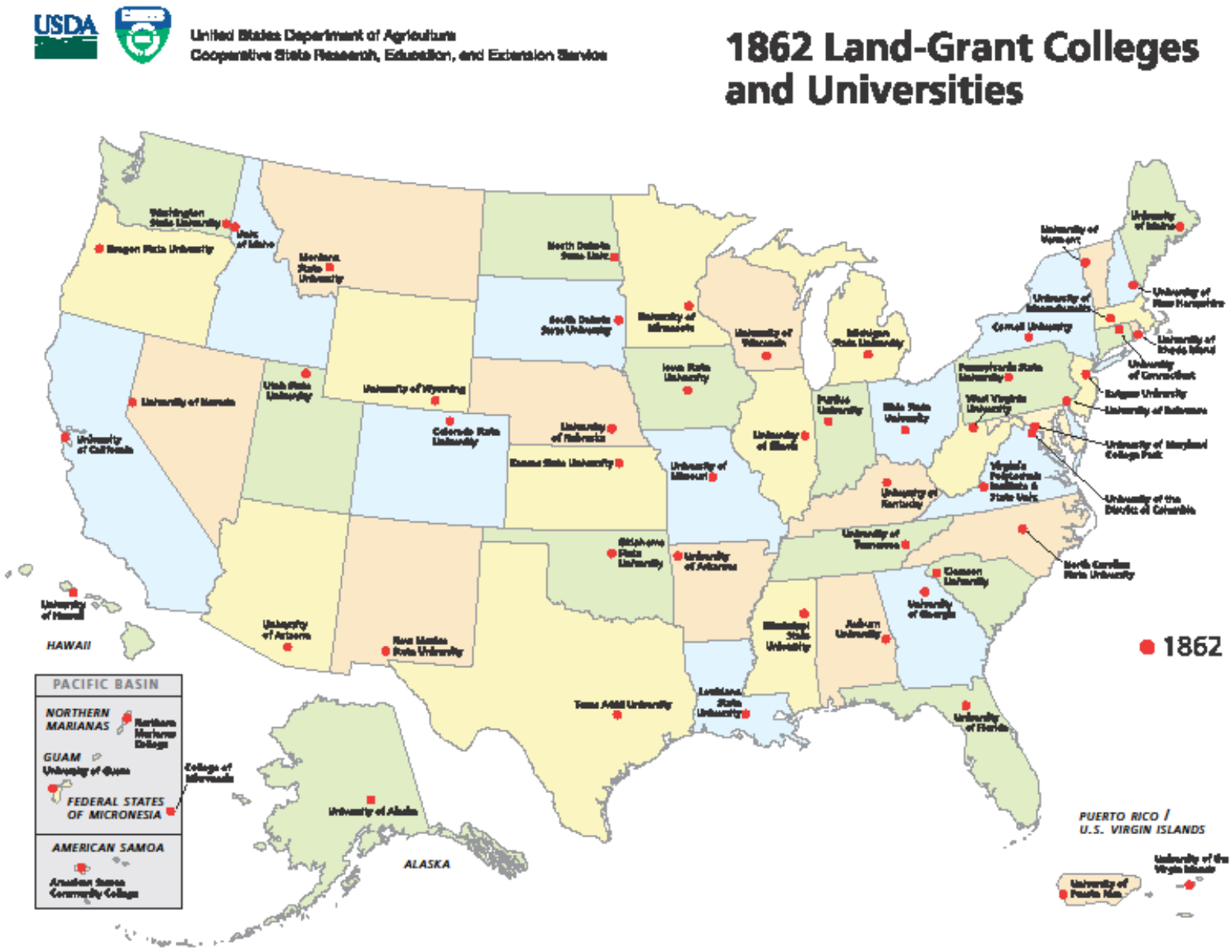
"…where the leading object shall be, without excluding other scientific and classical studies and including military tactics, to teach such branches of learning as are related to agriculture and the mechanical arts…"

What N.C. School was established as a result of the Morrill Act?

North Carolina State University

"Land-Grant Legacy"

"NC State is in the midst of celebrating its March 7, 1887 founding. But another anniversary, 25 years earlier, is just as significant to the university's history. On July 2, 1862, President Abraham Lincoln signed the Morrill Act, which led to the establishment of land-grant universities."


United States Department of Agriculture
Cooperative State Research, Education, and Extension Service
1862 Land-Grant Colleges and Universities
HAWAII
PACIFIC BASIN
NORTHERN MARIANAS
GUAM
FEDERAL STATES OF MICRONESIA
AMERICAN SAMOA
ALASKA
PUERTO RICO / U.S. VIRGIN ISLANDS
1862

The Federal Government started requiring matching funds in 1887…

Hatch Act of 1887: Established Agriculture Experiment Stations

- Annual appropriation – State match required

Smith-Lever Act of 1914: Established the Cooperative Extension Service

- Annual appropriation – State match required

…and for many projects, they still do today!

Second Morrill Act of 1890

The Civil War ended on May 9, 1865 and was followed by a period of Reconstruction throughout the South.

By 1890 much of the country, especially Congress considered equal access to publically-funded facilities to be an important issue!

Second Morrill Act of 1890

In order to qualify for these additional federal funds, States had to either:

- Prove that race wasn't a criteria for admission to their existing land-grant college.
- Establish a separate land-grant college for their black citizens!

Second Morrill Act of 1890

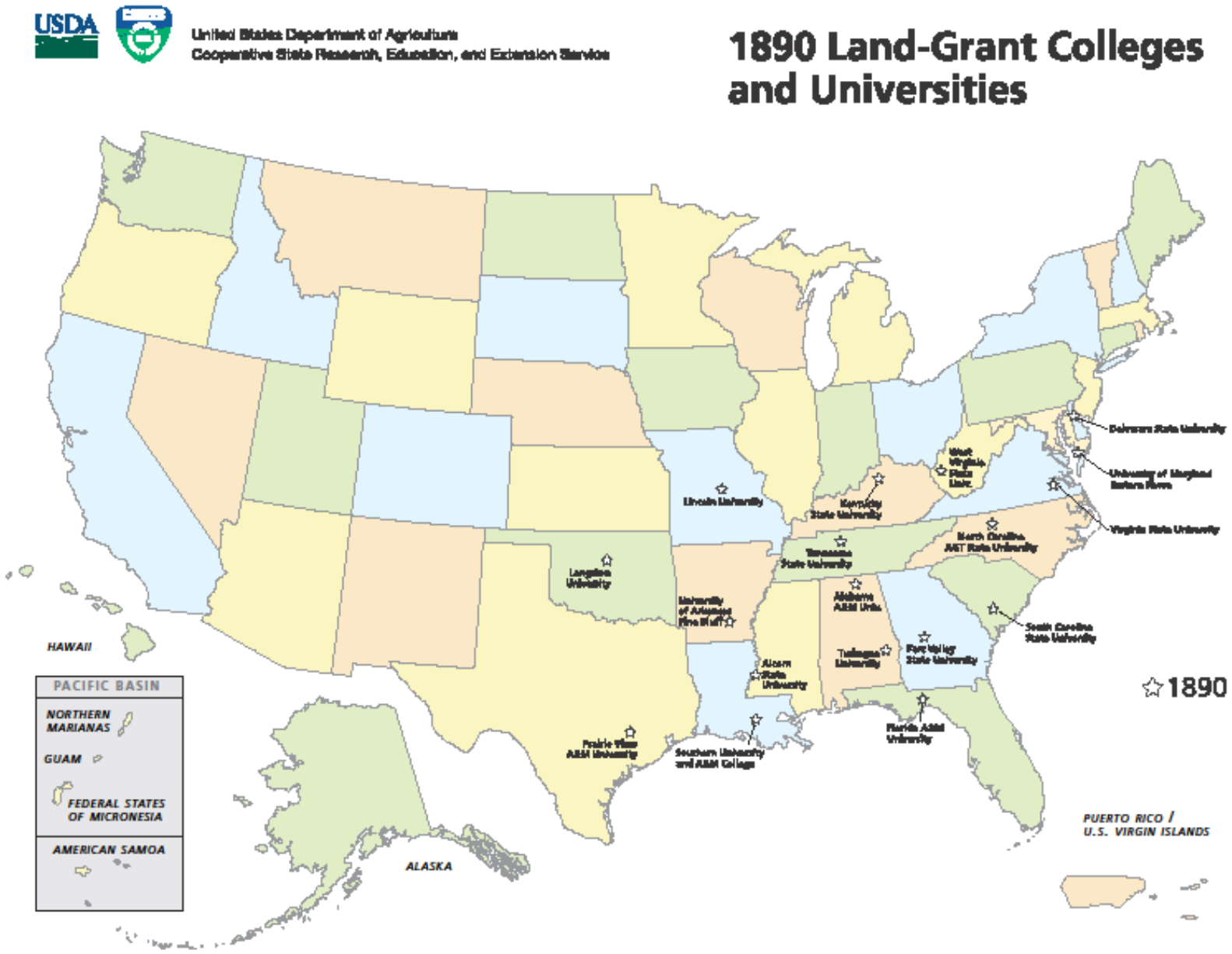
Every Southern state selected the second option and established a separate land-grant college for their black citizens. Thus the "1890 Land-Grants" were created all over the then-segregated South!

What N.C. School was established as a result of the Second Morrill Act?

North Carolina A&T University

"1890 Land-Grant Legacy"

In 1890, Congress enacted the Second Morrill Act that mandated "a separate college for the colored race." The Agricultural and Mechanical College for the Colored Race (now N.C. A&T) was established as that school in the state of North Carolina by an act of the General Assembly ratified on March 9, 1891.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☆1890
Delaware State University
University of Maryland Eastern Shore
Virginia State University
North Carolina A&T State University
South Carolina State University
Florida A&M University
Fort Valley State University
Alabama A&M Univ.
Tuskegee University
Alcorn State University
Southern University and A&M College
Prairie View A&M University
Langston University
University of Arkansas Pine Bluff
Tennessee State University
Kentucky State University
West Virginia State Univ.
Lincoln University

Fast forward to WWI (July 28, 1914 to November 18, 1918) - Congress established the Council of National Defense (CND).

On August 29, 1916, Congress passed the Army Appropriation Act which authorized the creation of the CND consisting of the Secretaries of War, the Navy, the Interior, Agriculture, Commerce, and Labor. It was assisted by an Advisory Commission appointed by President Woodrow Wilson on October 11, 1916.

Function: To coordinate resources and industries for national defense.

Major Limitation: Little attempt was made to coordinate government and industry research efforts with academic research.

In January 1920, the Council recommended the creation of an Expert Survey Board to conduct research studies over the next six months to enable facilitate mobilization in the event of another war. However…

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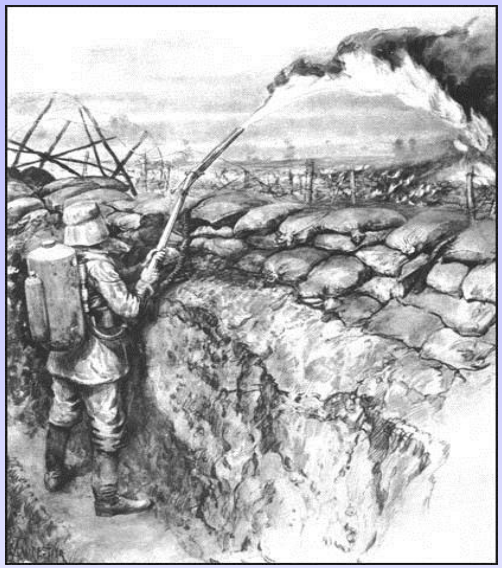
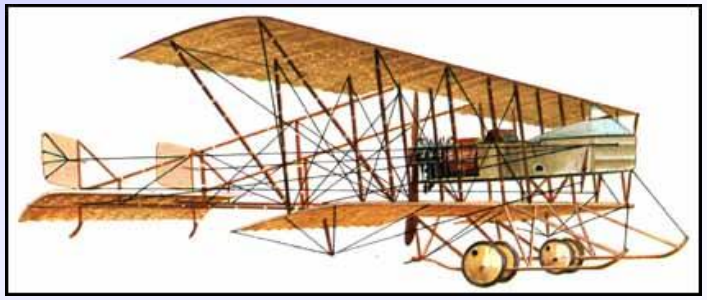
… few changes were made in how university research was funded. And no serious attempts to coordinate university research activities with industry/government research occurred until WWII!

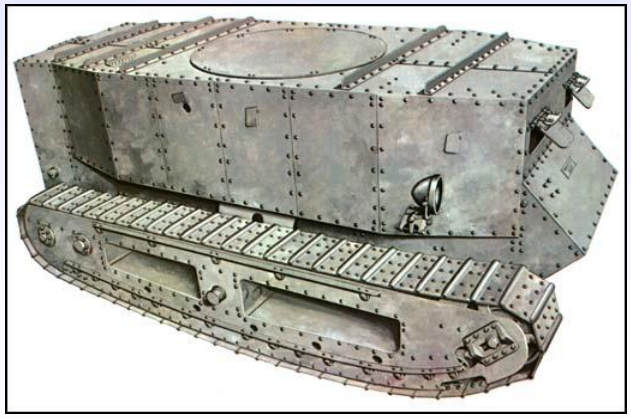
Important Military Inventions during WWI



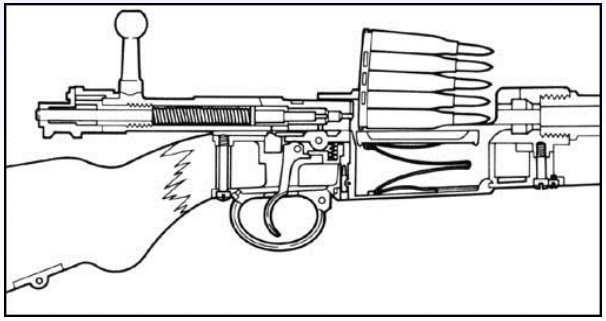
Flame Throwers



Aircraft (Farman)



Armored Tanks



Bolt Action Rifles

Federal support for research is and always has been closely tied to military needs!

WWII - National Defense Research Council (NDRC)

- GOAL: To coordinate, supervise, and conduct scientific research on the problems underlying the development, production, and use of mechanisms and devices of warfare.
- Brought scientists from academia, industry and government together to address the needs of the U.S. military in a collaborative fashion.

Learning from the WWI failure of the CND to coordinate with university scientists, in June of 1940 (a full 18 months before the December 7, 1941 attack on Pearl Harbor) **FDR established the NDRC!**

The NDRC was later renamed the OSRD and headed by Dr. Vannevar Bush!

Office of Scientific Research and Defense

- Inventor – Analog Computers
- Vice President and Dean of MIT School of Engineering
- Manhattan Project Administrator
- Raytheon Founder

Dr. Vannevar Bush

Invented Memex, an adjustable microfilm viewer with a structure analogous to that of the WWW.

"In 1945, Bush published As We May Think in which he predicted that wholly new forms of encyclopedias will appear, ready made with a mesh of associative trails running through them, ready to be dropped into the memex and there amplified. The memex influenced generations of computer scientists, who drew inspiration from its vision of the future."

Innovative characteristics of the Office of Scientific Research and Defense (OSRD) contributed to its success!

- Civilian, not military control.

Innovative characteristics of the Office of Scientific Research and Defense (OSRD) contributed to its success!

- Civilian, not military control.
- Authority to contract work that was previously conducted in government labs to universities, private labs and industry.
  - Carnegie Institute of Technology – Large Rocket
  - MIT – Radiation Lab
  - Western Electric and Bell Labs – Sound Amplification

Innovative characteristics of the Office of Scientific Research and Defense (OSRD) contributed to its success!

- Civilian, not military control
- Authority to contract work previously conducted in government labs to universities, private labs and industry.
- Highly centralized structure.

OSRD's highly centralized structure emphasized

- Vertical integration of methodology from fundamental science to production.
- Concentrated, massive rapid development and deployment!

Example

A device to jam Japanese torpedoes moved from a laboratory production prototype to full field deployment in just **one week!**

Imagine that speed in your lab?

Innovative characteristics of the Office of Scientific Research and Defense (OSRD) contributed to its success!

- Civilian, not military control
- Authority to contract work previously conducted in government labs to universities, private labs and industry
- Highly centralized structure
- Mission "to explore a possible government role in encouraging future scientific progress."

Military historians identify four critical technologies that contributed to the Allied victory in WWII! Name them!

1. Atomic bomb (Manhattan project)

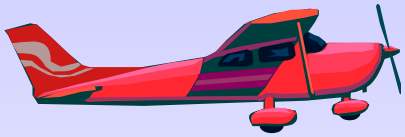
2. Radar

- 1935 – NRL – ship radar
- 1942 – MIT – high-frequency, narrow-beam, high-resolution

3. Cryptography

4. ???

Clue - What new "machines of war" were widely used by both sides in WWII?



Airplanes!

Military Challenge: Hit these highly maneuverable planes and knock them out of the sky!

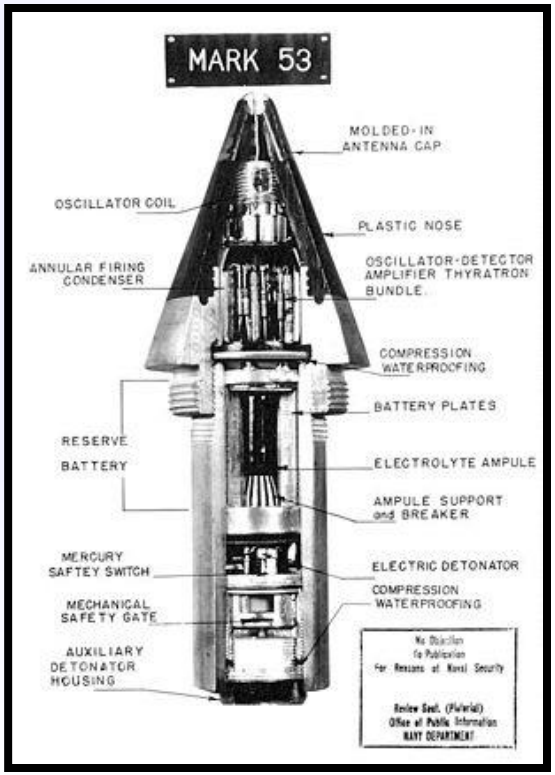
Prior to WWII the only options were to use either a **timed fuse** or a **contact fuse**.

Neither option was terribly effective against these highly maneuverable airplanes!

Section T – Applied Physics Lab at Johns Hopkins University was assigned the task of developing a new option – something called a proximity or variable time fuse to be deployed and used by the Navy with their 5" guns!

How did the Proximity Fuse work?

- Fuse contained a miniature radio transmitter-receiver which sent out a signal.
- When the signal which reflected back from a target reached a certain frequency (based on its proximity to the target), a circuit closed and fired a small charge which detonated the projectile.



Problems/Challenges

- Components contained tiny glass vacuum tubes.
- Force of 20,000 g's when fired (2800 feet/sec muzzle velocity).
- 25,000 revolutions/minute through rifling grooves.
- Moisture – application was from naval ships.
- Self-destruct feature for dudes was not well developed!

Importance to war effort

- **James V. Forrestal, Secretary of the Navy** - "The proximity fuse has helped me blaze the trail to Japan. Without the protection this ingenious device has given the surface ships of the fleet, our westward push could not have been so swift and the cost in men and ships would have been immeasurably greater."
- **Prime Minister, Winston S. Churchill** - "These so-called proximity fuses, made in the United States, proved potent against the small unmanned aircraft with which we were assailed in 1944."
- **Commanding General of the Third Army, George S. Patton** - "The funny fuse won the Battle of the Bulge for us. I think that when all armies get this shell we will have to devise some new method of warfare."

Why do I tell this story?

- It was not certain the U.S. would win WWII. Our survival as an independent country was in serious doubt.
- When the war was over, the American public:
  - recognized and appreciated the important role science and technology had played in helping the allies win the war,
  - had great confidence in the ability of science and technology to solve society's problems, and
  - held research, especially university-based research, in quite high regard!

Why do I tell this story?

- As a result, the public was ready to invest tax dollars in university-based research at levels never before seen in the U.S.!
- And they still do – President Obama's 2012 budget request was ~ $150 billion for R&D.
- For most U.S. universities, federal funds constitute 75% or more of all institutional research expenditures!

A Word of Caution

Public trust is fragile! What takes decades to earn can be lost in an instant if the public no longer believes universities are impartially acting in the public interest!

Everyone involved in university research is responsible for maintaining this trust!

Therefore, we must always conduct our research honestly, openly and consistent with the highest ethical standards!

This responsibility is the organizing principle for this course!

"The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true."

- Albert Einstein

"The only ethical principle which has made science possible is that the truth shall be told all the time…"

C.P. Snow "The Search" 1959

The Endless Frontier: Vannevar Bush's final report enumerated two principles for expanding R&D at U.S. universities.

- Federal government should be a patron of science.
- Government support should ensure a free rein of investigation by scientists into topics and methods of their choice!

The Endless Frontier: Vannevar Bush's final report enumerated two principles for expanding R&D at U.S. universities.

- Federal government should b… f science
- …e …thods of their choice!

These principles still dominate federal grants - Contracts are a whole different matter!

Submitted in 1945, The Endless Frontier report ultimately lead to the establishment of the National Science Foundation (NSF) in 1950!

Brief History of NIH

- 1798 – Marine Hospital Service was established to provide medical care for merchant seaman.
- 1891 – Hygienic Laboratory was established in Washington, DC with 1 employee working on what was then called bacteriology.
- 1901 – Congress appropriated $35K for construction of a new building for a Lab to investigate "infectious and contagious diseases and matters pertaining to the public health."
- 1904 – The Lab was renamed the Public Health and Marine Hospital Service with 3 Divisions - Chemistry, Pharmacology and Zoology.
- WWI – The primary mission for the PHS was to address sanitation issues in and around military bases.

Brief History of NIH

- 1930 – Ransdell Act changed the name of the Hygienic Laboratory to the National Institute (singular) of Health and authorized establishment of fellowships for research into "basic biological and medical problems." This was an amazing accomplishment in the middle of the Great Depression!
- 1937 – Congress, reacting to the public's growing concern with cancer, created the National Cancer Institute with every Senator voting in favor. This was the beginning of NIH's categorical-disease structure.
- NCI was authorized to award grants to nonfederal employee scientists – this was the beginning of the extramural research program!

WWII focus on war-related problems:

- Research on hazardous substances and ways to protect workers in war industries.
- Development of vaccines and therapies to address tropical diseases (yellow fever and typhus).
- Discovery that sodium deficiency was a leading cause of death after burns which lead to the widespread use of saline therapy on the battlefield.
- Discovery of the optimal altitude for administering oxygen to pilots to prevent "blackouts."
- And much more!

Some of this research was conducted at universities funded by NIH grants!

Extramural Research grants expanded throughout NIH

- 1944 – NCI was specifically designated as a component of NIH. To this day, only two NIH officers are direct Presidential appointments: the Directors of NIH and NCI.
- 1946 – Public Health Act expanded the successful grants program at NCI to all of NIH.
- New Institutes were created for mental health, dental disease and heart disease from 1946-49. By 1960 there were 10 Institutes, by 1970 there were 15 and by 2000 there were 27 Institutes and Centers.

Major DOD Funding Agencies

- **DARPA** – The Defense Advanced Research Projects Administration was established in 1958 in response to the launching by the Soviet Union of Sputnik. DARPA is the main research and development office for the U.S. Department of Defense. It's mission is to "maintain technological superiority of the U.S. military and prevent technological surprise from harming our national security."

- **ARO** – The Army Research Office was established as the Army's "premier extramural basic research agency in the engineering, physical, information and life sciences; developing and exploiting innovative advances to ensure the Nation's technological superiority."

Major DOD Funding Agencies

- **ONR** – The Navy established its first Naval Research Lab (NRL) in 1923. In 1946, President Truman signed legislation establishing the Office of Naval Research (ONR) to "plan, foster and encourage scientific research in recognition of its paramount importance as related to the maintenance of future naval power and the preservation of national security."

- **AFOSR** – The Air Force Office of Scientific Research, which began in 1948 as the Office of Air Research at Wright Field in Ohio, grew dramatically after the launch of the Sputnik by the Soviet Union. Its mission was to "support Air Force goals of control and maximum utilization of air, space and cyberspace."

Observations concerning DOD funding of university research

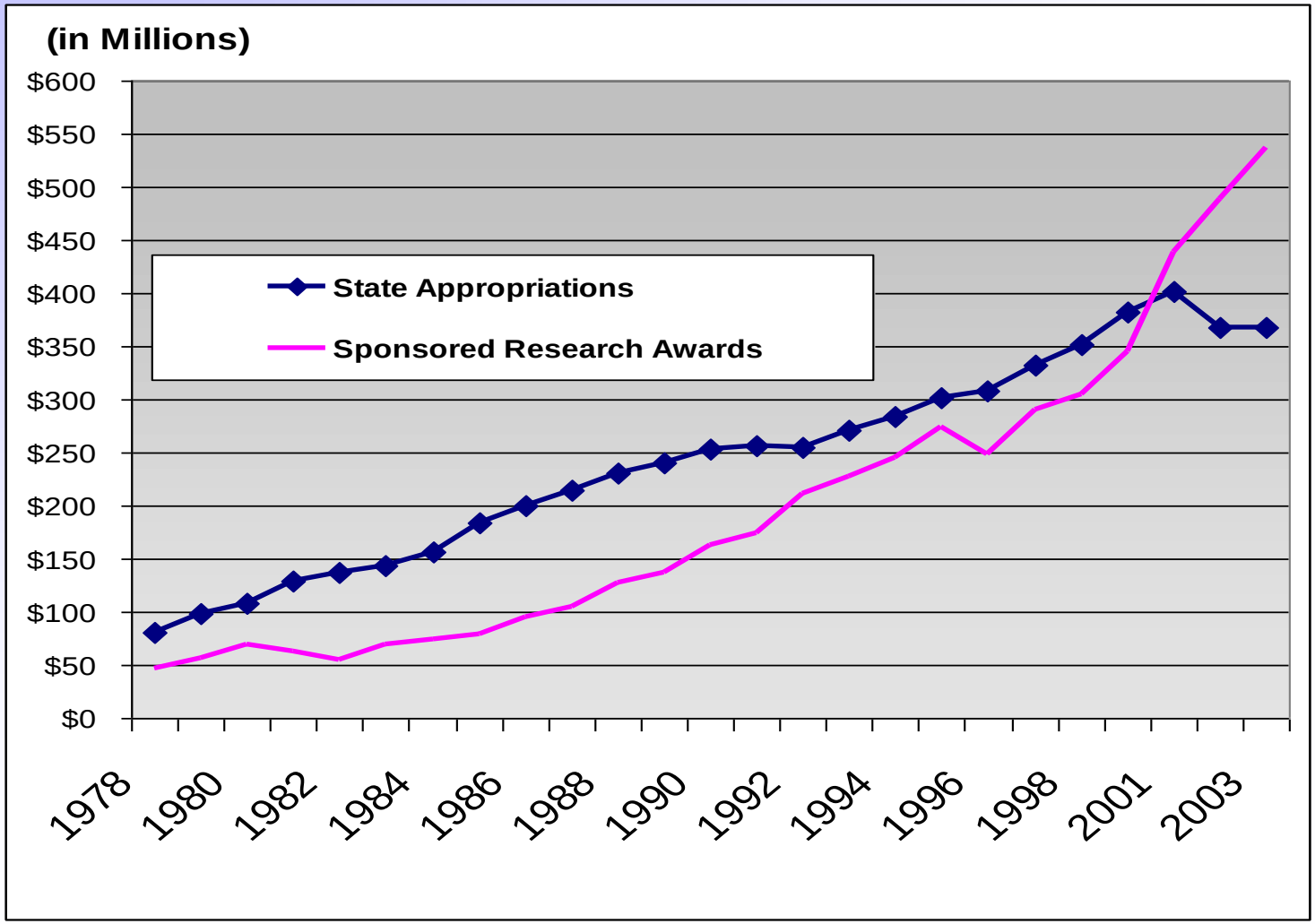
- Preference for contracts over grants.
- Importance of deliverables in contracts.
- A nice arrangement (if you can get it) – On large projects, commercial defense contractors are the prime, handle integration of basic science with applied research, and produce/submit contract deliverables. Universities are subcontractors with responsibility for targeted components involving more of the basic science.
- Note: Many DOD-funded projects often have significant civilian applications!

How federal funding of research has impacted universities!

- Since WWII, the federal government has become the primary source for funding university research – often 75-90% of an institution's entire research portfolio.

- Many universities (including UNC-CH) receive more money from competitively awarded research contracts/grants than from any other source - including state government appropriations.

Sponsored Awards v. State Appropriations at UNC-CH



UNC-Chapel Hill Funding

- The annual allocation to UNC-Chapel Hill from N.C. state government is ~ $440 million.
- Funding has been reduced during the recession, but N.C. and Wisconsin are the only states currently providing this level of funding to their flagship public university – the norm is just below $200 million.
- Even as state funding for UNC-CH has declined, the state has maintained 100% control, e.g., state personnel policies, state purchasing requirements, state construction rules.

Special Issues: Public Universities!

- As other states have reduced funding, many have followed the national trend to grant more flexibility and autonomy to their public universities – some now use the term "state affiliated" rather than "state supported."

- Setting tuition rates, modifying in-state and out-of state admission limits, modifying personnel policies, providing greater budget flexibility – these are just a few examples of the changes at many public universities as state financial support has been reduced.

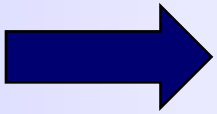
Special Issues: Public Universities!

- The competition for scarce state dollars has, in some situations, created additional tension between the research-intensive flagship universities and the smaller more teaching-oriented campuses within statewide university systems.

- The mistaken perception that flagship universities are better able to handle larger state funding cuts because they can "off-load" large portions of their budgets to federal research grants only adds to this tension!

Important Implications for Institutional Governance

Faculty are "funding" an ever greater portion of university research through competitively awarded grants/contracts…



…and they frequently provide funding for most (sometimes all) of their own salary from these awards.

When employees are responsible for funding their own salary, how does that impact the traditional employer-employee relationship?

Important Implications for Institutional Governance

- Are faculty pursuing knowledge or just "chasing available money?"
- How does an institution maintain balance between teaching, research and public service when funding for each varies so widely?
- As faculty work more closely with industry and become more dependent upon industry money to support their research, how do universities protect academic integrity and scientific impartiality?

Conflict of Interest Issues!

Last Thoughts for Today!

- The current federal budget crisis (and the overall mood of the country concerning the budget deficit) may jeopardize future funding of university-based research!
- The loss of future industries and the jobs these industries would create may be the unintended consequence of these cuts.
- This disturbing trend is not new - from 1970 to 1995 federal support for research in the physical sciences as a fraction of GDP declined by 54% and in engineering by 51%.

Last Thoughts for Today!

Reducing research funding to balance the budget is sort of like making an overweight aircraft flight-worthy by removing an engine!

Or, to use an agricultural example:

It's like eating your seed corn!

COMP 918: Research Administration for Scientists

The Federal Budgetary Process, Federal Funding for Research and UNC's Share!

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The U.S. Federal Budget

How does the budget process work? Where does the money go? And why should you care?

These are important questions for any citizen, but if you are interested in federal support for research, they are of particular importance.

The U.S. Federal Budget

How does the budget process work? Where does the money go? And why should you care?

Here are five reasons why you should care!

First, it's a lot of money and a part of it used to be yours!

- The federal government spends almost $4 trillion a year, 1/5 of the U.S. economy.
- More than 80 percent of the money comes directly from YOU through income taxes, payroll taxes and…

BORROWING!

Second, it's not possible to "do" policy in Washington without money!

- Bills can be passed, but without money policies can't be implemented.
- In these times of huge budget deficits, every program and expenditure has to be considered in the context of its impact on the budget.

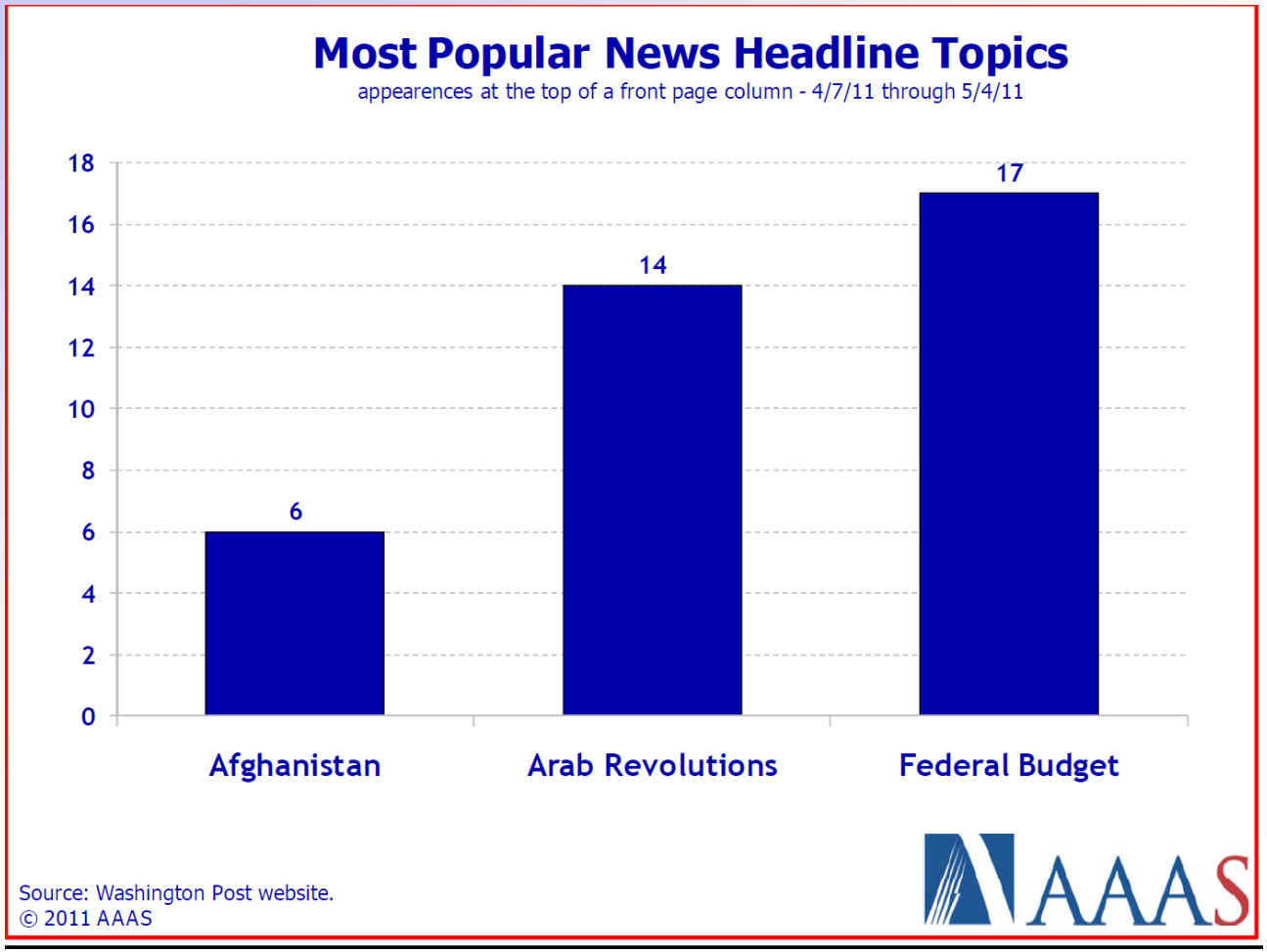
"Vision without funding is just a hallucination!"

Third, the budget process consumes much time and effort in Washington!

The Government is always involved with three budget years at a time:

- Current year appropriations are being "spent."
- The next year's budget has been "proposed" by the President and is being "disposed" by the Congress - budget resolutions, hearings, passage of 12 separate appropriations bills.
- Federal agencies and OMB are working on the following year budget requests.

Fourth, the media is obsessed with covering the budget and deficit!



Finally, the federal budget influences the health of U.S. science!

- The federal government spends ~ $150 billion a year on R&D.
- It funds nearly 75% of all university research and supports fellowships, scholarships, student loans, and other aid.
- R&D funding is in the discretionary portion of the federal budget, thus it is the most vulnerable to cuts!

There is no better way to measure the priorities of an organization than to examine where the organization spends its money.

The budget reveals what it really values!

We'll review the federal budget in a few moments, but first…

There is no better way to measure the priorities of an organization than to examine where the organization spends its money.

The budget reveals what it really values!

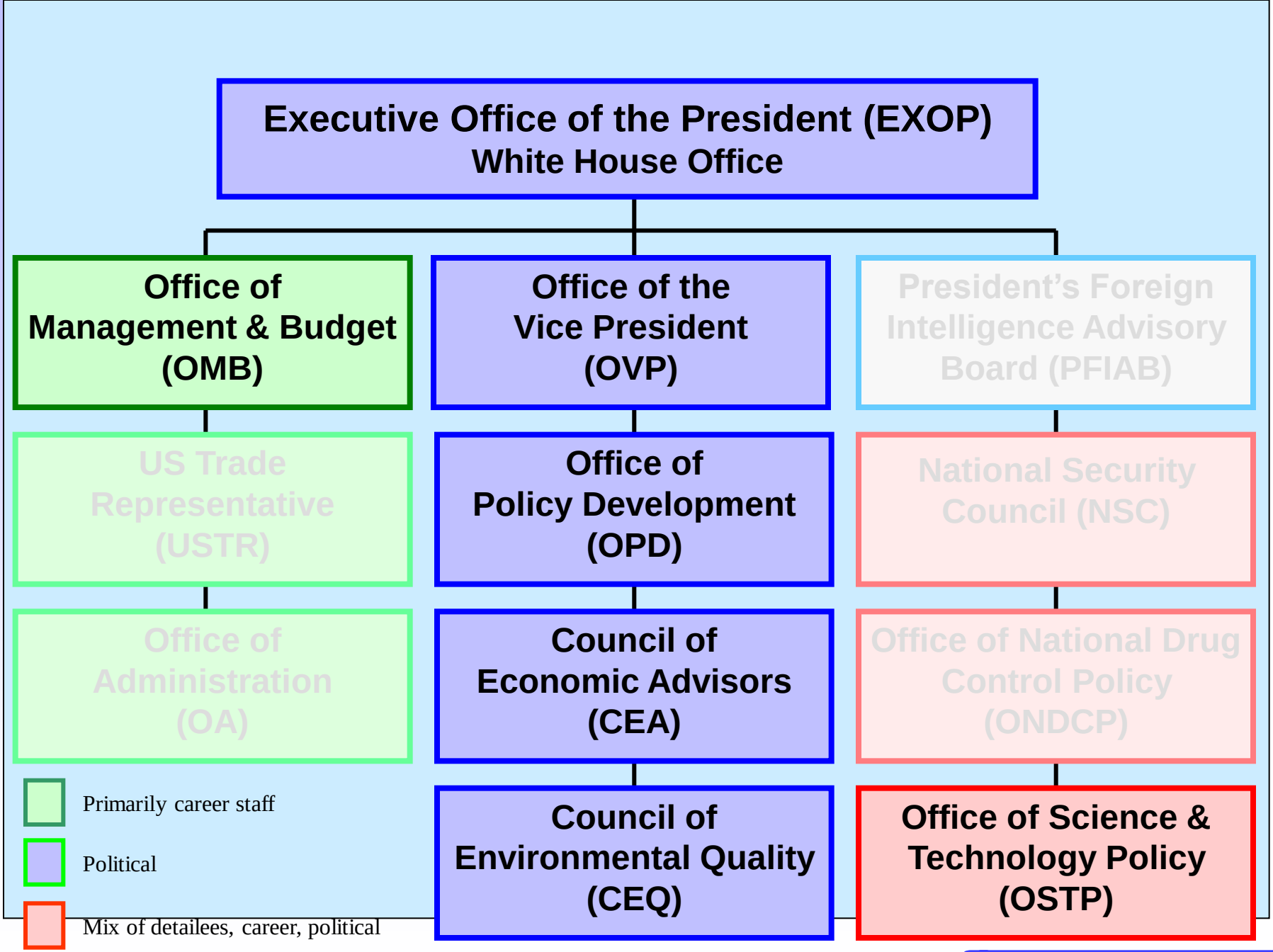
Let's look at the federal budgeting process to see how it works!

There is no better way to measure the priorities of an organization than to examine where the organization spends its money.

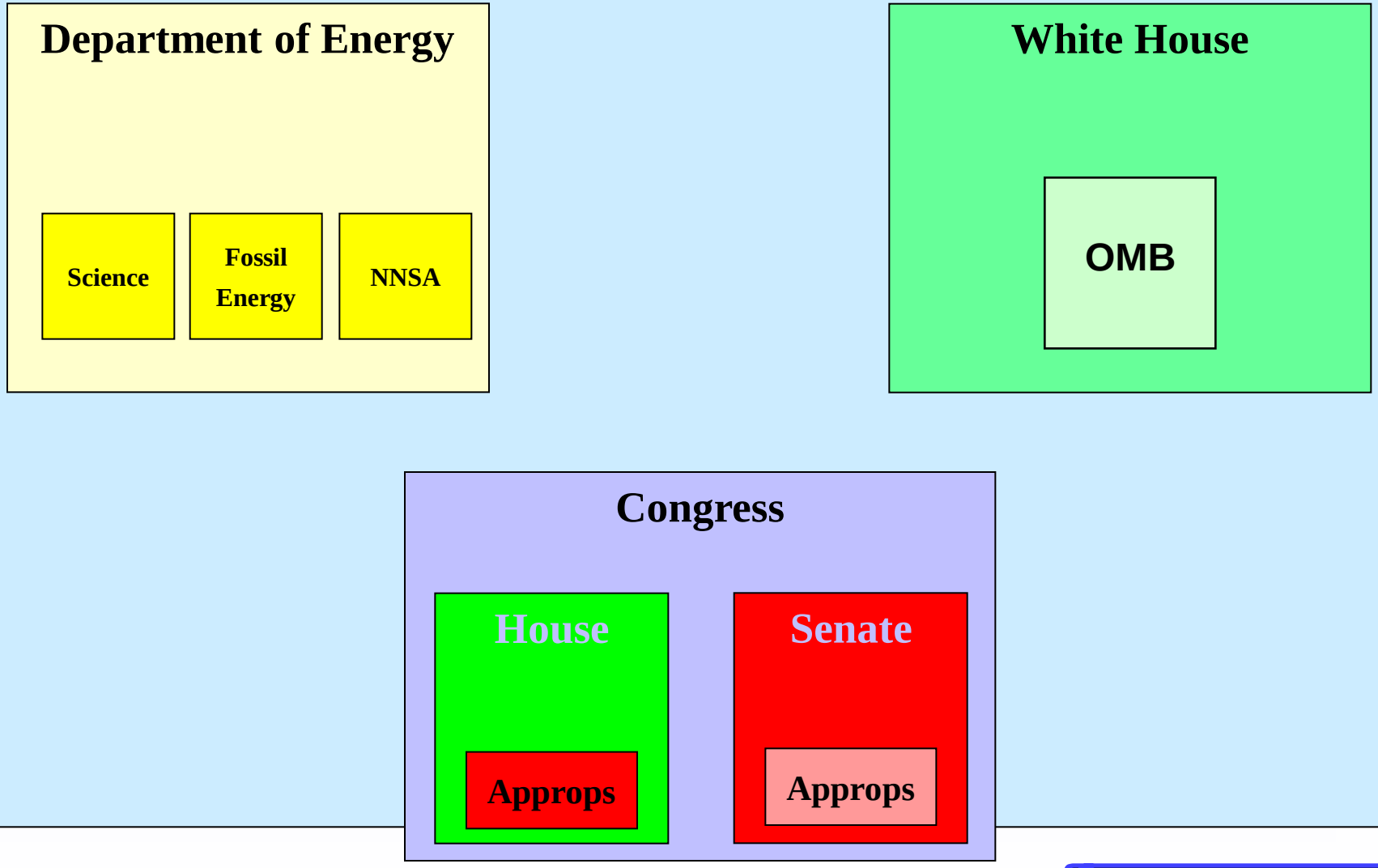
The budget reveals what it really values!

Let's look at the f udgeting proces rks!

Well, how it "sort of" works!


Executive Office of the President (EXOP)
White House Office
Office of Management & Budget (OMB)
Office of the Vice President (OVP)
President's Foreign Intelligence Advisory Board (PFIAB)
US Trade Representative (USTR)
Office of Policy Development (OPD)
National Security Council (NSC)
Office of Administration (OA)
Council of Economic Advisors (CEA)
Office of National Drug Control Policy (ONDCP)
Council of Environmental Quality (CEQ)
Office of Science & Technology Policy (OSTP)
Primarily career staff
Political
Mix of detailees, career, political

The Budget Process



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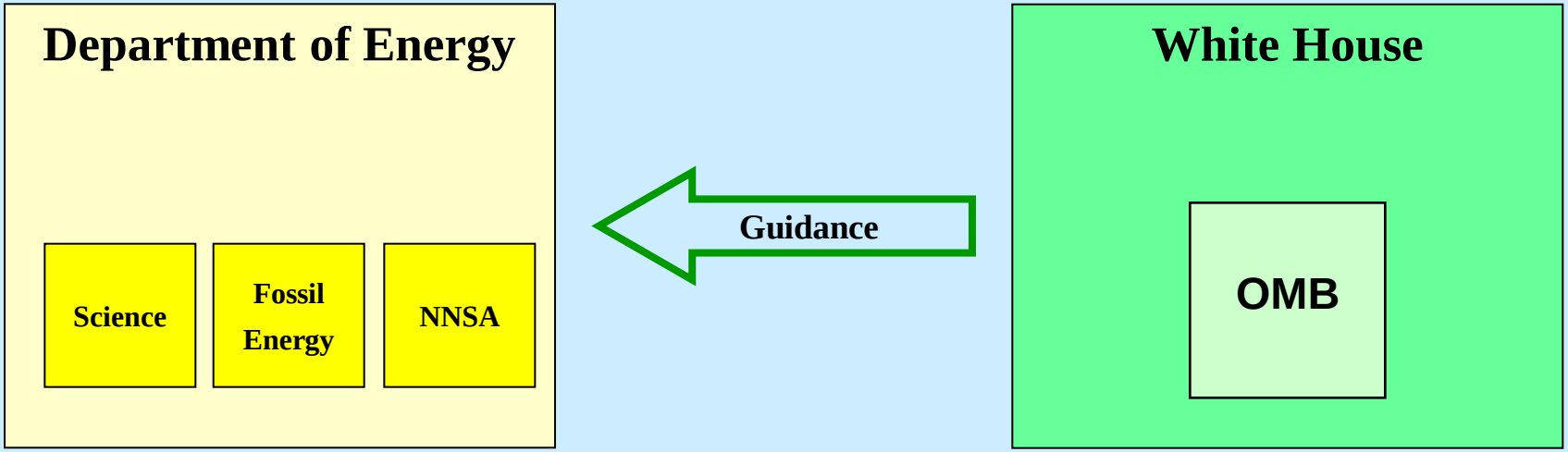
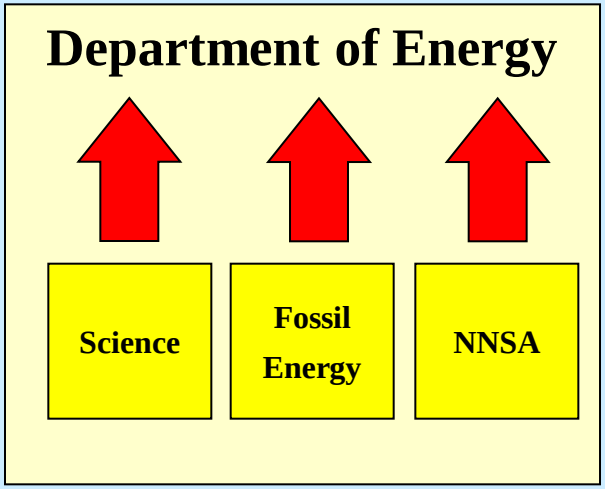
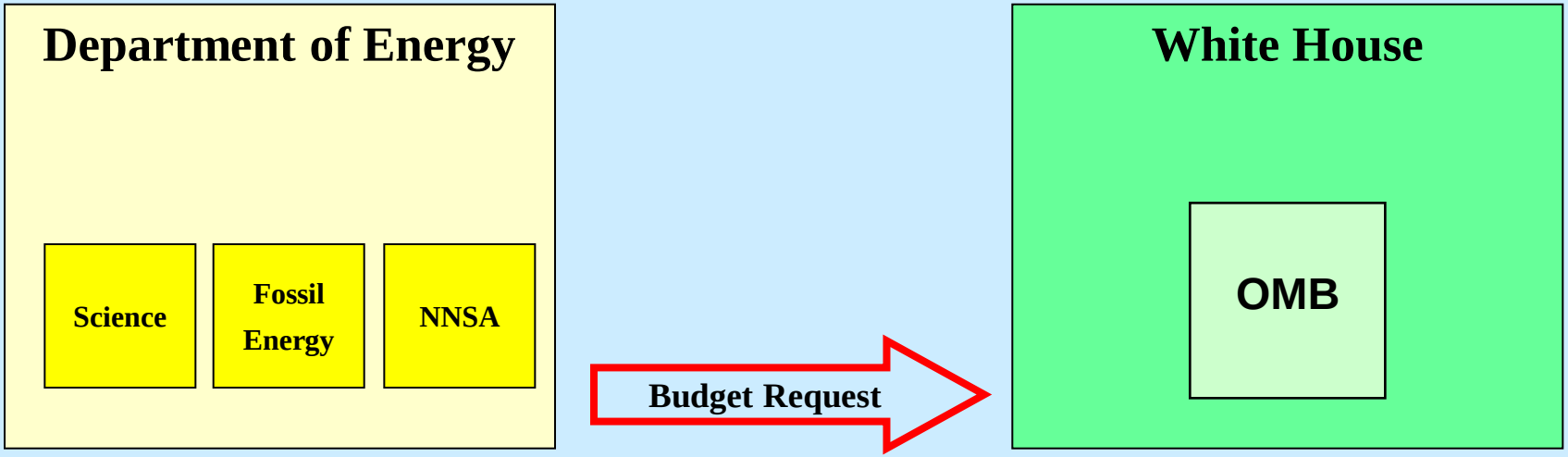


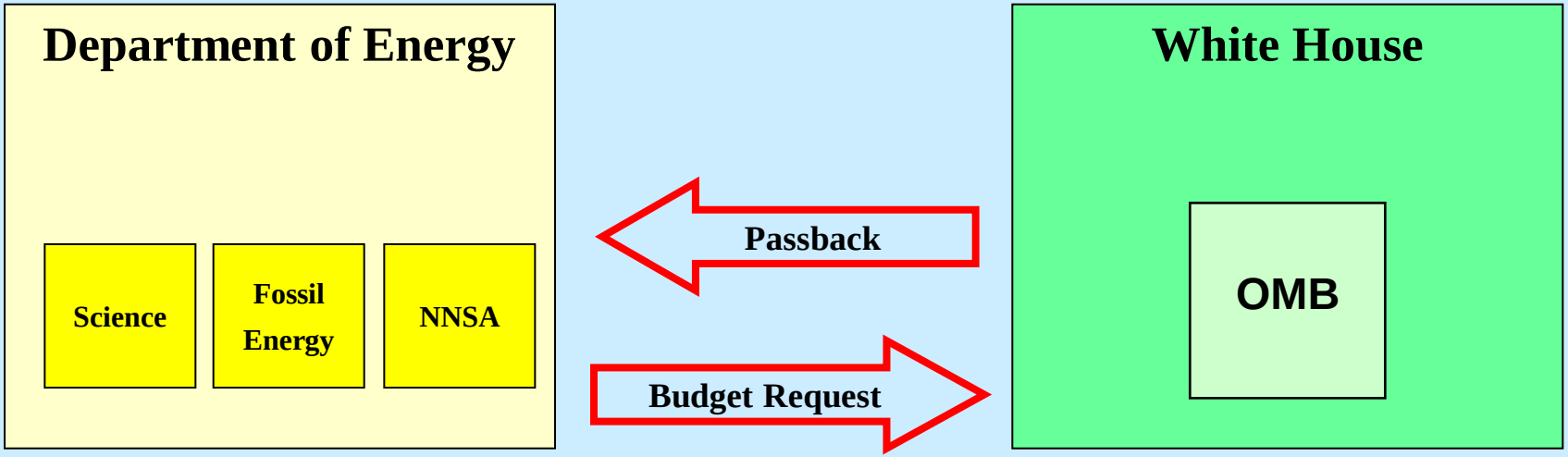
The Budget Process



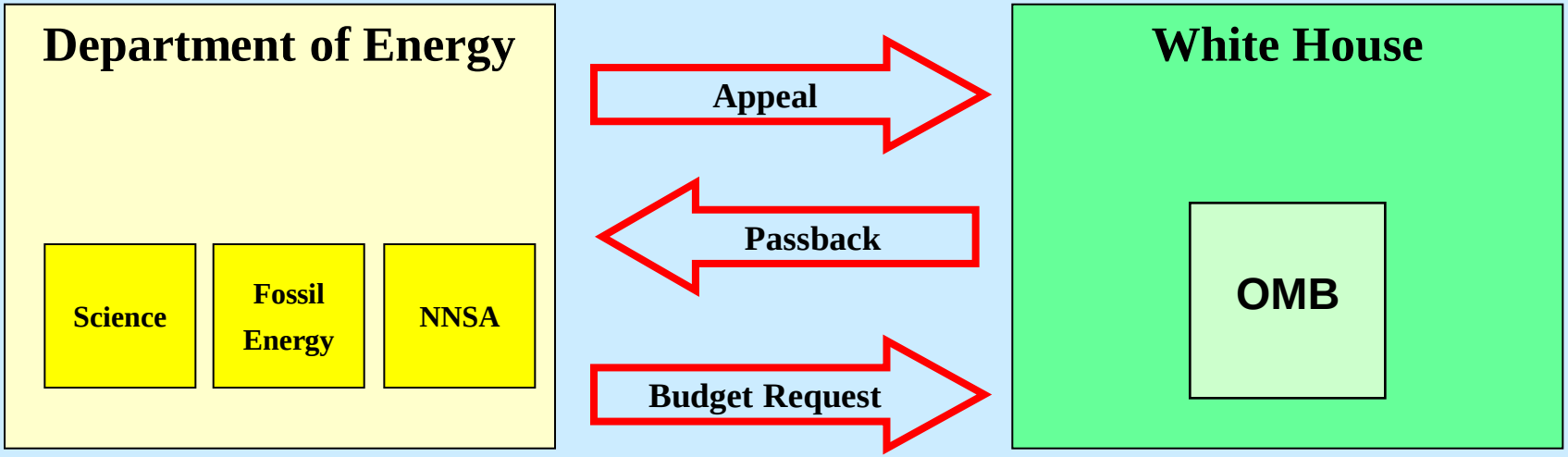
The Budget Process



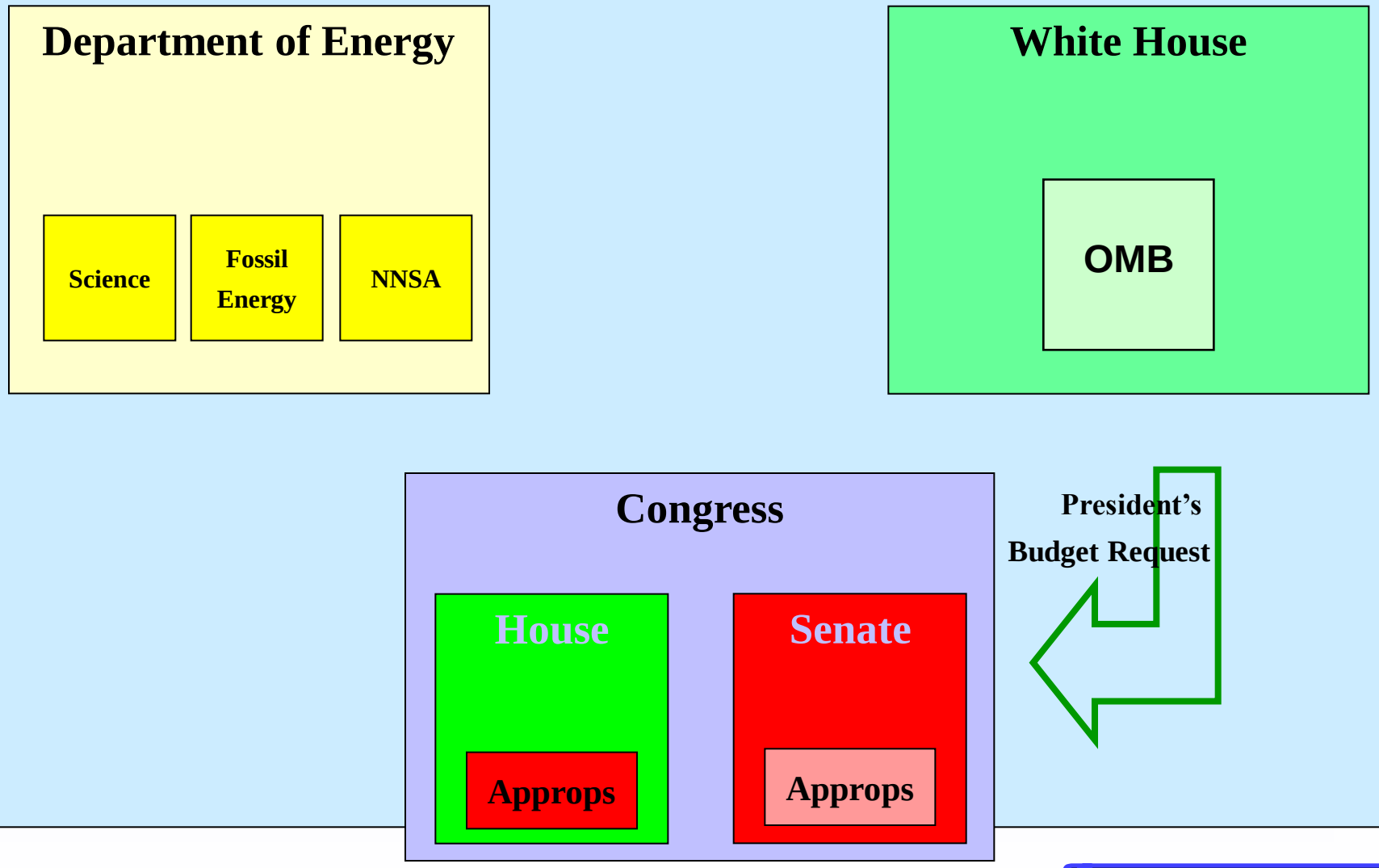
The Budget Process



The Budget Process



The Budget Process



The Budget Process

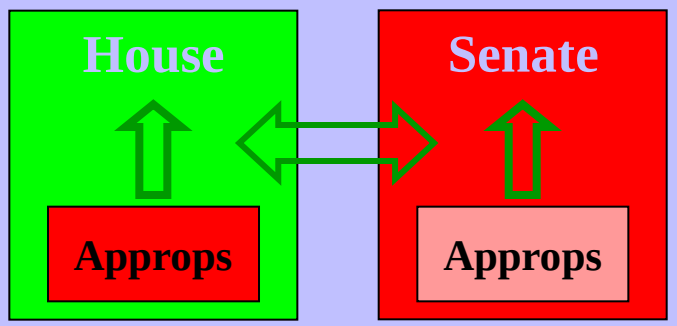
Department of Energy

- Science
- Fossil Energy
- NNSA

White House

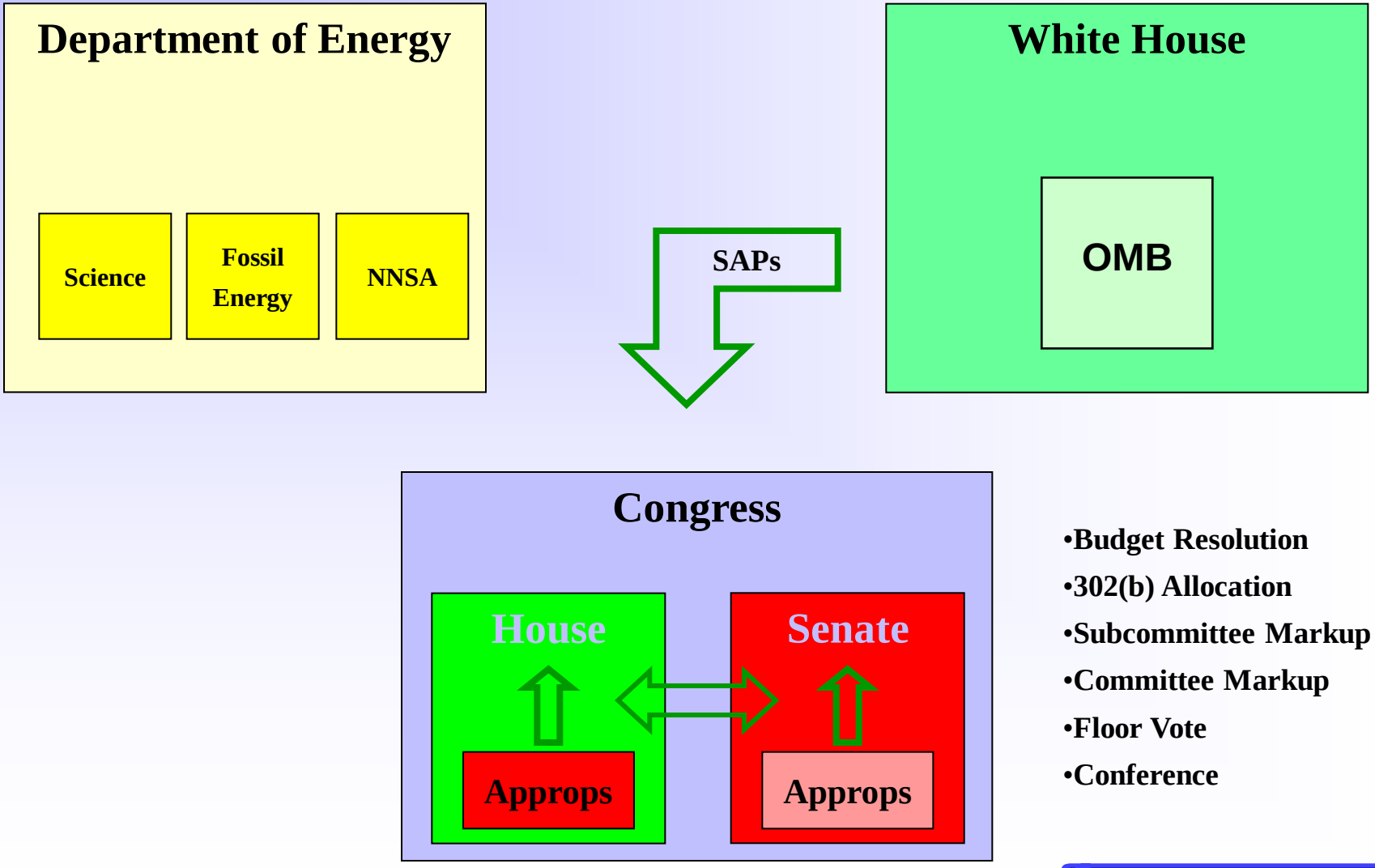
- OMB

Congress



- Budget Resolution
- 302(b) Allocation
- Subcommittee Markup
- Committee Markup
- Floor Vote
- Conference

The Budget Process



- Budget Resolution
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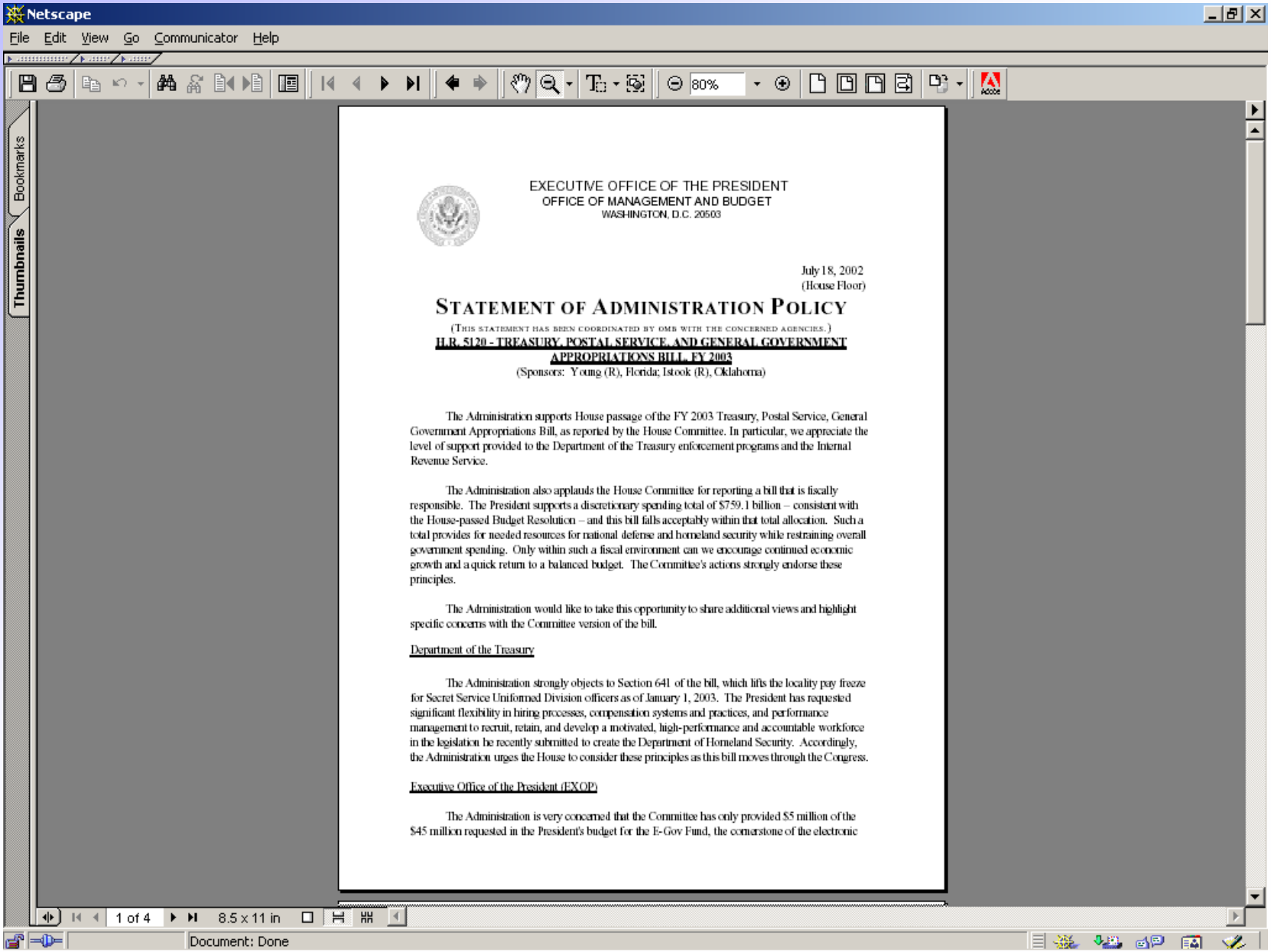
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EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF MANAGEMENT AND BUDGET
WASHINGTON, D.C. 20503
July 18, 2002
(House Floor)
STATEMENT OF ADMINISTRATION POLICY
(THIS STATEMENT HAS BEEN COORDINATED BY OMB WITH THE CONCERNED AGENCIES.)
H.R. 5120 - TREASURY, POSTAL SERVICE, AND GENERAL GOVERNMENT APPROPRIATIONS BILL, FY 2003
(Sponsors: Young (R), Florida; Istook (R), Oklahoma)
The Administration supports House passage of the FY 2003 Treasury, Postal Service, General Government Appropriations Bill, as reported by the House Committee. In particular, we appreciate the level of support provided to the Department of the Treasury enforcement programs and the Internal Revenue Service.
The Administration also applauds the House Committee for reporting a bill that is fiscally responsible. The President supports a discretionary spending total of $759.1 billion – consistent with the House-passed Budget Resolution – and this bill falls acceptably within that total allocation. Such a total provides for needed resources for national defense and homeland security while restraining overall government spending. Only within such a fiscal environment can we encourage continued economic growth and a quick return to a balanced budget. The Committee's actions strongly endorse these principles.
The Administration would like to take this opportunity to share additional views and highlight specific concerns with the Committee version of the bill.
Department of the Treasury
The Administration strongly objects to Section 641 of the bill, which lifts the locality pay freeze for Secret Service Uniformed Division officers as of January 1, 2003. The President has requested significant flexibility in hiring processes, compensation systems and practices, and performance management to recruit, retain, and develop a motivated, high-performance and accountable workforce in the legislation he recently submitted to create the Department of Homeland Security. Accordingly, the Administration urges the House to consider these principles as this bill moves through the Congress.
Executive Office of the President (EXOP)
The Administration is very concerned that the Committee has only provided $5 million of the $45 million requested in the President's budget for the E-Gov Fund, the cornerstone of the electronic
1 of 4
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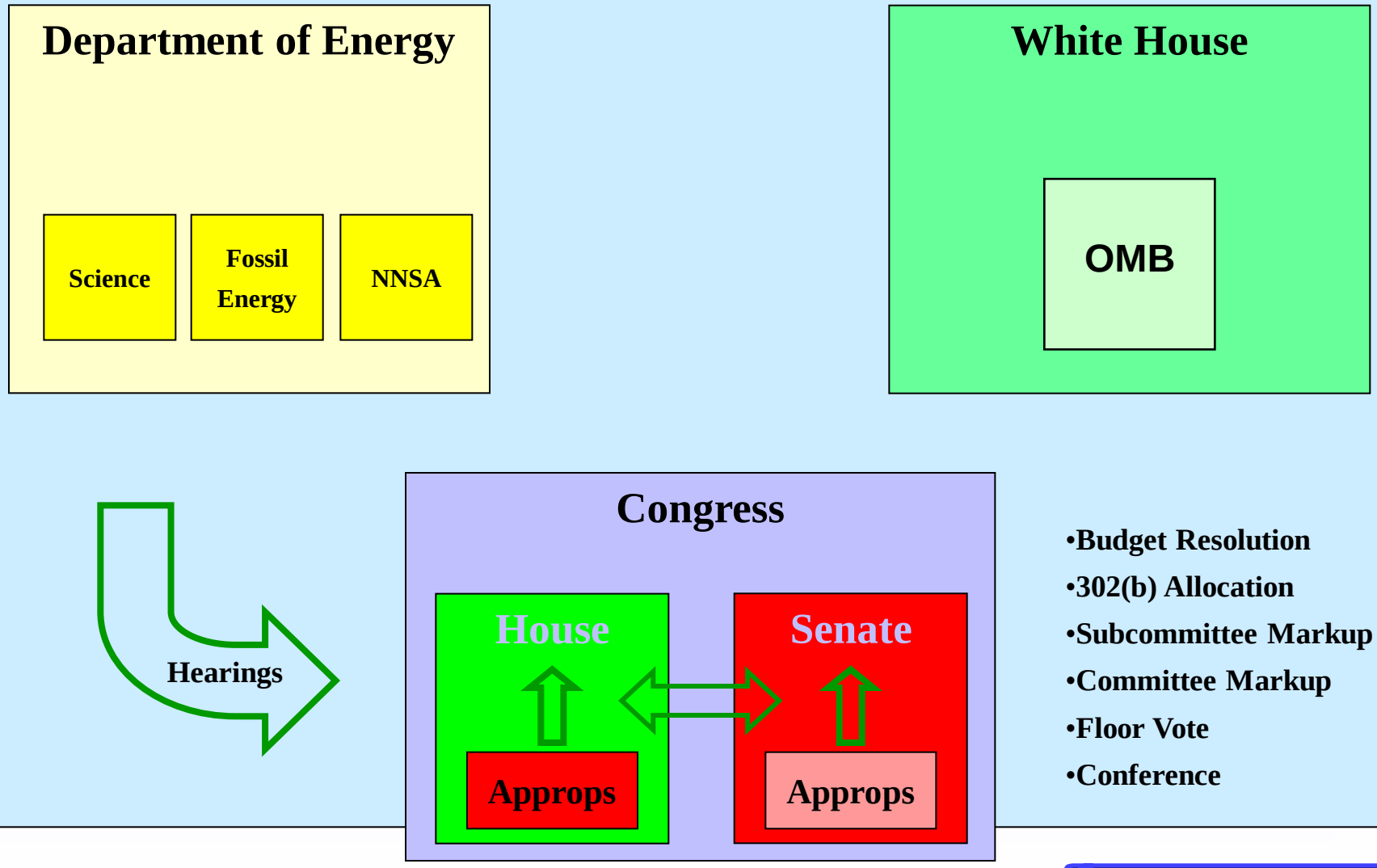
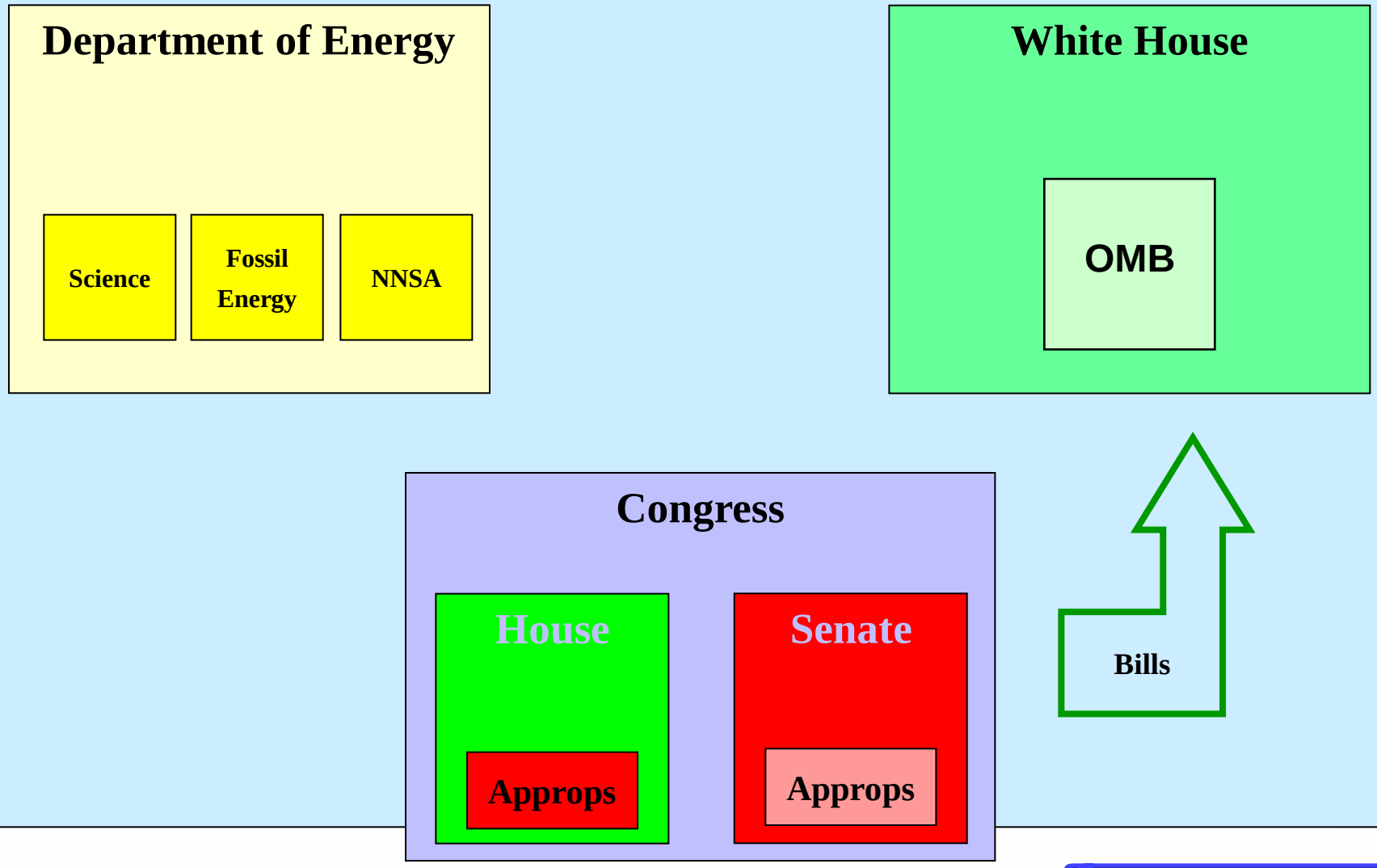
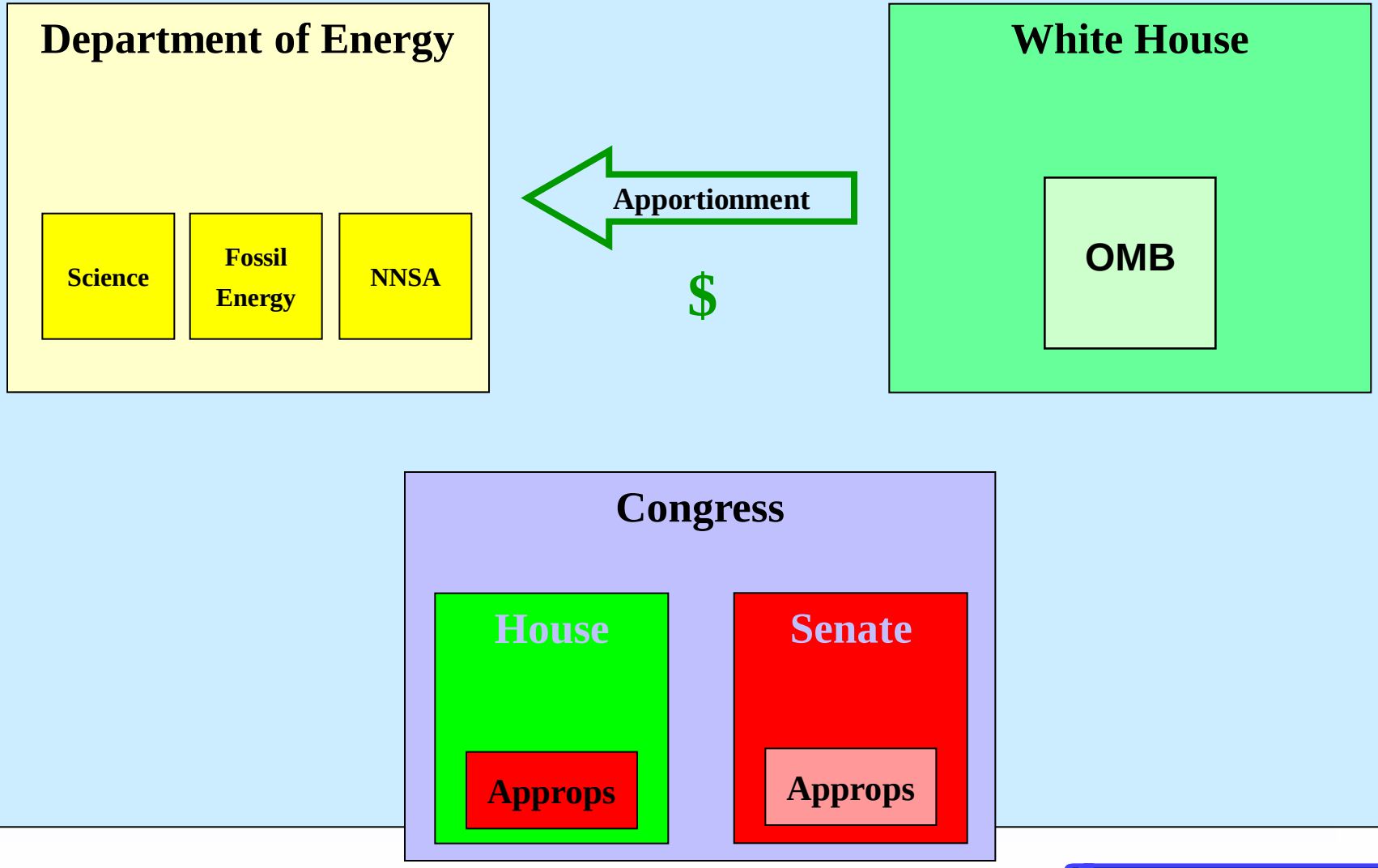
The Budget Process



The Budget Process



The Budget Process



BUDGET GLOSSARY

Glossary of Federal Budget Terms

Gross Domestic Product (GDP): The value of all finished goods and services produced in a country during a given period - usually a fiscal year. GDP serves as the principal measure of the size of a country's economy.

Fiscal Year: The federal government's accounting period which begins October 1 and ends September 30. Most state government fiscal years, North Carolina included, run from July 1 to June 30.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Congressional Budget Office (CBO): A non-partisan legislative agency that assists Congress in preparing and analyzing all budget-related issues. The CBO is responsible for estimating the budgetary effects of all spending and revenue bills, commonly called a "mark-up" and the process is referred to as "scoring a bill."

Office of Management and Budget (OMB): An executive agency located in the White House that prepares the President's budget for submission to Congress, manages the distribution and expenditure of appropriated funds, and distributes budget and spending rules applicable to all federal agencies.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Authorization: Legislation that either establishes or continues a federal program or agency, specifies its general goals and conduct, and sets a ceiling for the amount of money that can later be appropriated. Total accumulated appropriations may not exceed the amount authorized for a given program, but Congress is under no obligation to fully or even partially fund any program.

Appropriation: The amount of funding Congress provides for a federal program to spend in a given fiscal year. The appropriation bill may also set the terms under which the funds may be spent.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Sequestration: The Congressional Research Service defines sequestration as "the permanent cancellation of budgetary resources by a uniform percentage. This uniform percentage reduction is applied to all programs, projects, and activities within a budget account."

Authority for sequestration can come from either the Balanced Budget and Emergency Deficit Control Act of 1985 or the Pay As You Go Act of 2010. In the later case, the federal government must continue to pay Social Security, unemployment benefits, veterans benefits, Medicaid, food stamps, and Supplemental Security Income. Medicare may be cut under sequestration authorized by this bill, but reductions cannot be more than 2 percent.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Continuing Resolution (CR): Legislation that extends appropriations for specific ongoing programs when the regular appropriation bills have not been enacted by the beginning of the fiscal year - October 1. A CR may authorize spending at the previous year's level or at some percentage increase or decrease. It is intended to cover brief periods (weeks) to provide time for Congress to complete work on the new budget. However, when Congress fails to approve new budgets (increasingly common in recent years), they have resorted to passing many consecutive CRs making effective planning difficult at all levels of government.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Discretionary Programs: Programs funded by one of the twelve (12) annual congressional appropriation bills - currently about 1/3rd of the federal budget.

Discretionary Spending Cap: A self-imposed limit that Congress places on the total amount of budget authority and outlay for all discretionary programs in a given fiscal year.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Earmarks: Often referred to as "pork" these are appropriations that fund specific projects, e.g., a new research center at a university or a bridge in a particular state. Earmarks by-pass the normal process within an agency for determining what projects to fund - in the case of science, by peer review. The cost of earmarks are often charged against the agency's appropriation, thus limiting the funds available for projects through the agency's normal funding process.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Hard Earmarks: Contained in legislative text, therefore required by law.

Soft Earmarks: Contained in a Congressional committee report only, therefore not required by law.

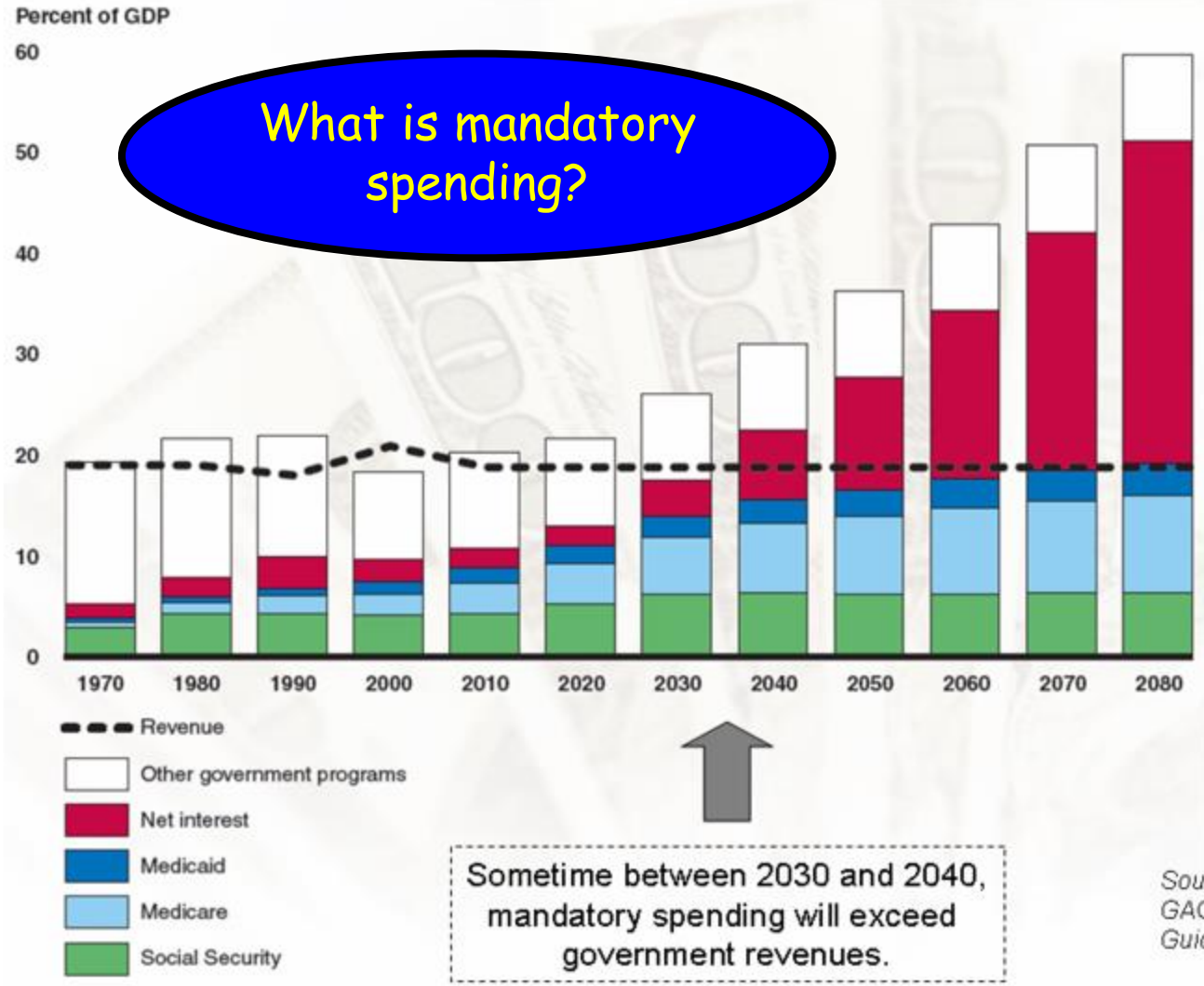
- Not binding, but customarily acted upon.
- Most earmarks are soft earmarks - not as easily traceable to a specific Congressman.
- FY 2010 there were 9,192 soft earmarks for a total of $11.1 billion.

BUDGET GLOSSARY

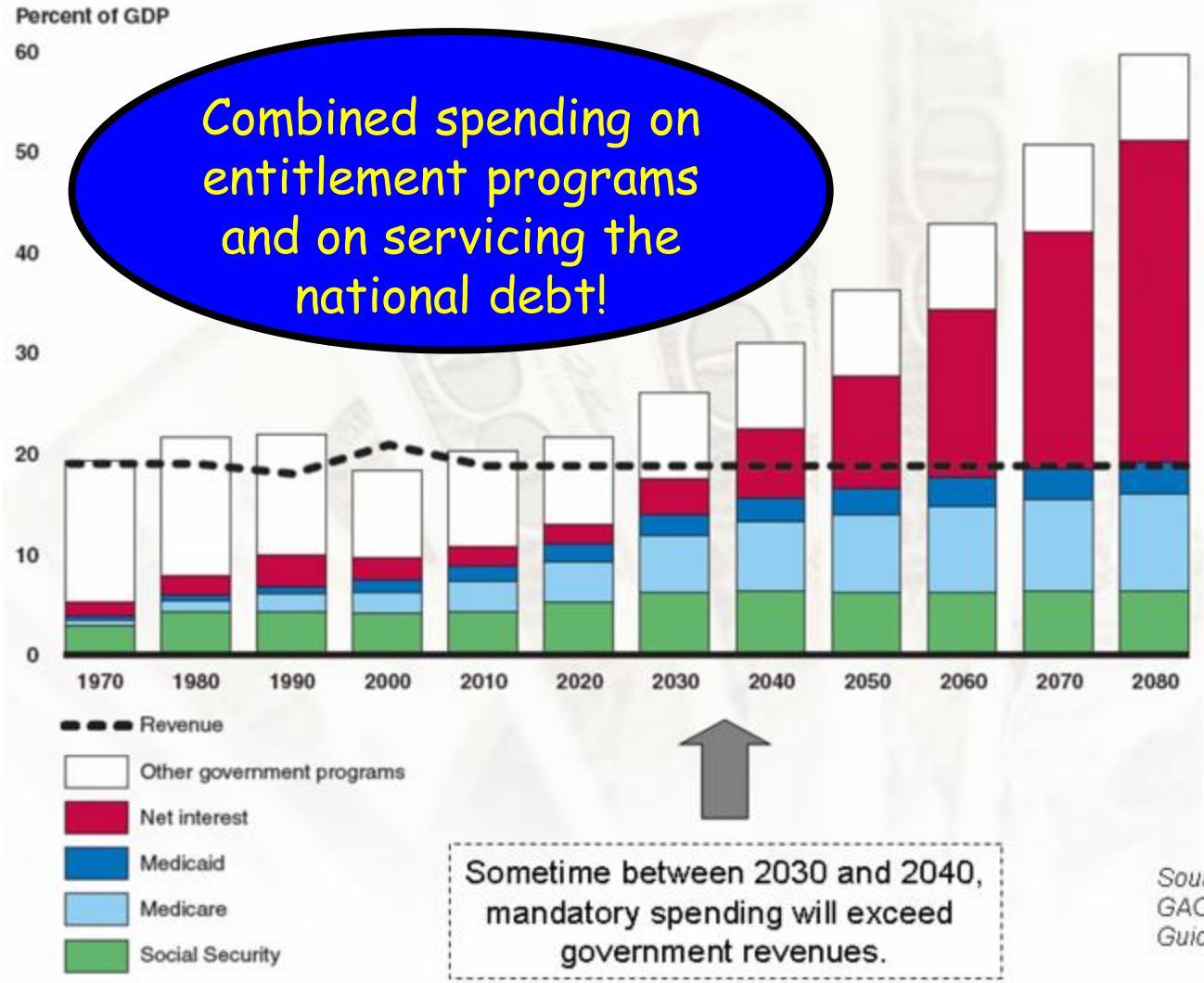
Glossary of Federal Budget Terms

Entitlement: A program which mandates the payment of benefits to any person meeting certain eligibility requirements established by statute. Therefore, the total amount spent is determined by the number of people applying for and meeting the eligibility requirements, not by annual congressional appropriations. Entitlement programs include Social Security, Medicare and Medicaid.

The Risks of Growing Entitlement Spending



The Risks of Growing Entitlement Spending

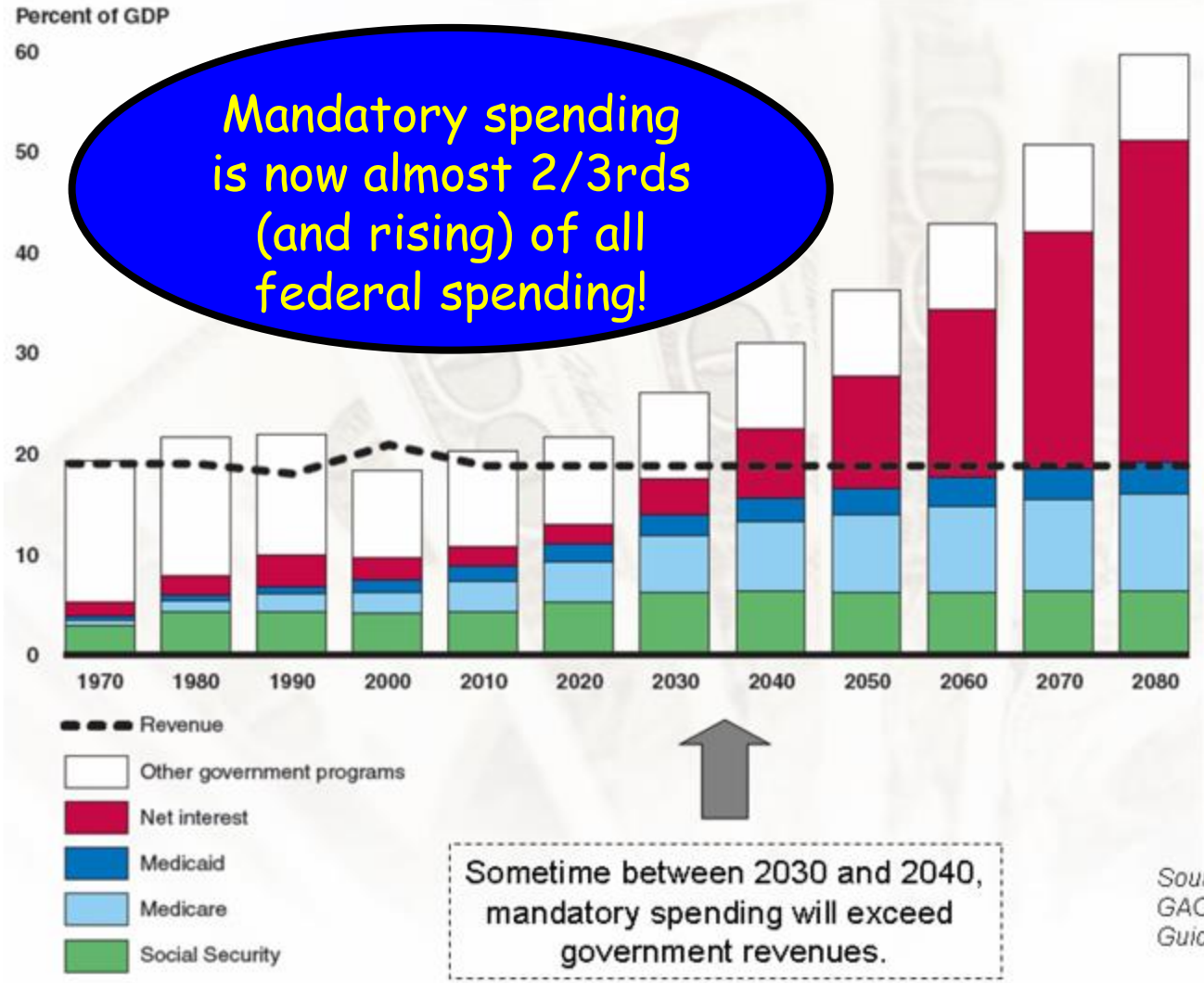


Combined spending on entitlement programs and on servicing the national debt!

Sometime between 2030 and 2040, mandatory spending will exceed government revenues.

Source: GAO Citizen's Guide 2007

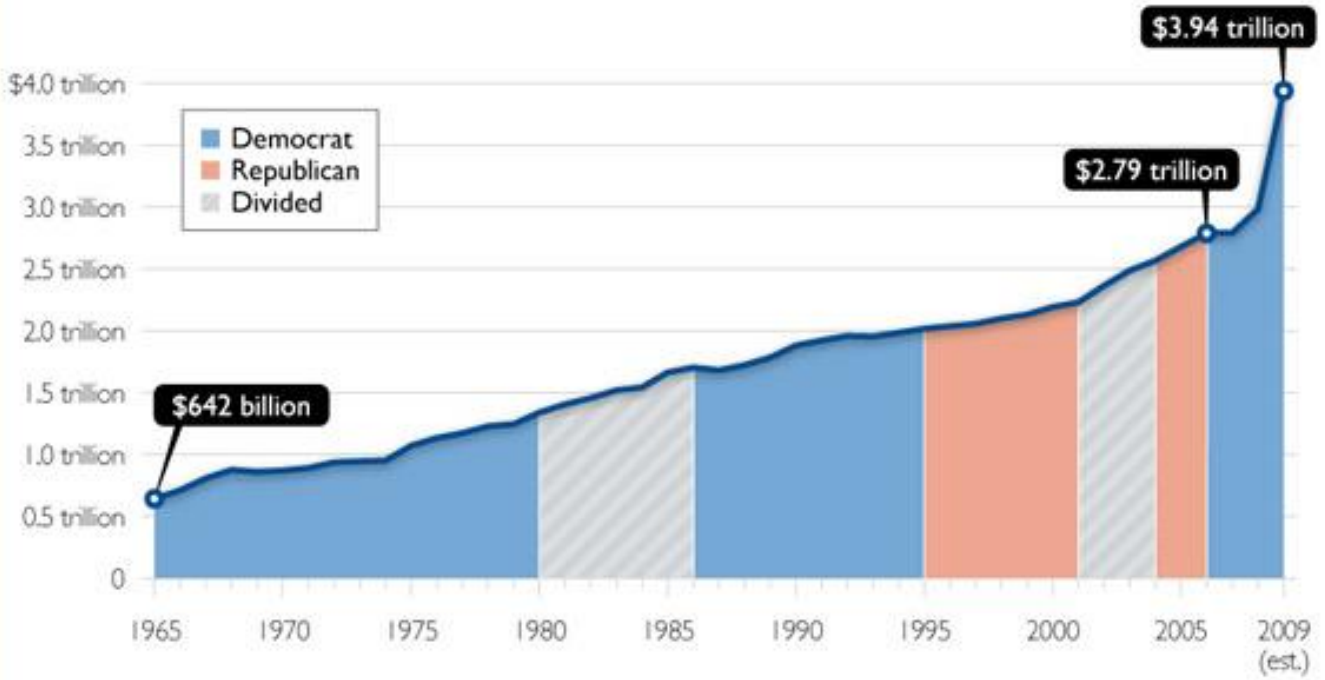
The Risks of Growing Entitlement Spending



Federal Spending Has Increased Steadily Regardless of Congressional Leadership

Real annual federal spending has more than quintupled since 1965 and more than doubled since 1980. Since 2006, federal spending has increased by nearly $1 trillion.

Total Federal Spending in Inflation-Adjusted Dollars (2008)



Source: White House Office of Management and Budget.

Federal Spending Chart 1 • 2009 Federal Revenue and Spending Book of Charts heritage.org

BUDGET GLOSSARY

Glossary of Federal Budget Terms

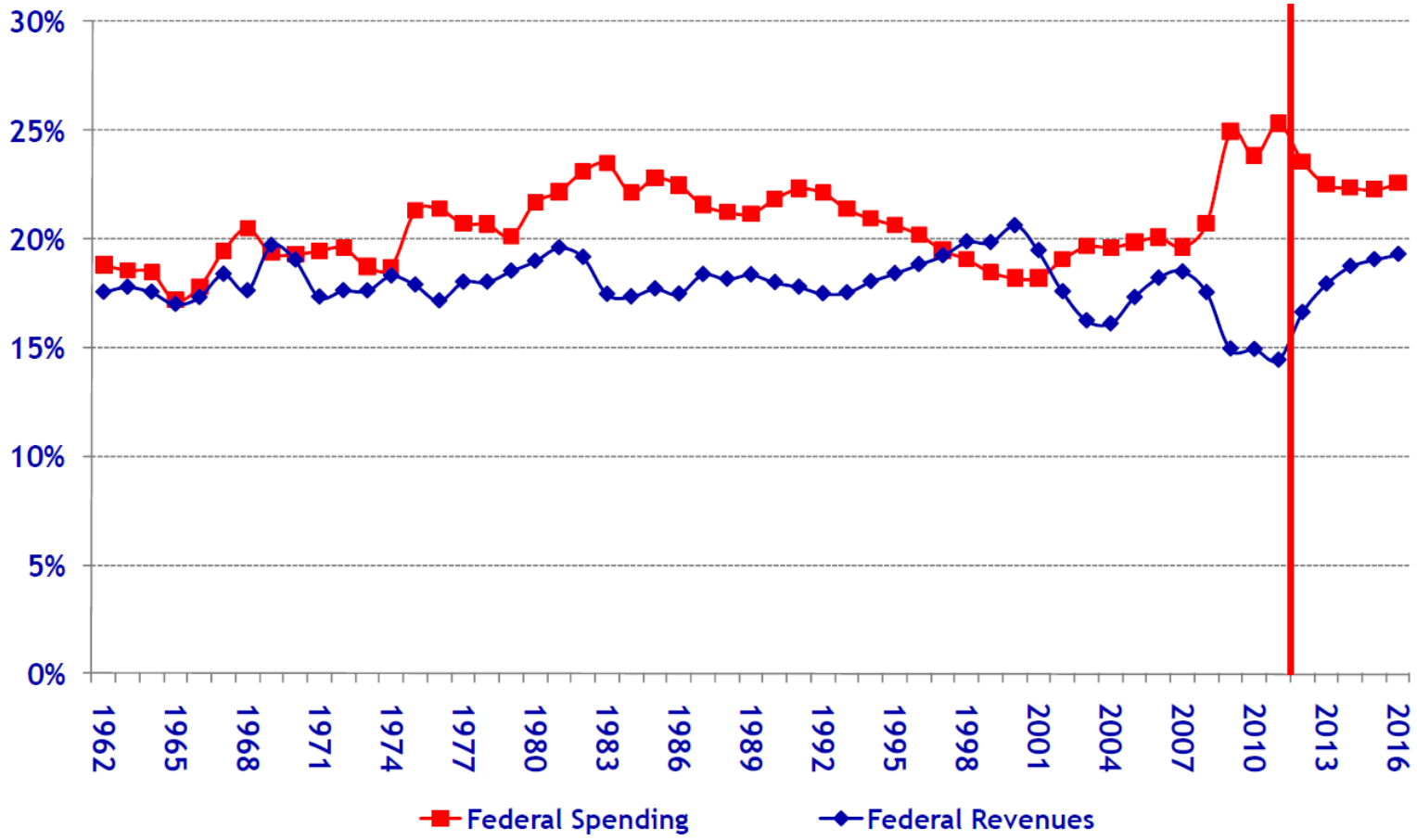
Deficit: The amount by which the government's spending exceeds its revenues in a single fiscal year. In 2011 nearly 40 cents of every dollar spent was borrowed!

Unified Deficit: The most commonly used measure of the federal deficit, it includes all federal spending and all federal revenues.

Federal Funds Ceiling: A measure of the federal deficit that excludes the spending and revenue from federal government trust funds such as Social Security.

Federal Spending and Revenues

(percent of GDP)



Source: *Budget of the United States Government, FY 2012.*
FY 2011 data are estimates. FY 2012-2016 data are budget projections.
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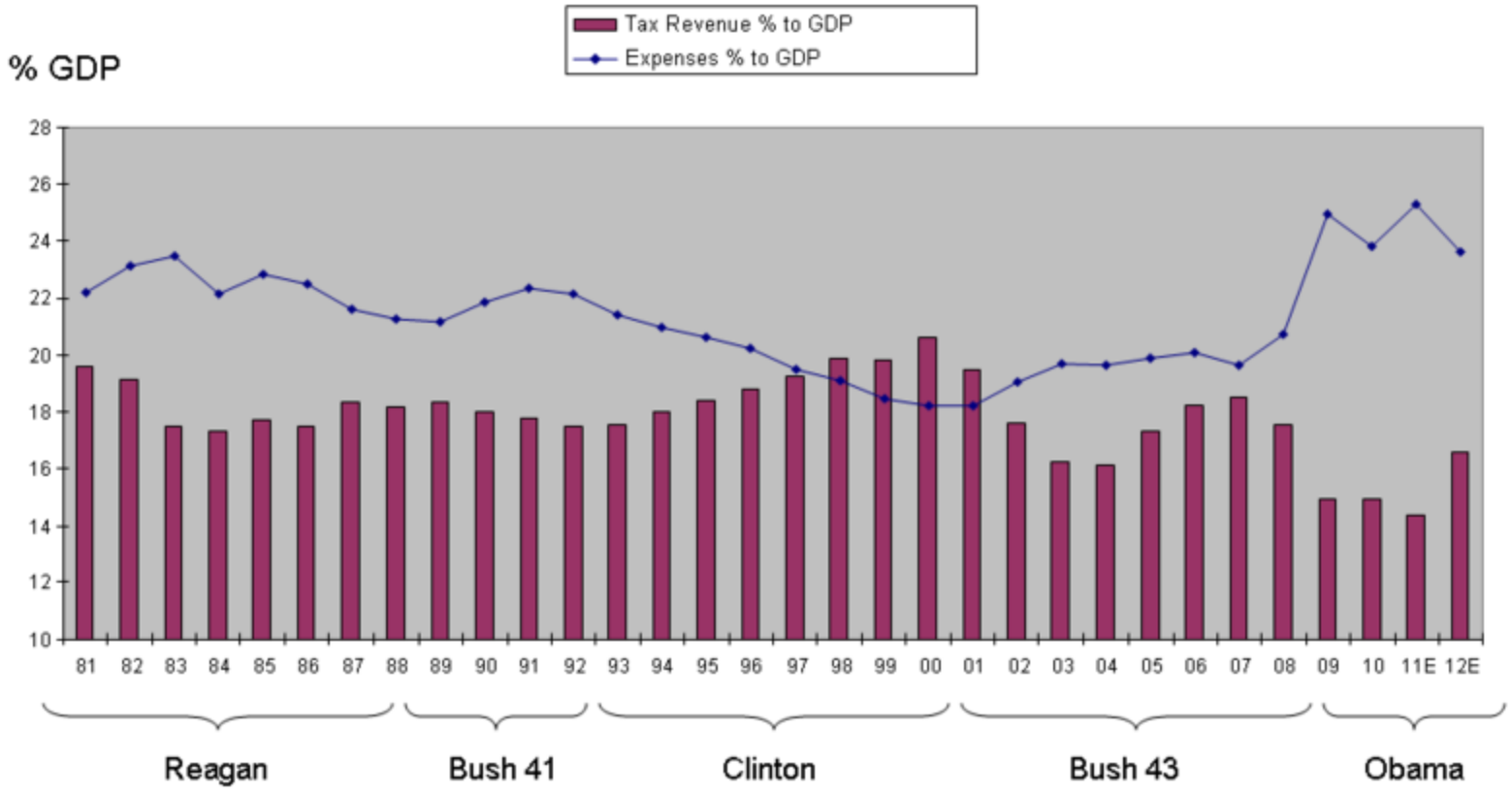
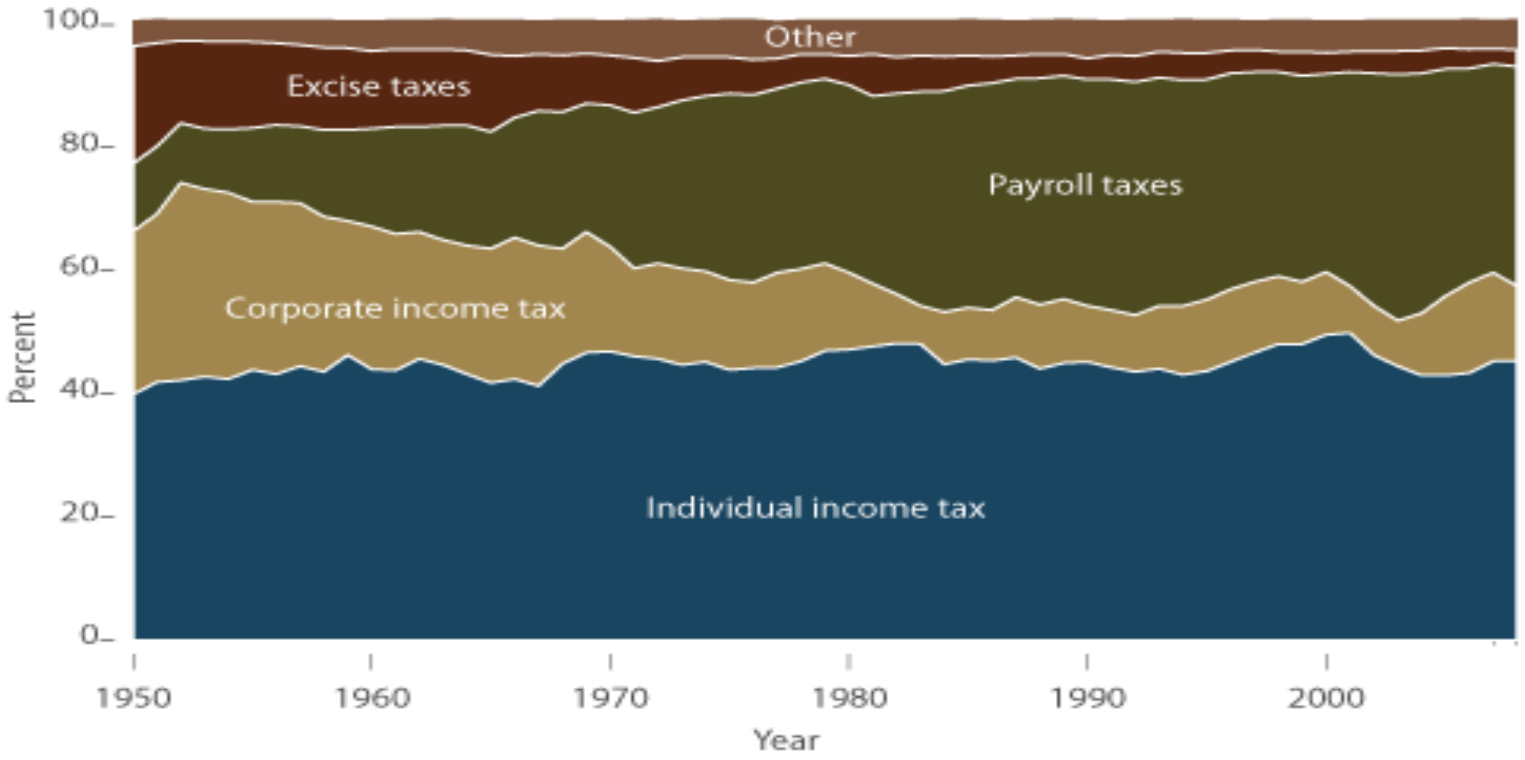
Federal Tax Revenue & Expenses as % to GDP (FY 1981 – 2012)



Averages	Reagan	Bush 41	Clinton	Bush 43	Obama
Expenses:	22.4	21.9	19.8	19.6	24.4
Revenue:	18.2	17.9	19.0	17.6	15.2

Source Data: Congressional Budget Office; 2011 Budget

Figure 2. Sources of Federal Revenue, Fiscal 1950-2008



Source: 1950-2006:Budget of the United States Government, Fiscal Year 2008, HISTORICAL TABLES, Table 2.1 Receipts by Source: 1934-2012, available at http://www.whitehouse.gov/omb/budget/fy2008/sheets/hist02z3.xls 2007-2008: Congressional Budget Office, A Preliminary Analysis of the President's Budget and an Update of CBO's Budget and Economic Outlook, March 2009, Table F-3, available at http://www.cbo.gov/ftpdocs/100xx/doc10014/HistoricalMar09.pdf

BUDGET GLOSSARY

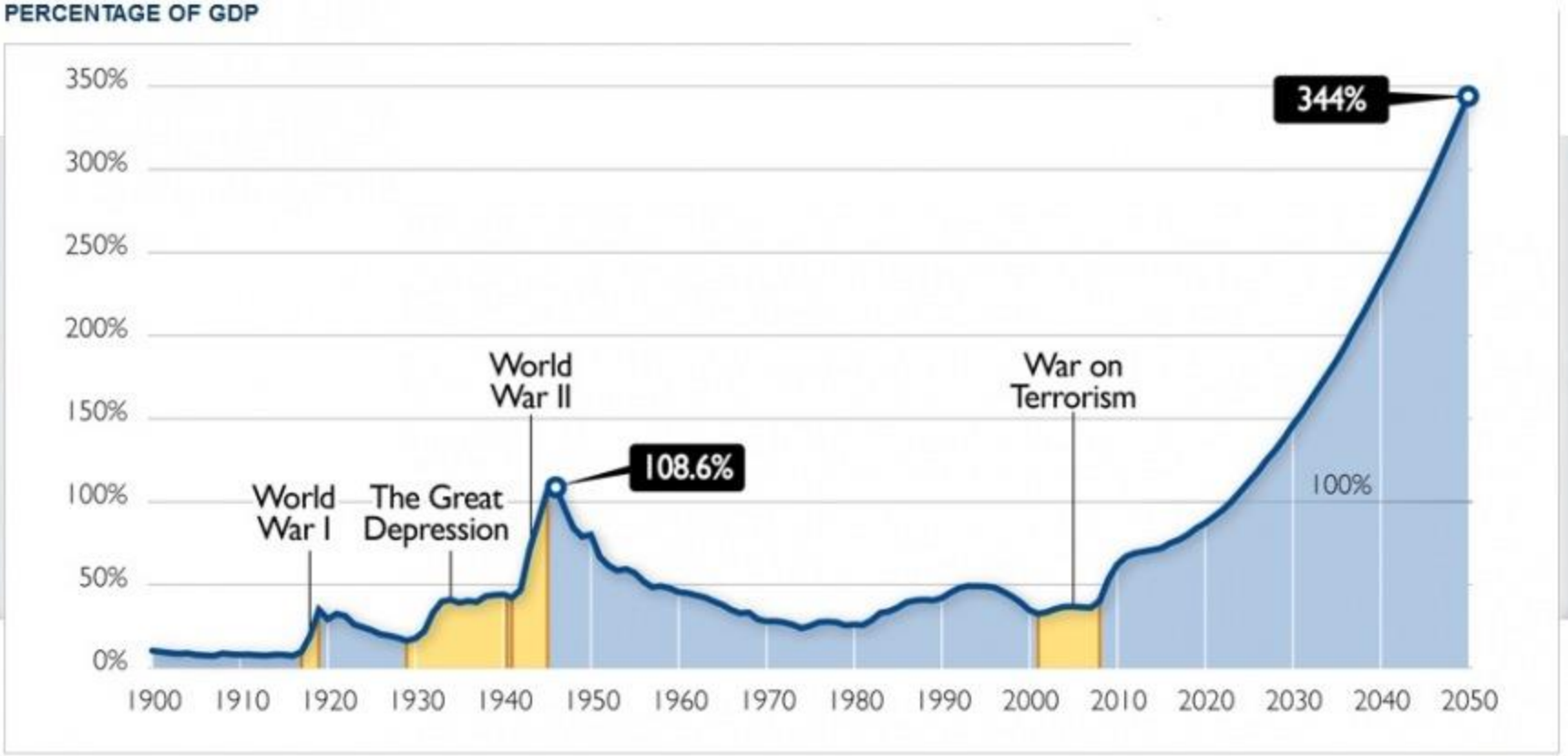
Glossary of Federal Budget Terms

Debt: The total accumulated amount of money the federal government has borrowed and not paid back from President Washington's administration to President Obama's - currently over $16 trillion.

Treasury Bills: The government "borrows" by selling T-bills which pay interest and mature on specific future dates. Example – one might purchase a $100 T-bill for $92. At a specified date in the future the T-bill will mature and be redeemable for $100. The government normally pays-off maturing T-bills with cash derived from issuing new T-bills!

National Debt Set to Skyrocket

In the past, wars and the Great Depression contributed to rapid but temporary increases in the national debt. Over the next few decades, runaway spending on Medicare, Medicaid, and Social Security will drive the debt to unsustainable levels.



Source: Heritage Foundation calculations based on data from the U.S. Department of the Treasury, Institute for the Measurement of Worth, Congressional Budget Office, and White House Office of Management and Budget.

Chart 13 *of* 24

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Debt Ceiling: A statutory limit imposed on the total allowable federal debt. The ceiling can only be raised by an act of Congress.

History - A statutorily imposed debt ceiling limit has been in effect since 1917 when Congress passed the Second Liberty Bond Act. Prior to that time Congress limited the amount of debt by virtue of its authority to approve or disapprove of individual bonds. This law allowed the executive branch to issue bonds and take on additional debt without congressional approval, as long as the debt fell under the statutory debt ceiling.

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Debt Ceiling: A statutory limit imposed on the total allowable federal debt. The ceiling can only be raised by an act of Congress.

If Congress fails to raise the debt ceiling before it is exceeded by debt obligations, the U.S. Treasury would neither have adequate funds to meet the government's obligations nor would it have the authority to borrow additional funds. This would result in default by the federal government – a situation which has never occurred!

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Debt Ceiling: A statutory limit imposed on the total allowable federal debt. The ceiling can only be raised by an act of Congress.

Think of the debt ceiling as the borrowing limit on a credit card!

And you're only allowed to have one credit card!

BUDGET GLOSSARY

Glossary of Federal Budget Terms

Debt Held by the Public: Federal debt held by all investors outside the federal government including individuals, corporations, state and local governments, the Federal Reserve banking system, and foreign governments. When the debt held by the Federal Reserve is excluded, the remaining amount is referred to as privately held debt.

Debt Held by Government Accounts: Federal debt held by the federal government itself. Most of this debt is held by trust funds, such as Social Security.

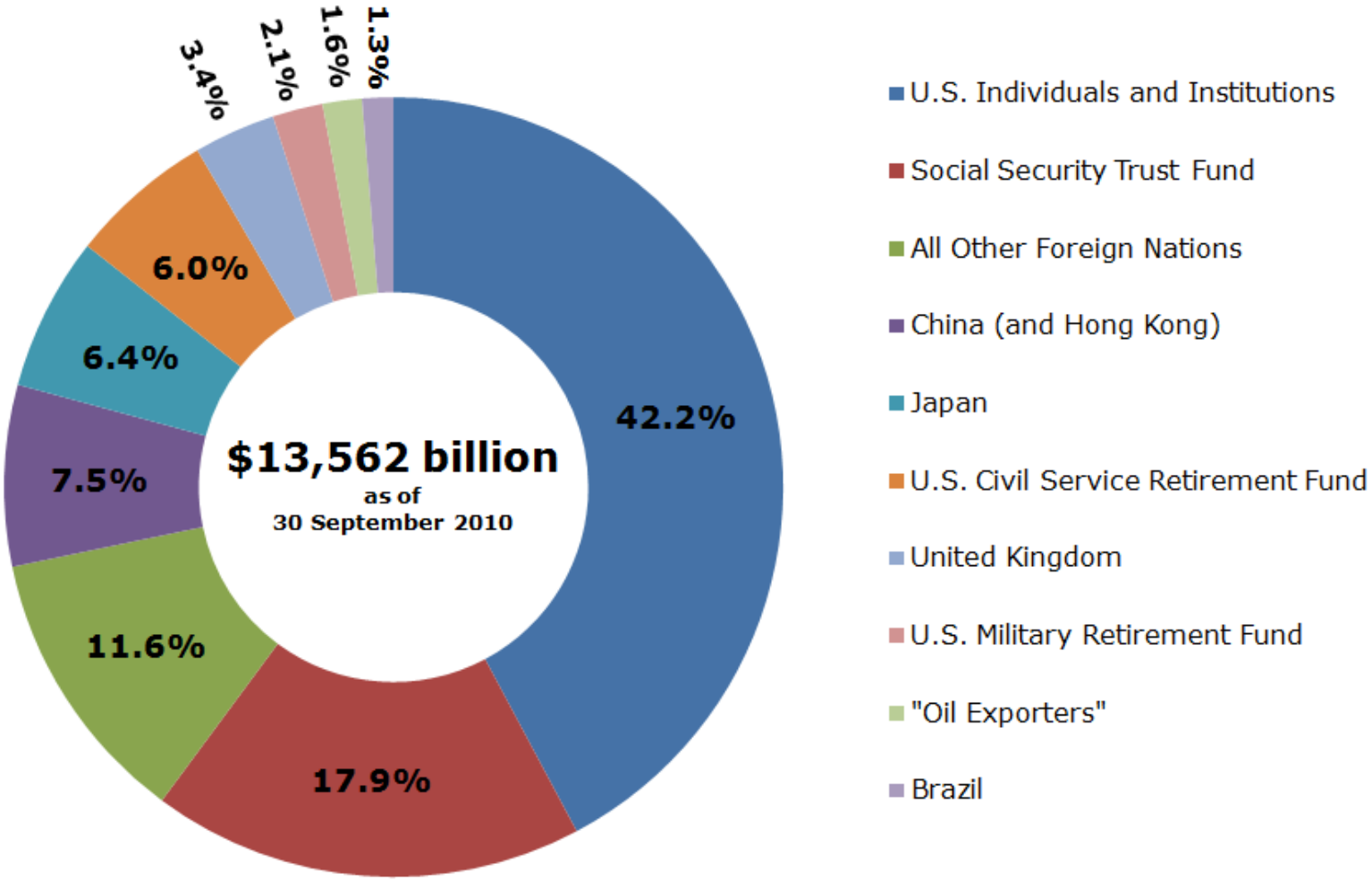
BUDGET GLOSSARY

Glossary of Federal Budget Terms

Gross Debt: The total amount of outstanding federal debt whether issued by the Treasury or by other agencies and held by either the public or by federal government accounts.

Debt-to-GDP Ratio: A useful measure of a country's debt in relation to its GDP. It compares what a country owes (cumulative) to what it produces (within a year), and is used as an indication of a country's ability to service its debt.

To Whom Does the U.S. Government Owe Money?



Source: U.S. Treasury Department

© Political Calculations 2011

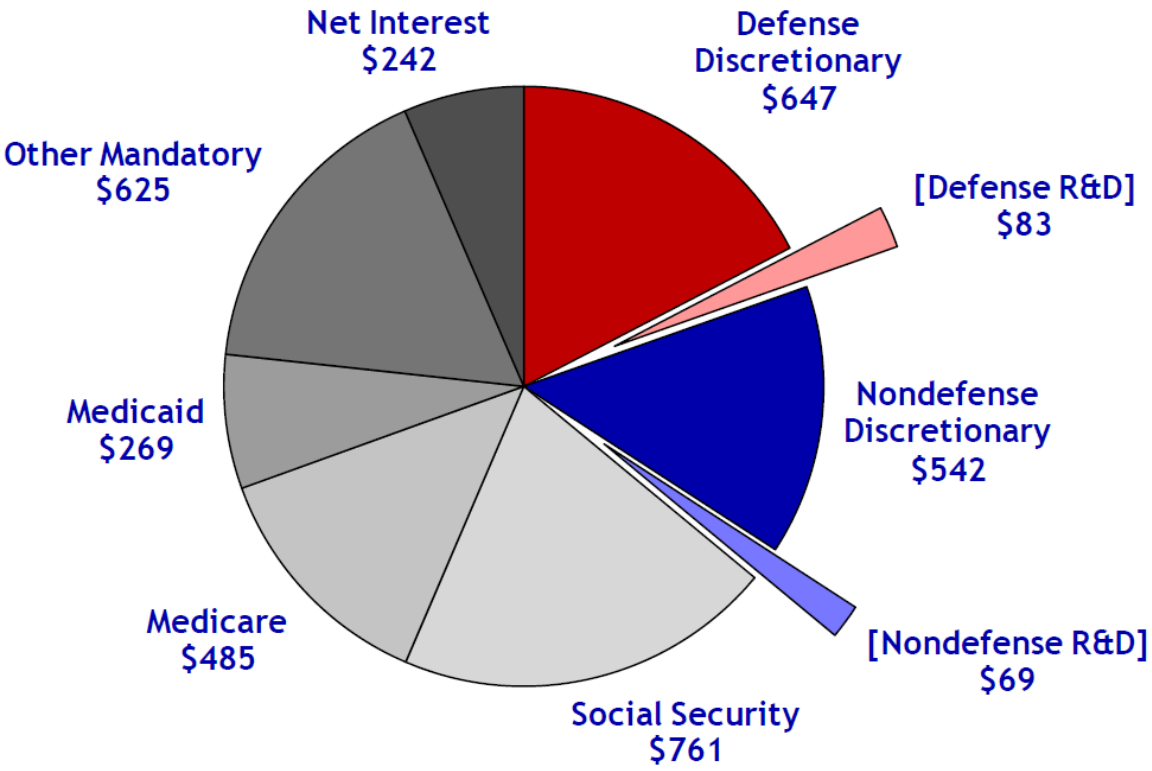
FY 2012 Budget Overview

Mandatory	
Social Security	20.5%
Medicare	13.0%
Medicaid	07.0%
Other (VA, Fed. Retirement)	16.0%
Interest on Debt	07.0%
Subtotal	63.5%
Discretionary	
Defense	20.0% *
Non-Defense	16.5% *
Subtotal	36.5%

* ~ 2% is for R&D (4% of total federal expenditures)

Composition of the Proposed FY 2012 Budget
Total Outlays = $3.7 trillion

outlays in billions of dollars



Source: *Budget of the United States Government FY 2012.*
Projected unified deficit is $1.1 trillion.
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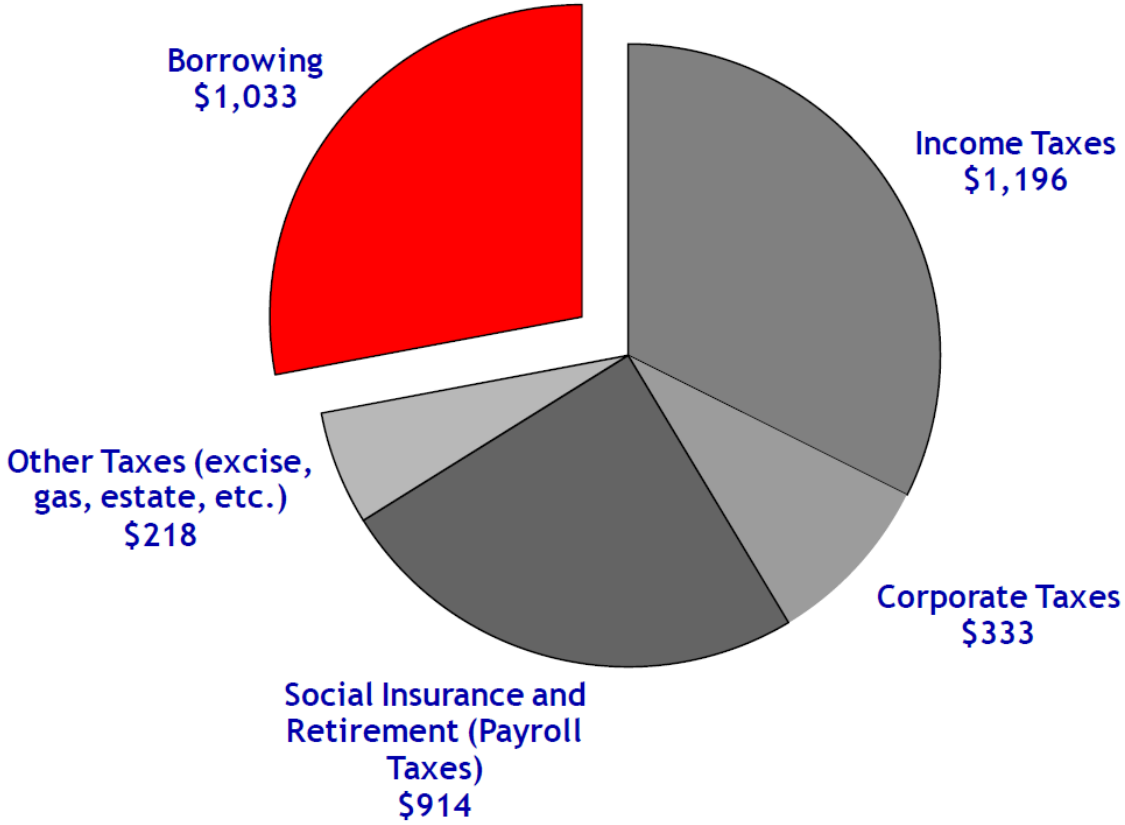
FY 2012 Budget by Source of Funds
Total Outlays = $3.7 trillion
Total Receipts (without borrowing) = $2.7 trillion



Source: *Mid-Session Review: Budget of the United States Government FY 2012.*

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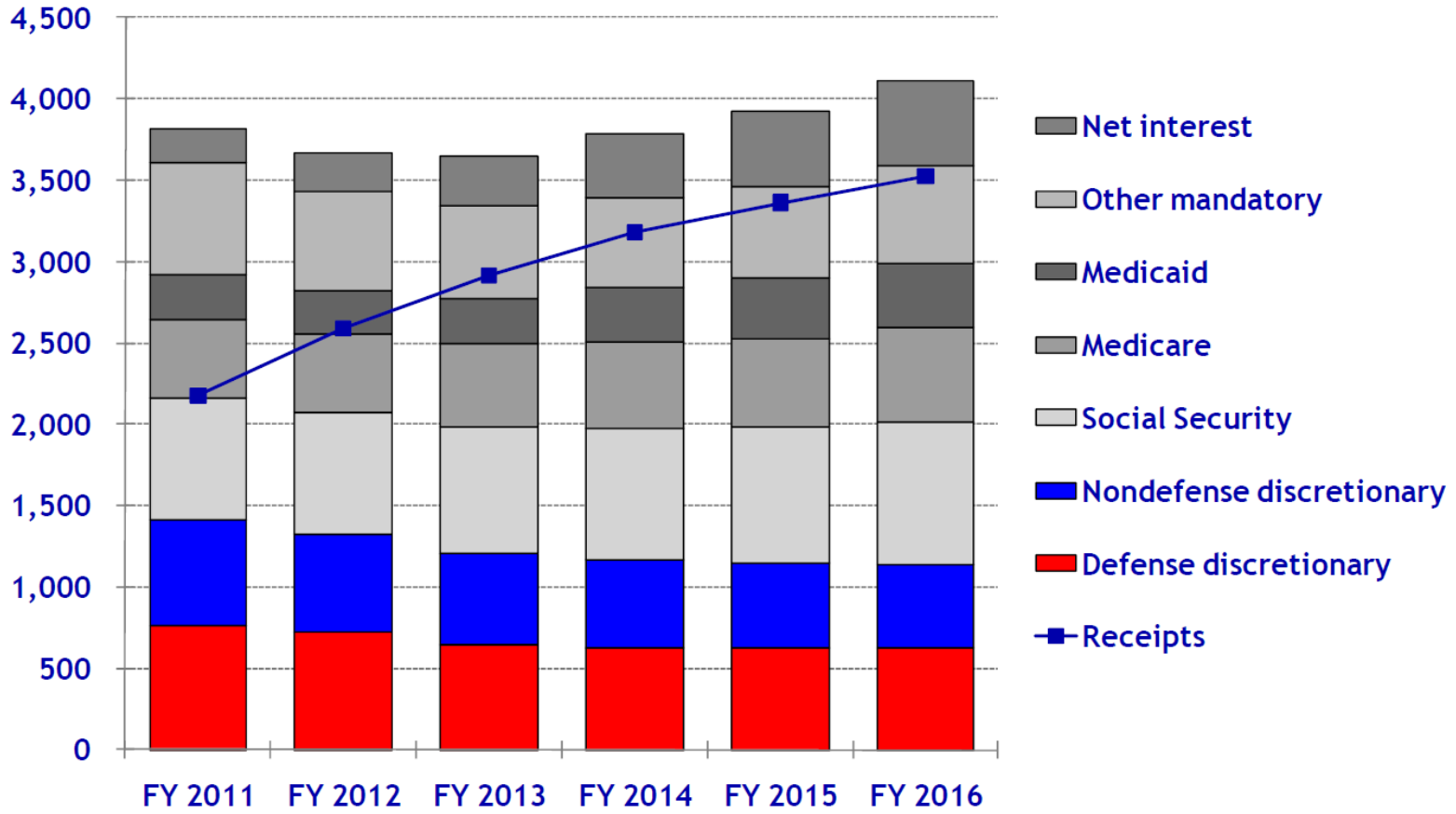
FY 2012 Budget Projections

outlays in billions of constant FY 2011 dollars



Source: *Budget of the United States Government FY 2012.*

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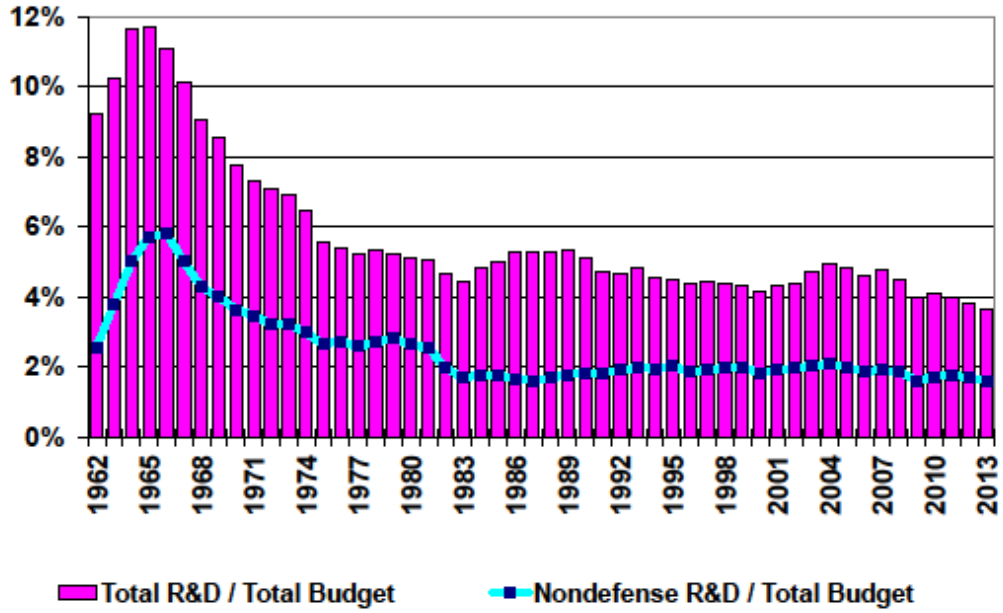
R&D as Percent of the Federal Budget:

FY 1962-2013, in outlays



Source: AAAS, based on *Budget of the U.S. Government FY 2013* Historical Tables. FY 13 data are budget proposals.

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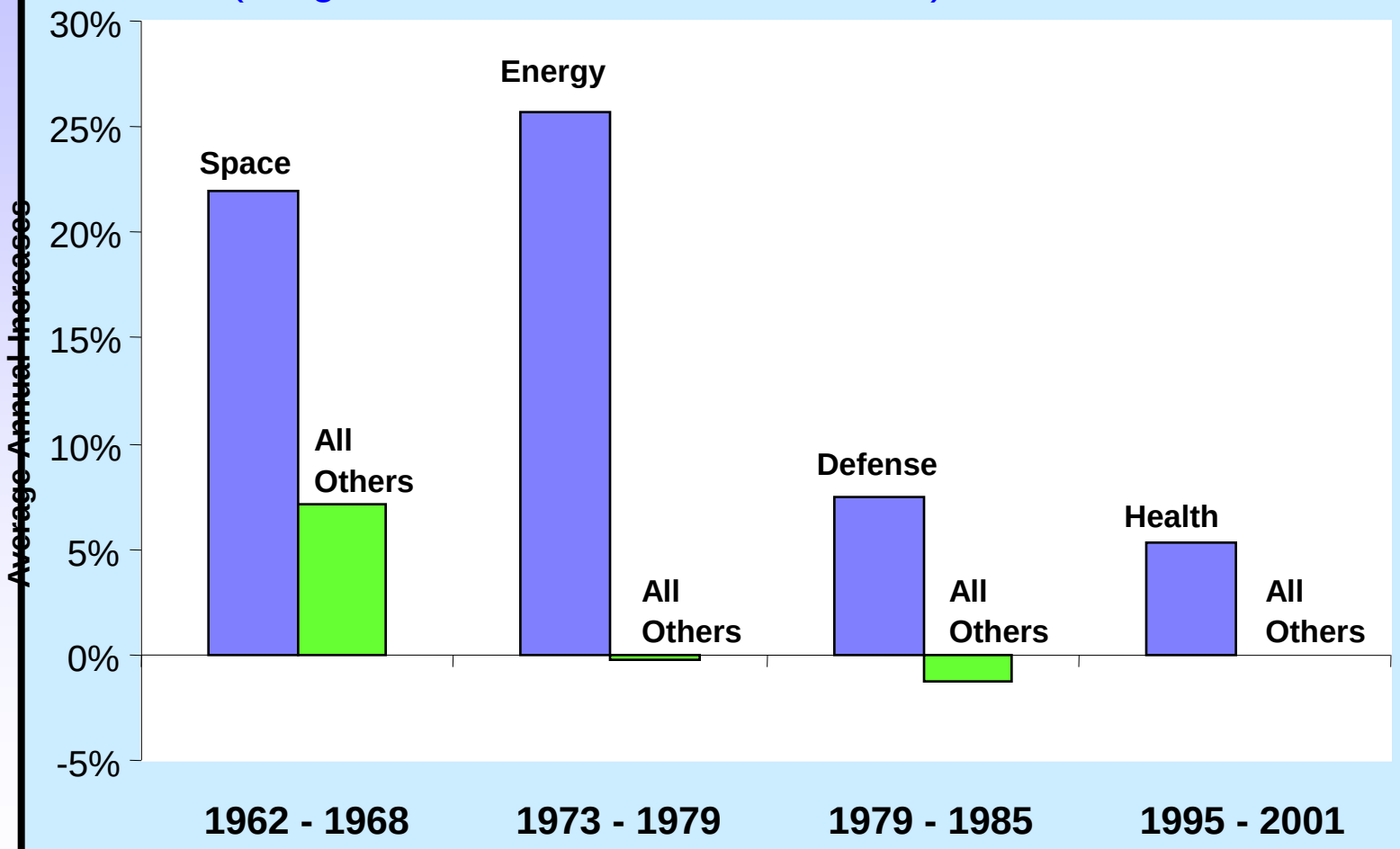
Historical R&D Priorities

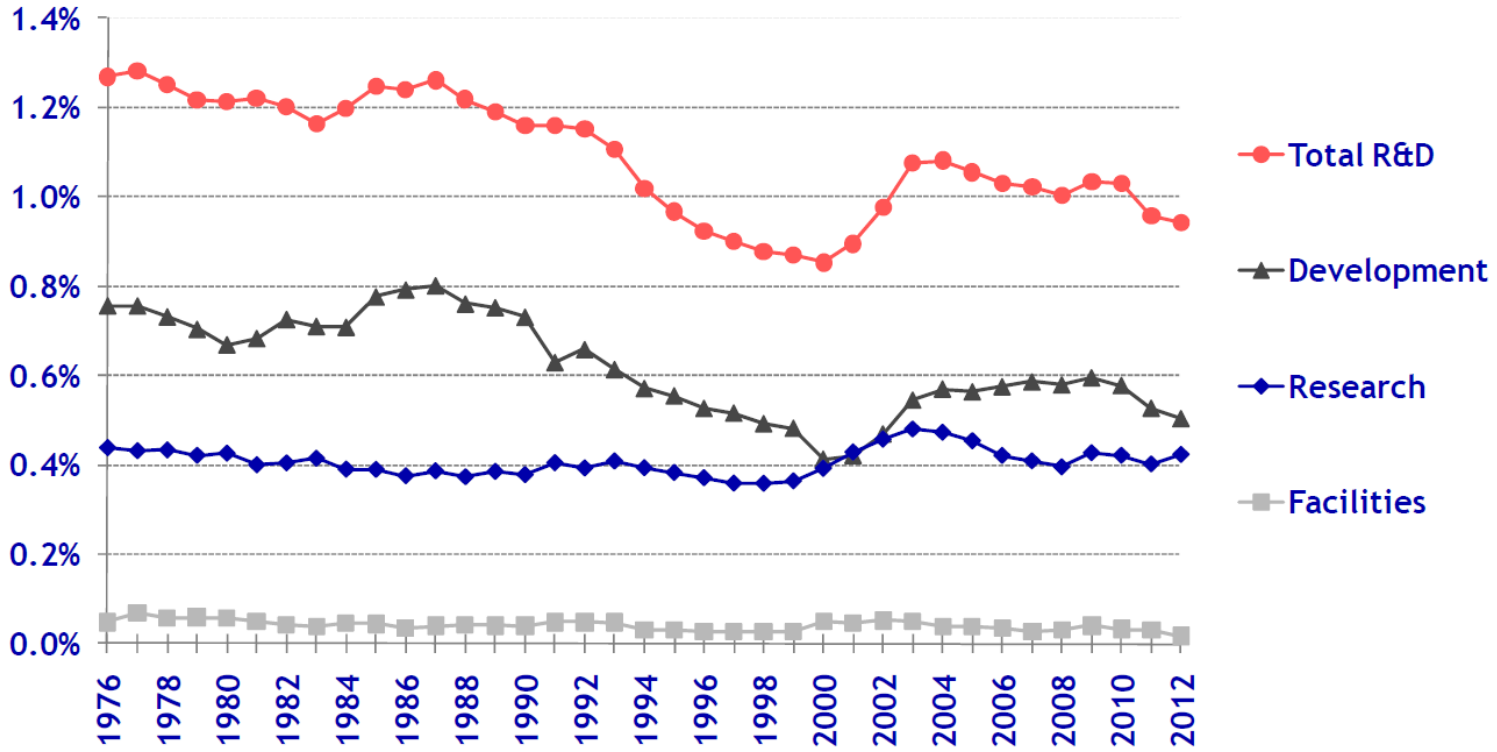
(obligations, in 1996 constant dollars)



Source: National Science Foundation

Trends in Federal R&D

percent of GDP



Source: Up to 1994 - National Science Foundation / National Center for Science and Engineering Statistics, Survey of Federal Funds for Research and Development; 1995 to Present - *AAAS Report: Research and Development* series; GDP figures are from *Budget of the U.S. Government FY 2012*.
FY 2011 and FY 2012 figures are latest estimates.
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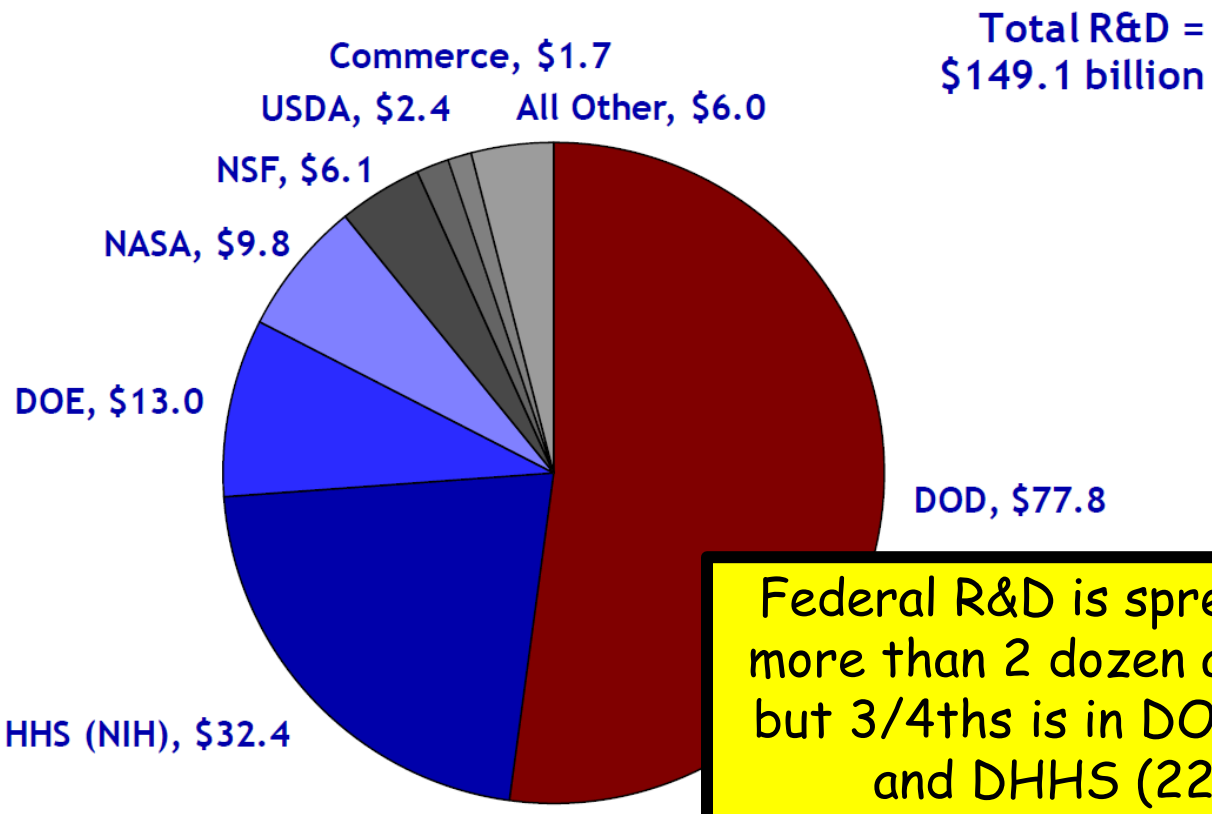
Total R&D by Agency, FY 2012

budget authority in billions of dollars



Total R&D = $149.1 billion

Federal R&D is spread over more than 2 dozen agencies, but 3/4ths is in DOD (52%) and DHHS (22%)!

Source: OMB R&D data, agency budget justifications, and other agency documents.
R&D includes conduct of R&D and R&D facilities.

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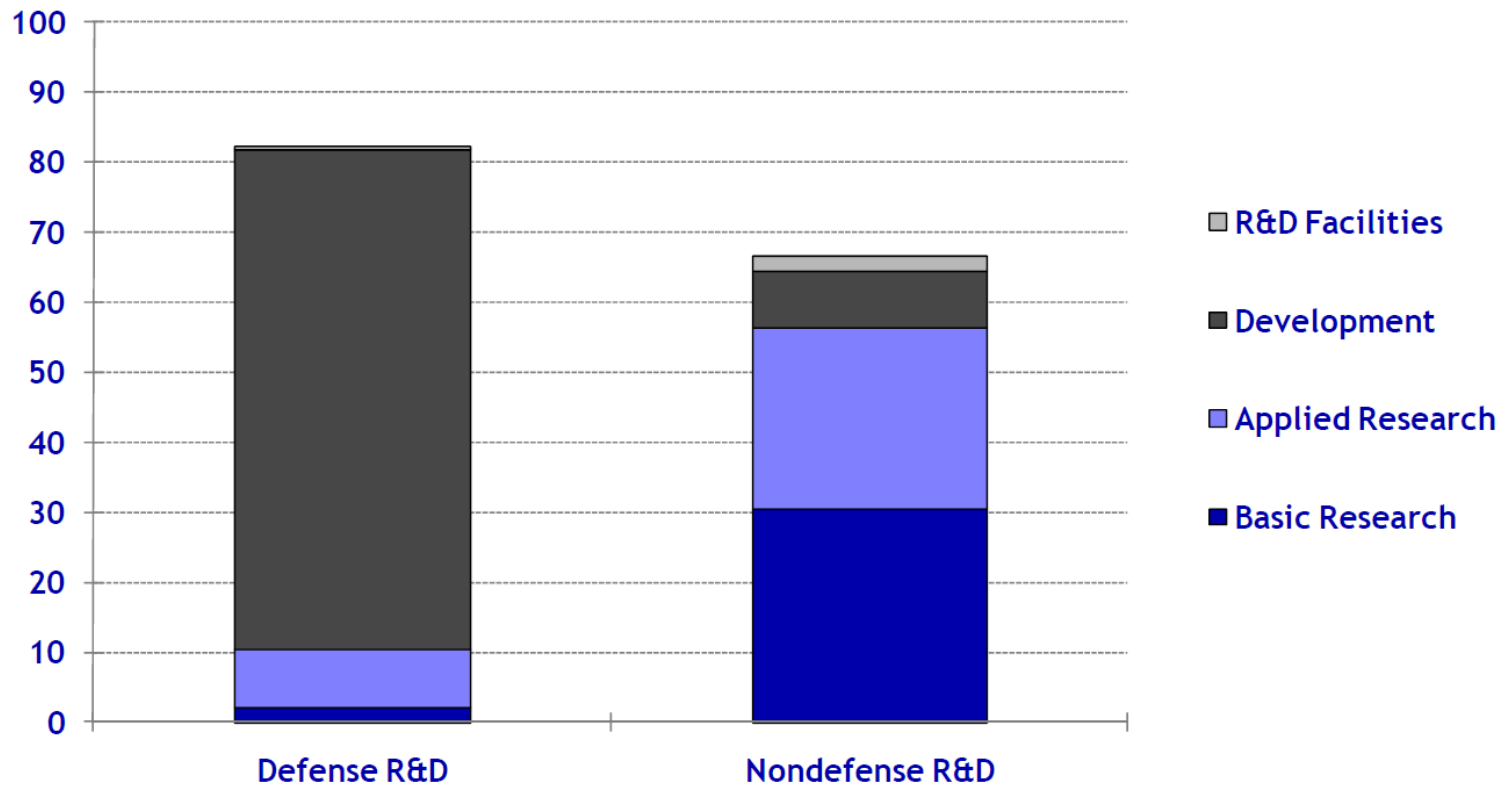
Character of R&D, FY 2012

budget authority in billions of dollars



Source: OMB R&D data, agency budget justifications, and agency budget documents.
Defense R&D = DOD + DOE defense.
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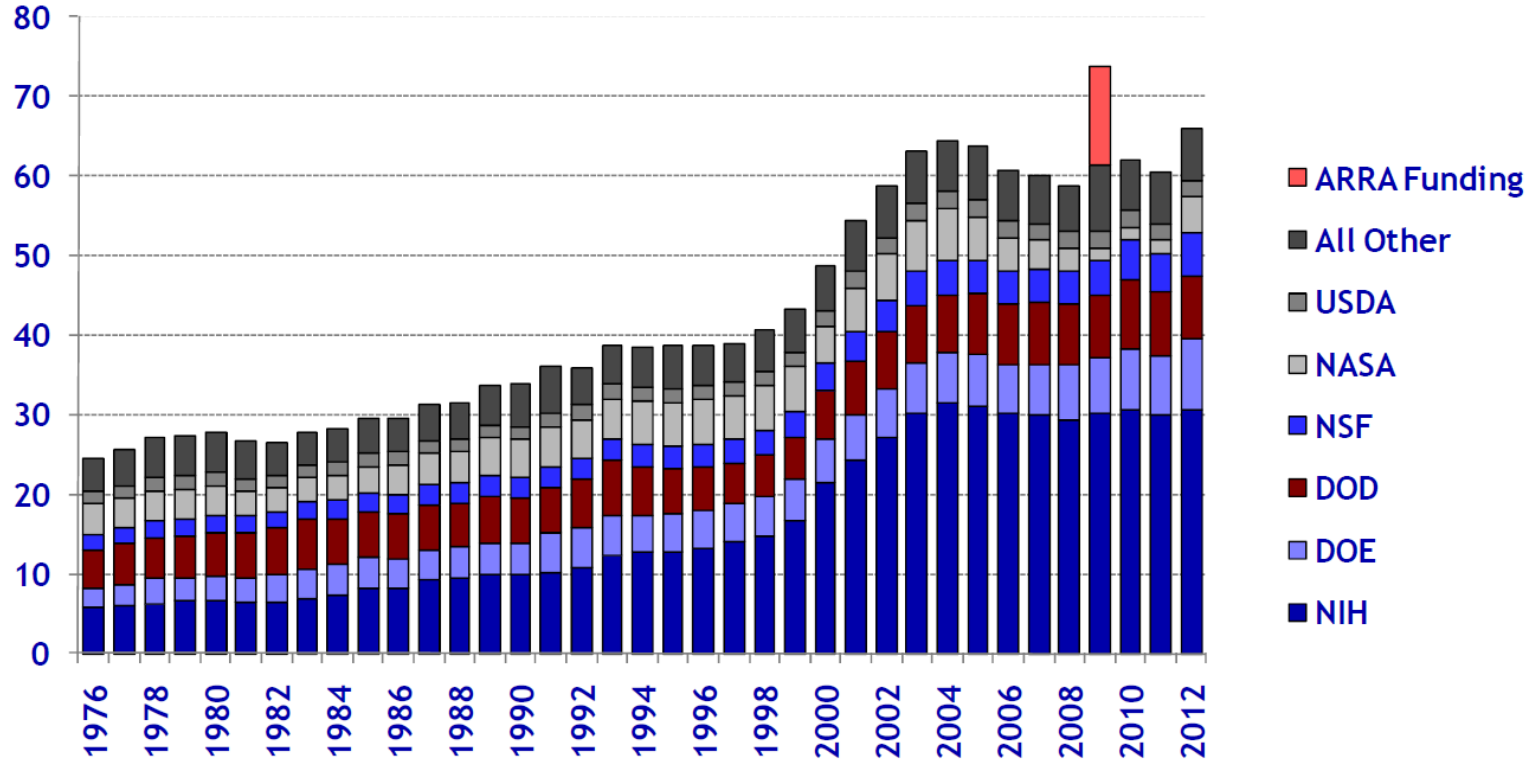
Trends in Research by Agency

in billions of constant FY 2011 dollars



Source: Up to 1994 - National Science Foundation / National Center for Science and Engineering Statistics, Survey of Federal Funds for Research and Development; 1995 to Present - *AAAS Report: Research and Development* series;
FY 2011 and FY 2012 figures are latest estimates.
Research includes basic research and applied research.
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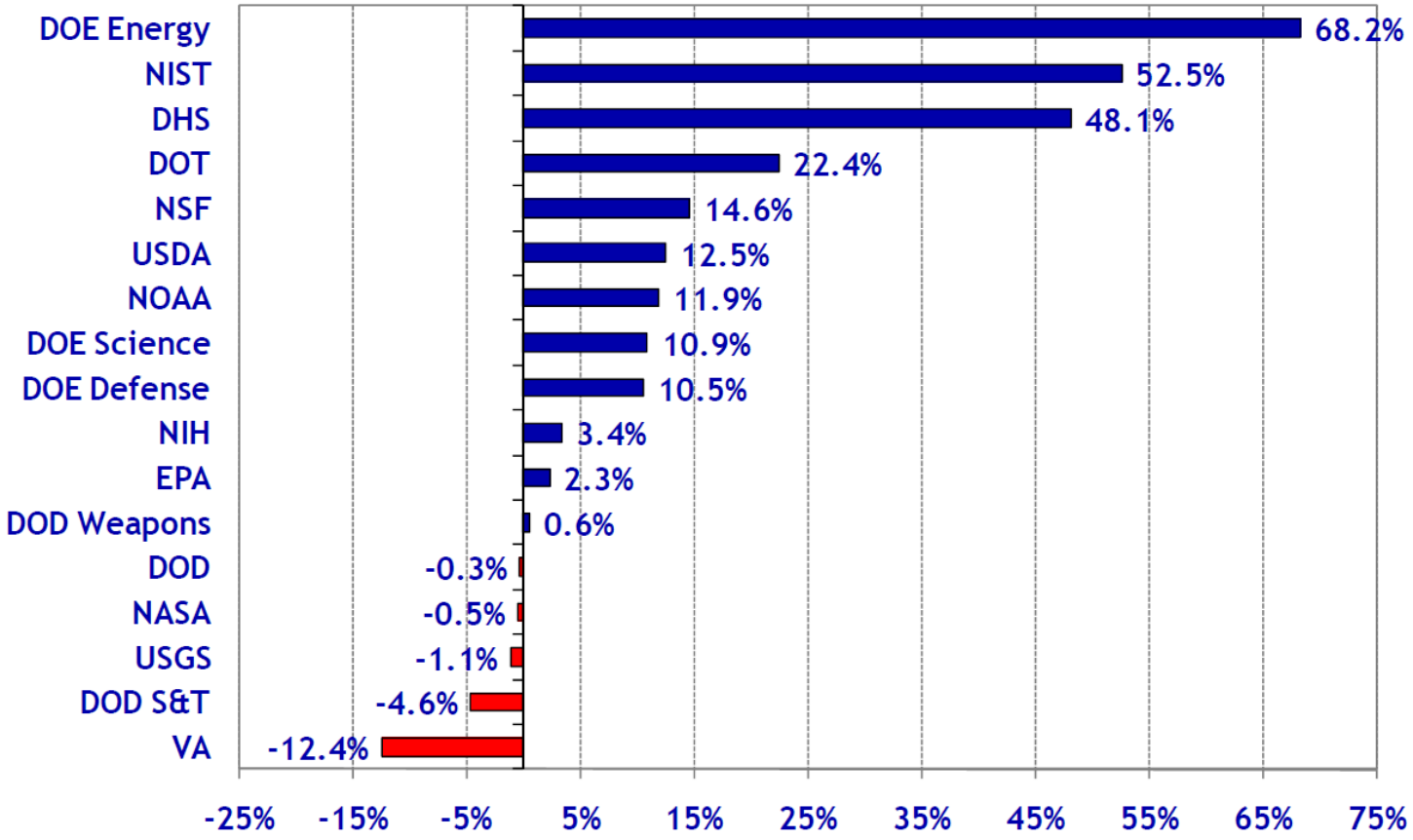
R&D in the FY 2012 Budget Request

percent change from FY 2011



Source: OMB R&D data, agency budget justifications, and other agency documents.

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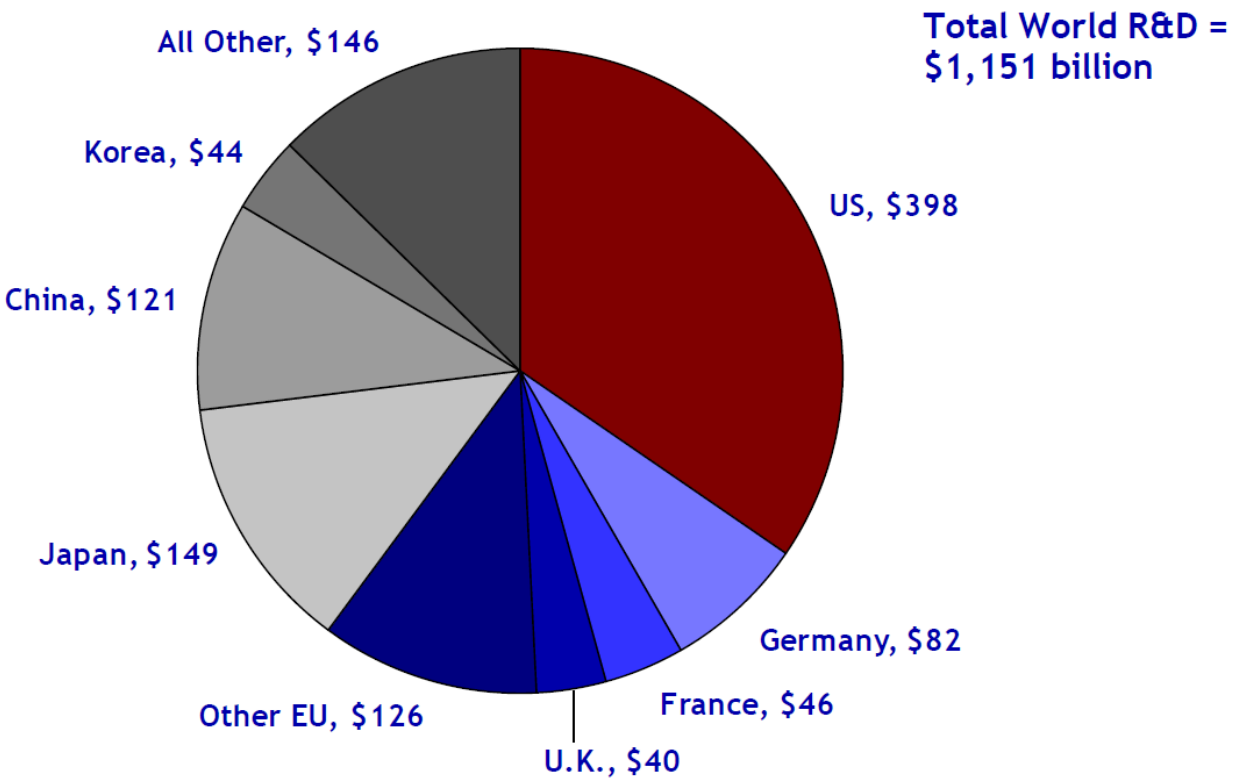
Total World R&D, 2008

in billions of PPP $



Source: OECD, Main Science and Technology Indicators, February 2011.
World = OECD members plus Argentina, China, Romania, Russian Federation, Singapore, South Africa, Taiwan.
Calculated using purchasing power parities.
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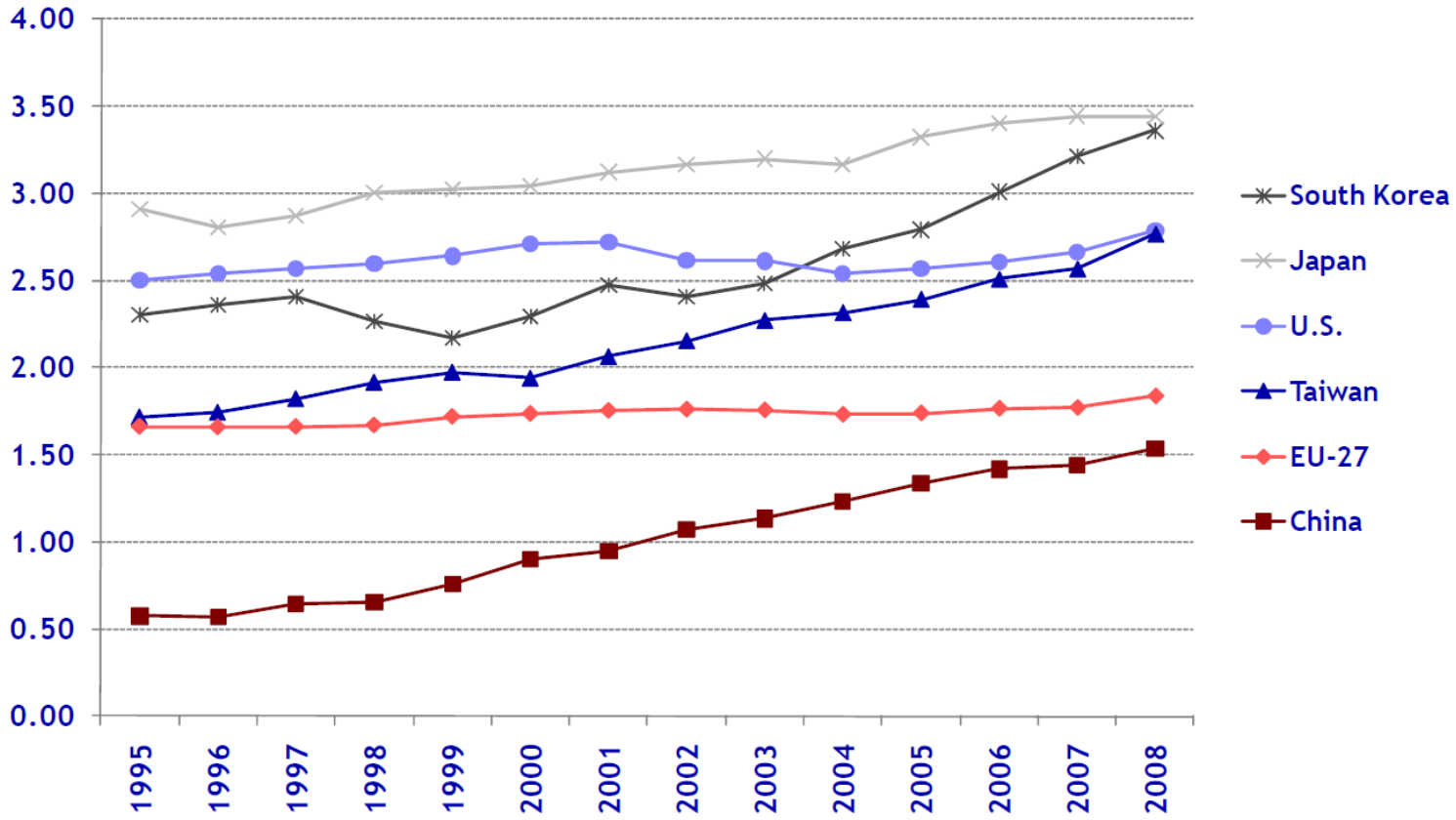
National R&D Investment

percent of GDP



Source: OECD, Main Science and Technology Indicators, Febuary 2011.

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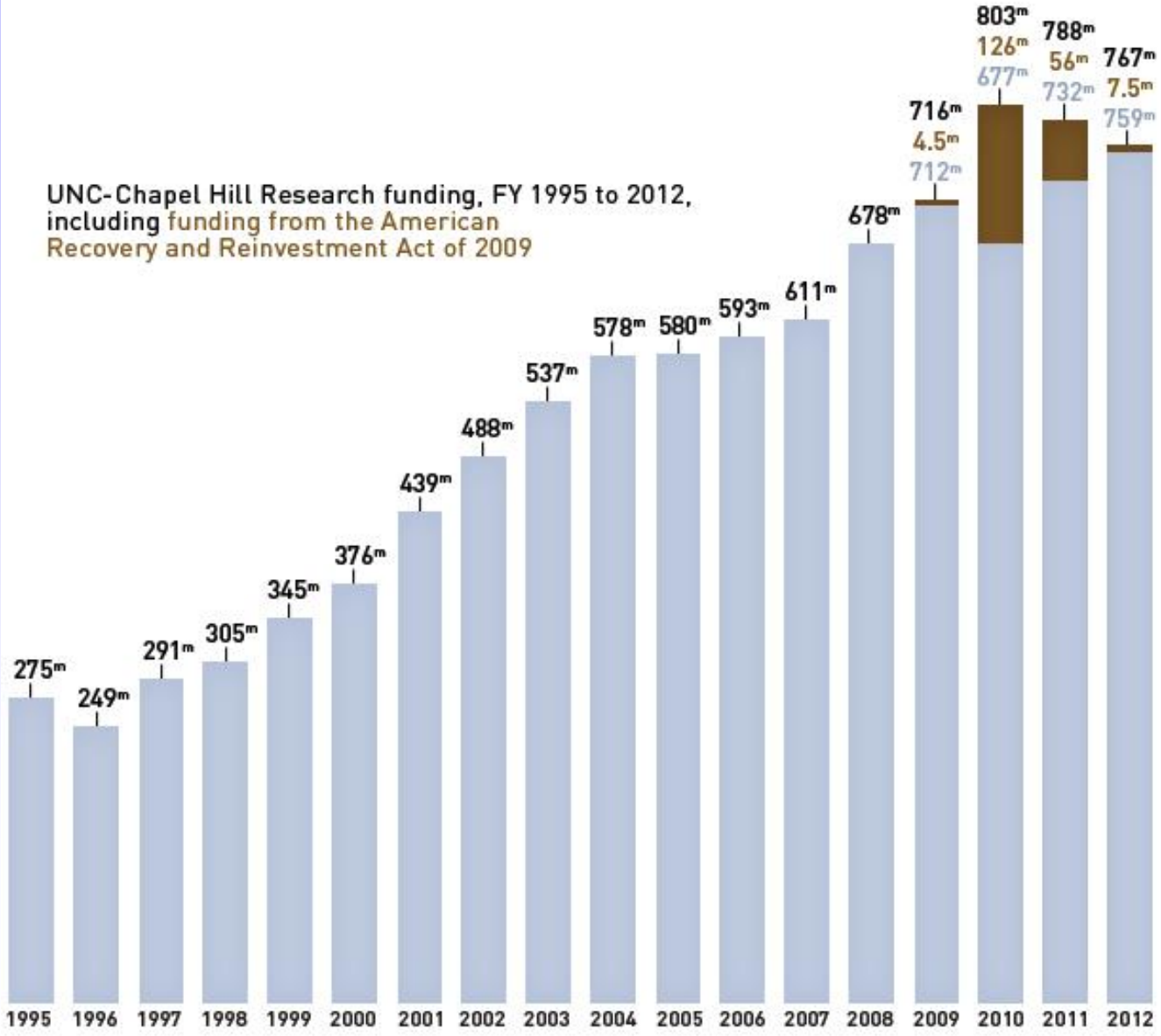
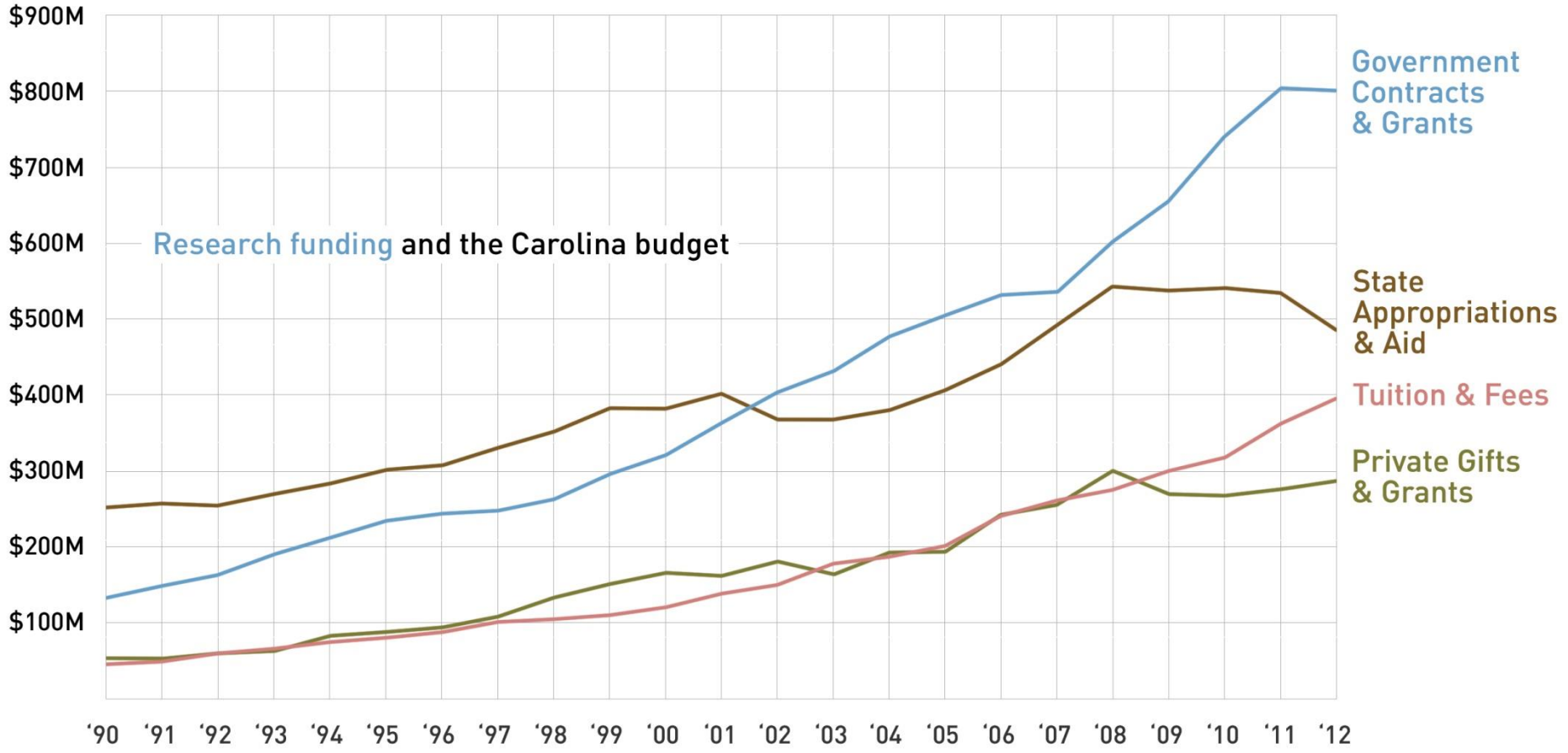
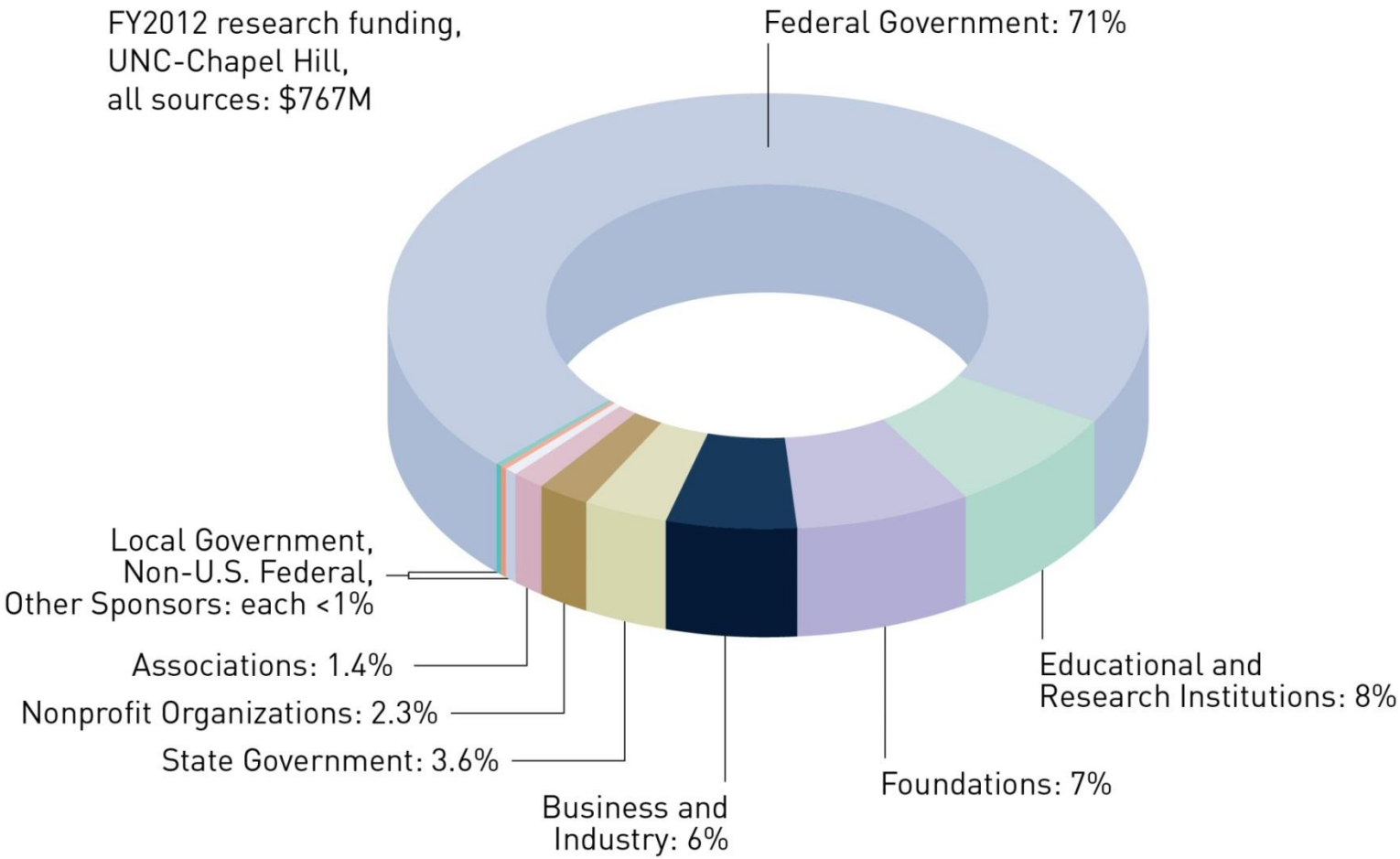
UNC-CH Research Funding: 1995-2112



Research Funding and the UNC-CH Budget

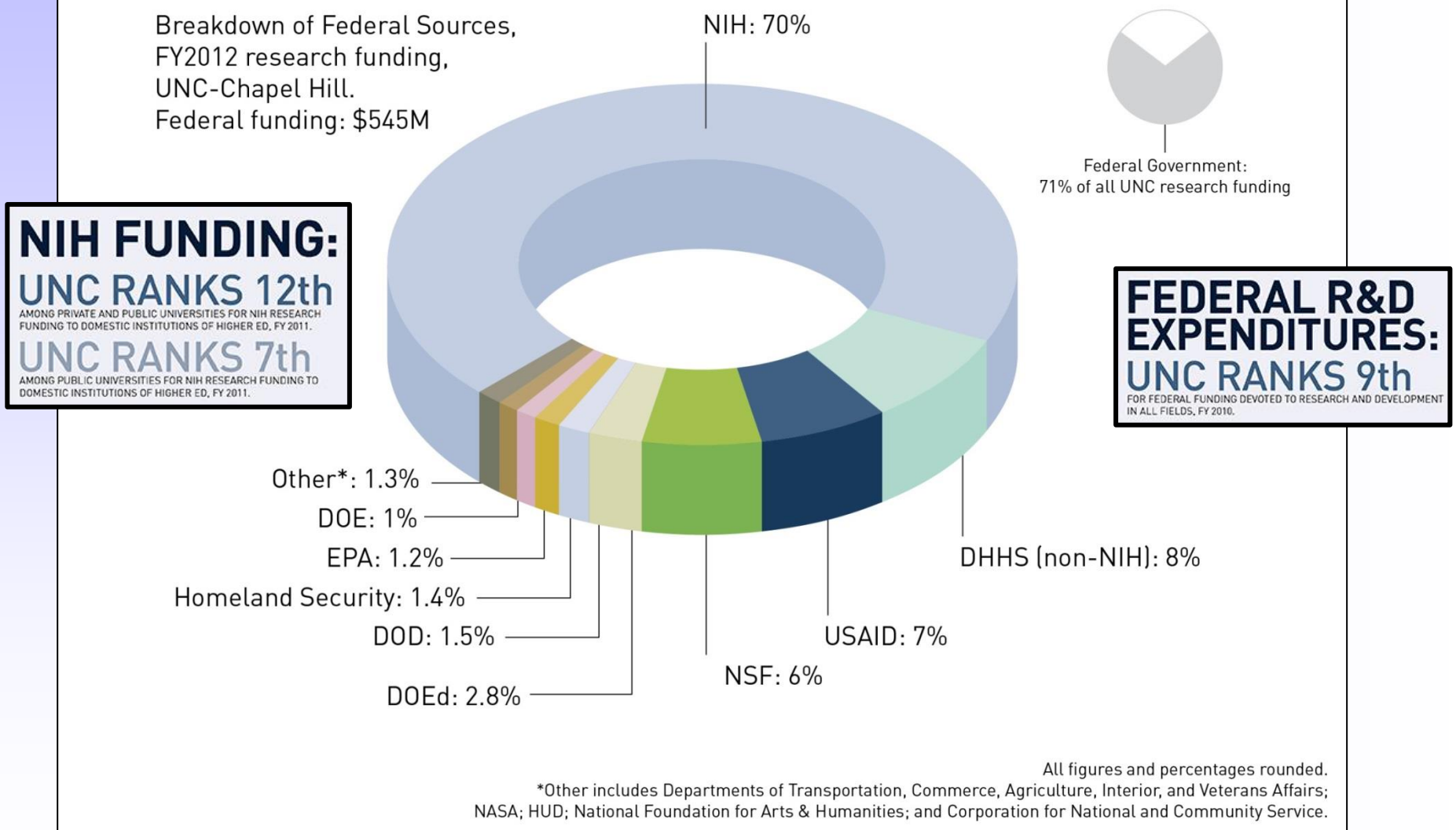


Research Funding by Source for FY2012



All figures and percentages rounded.

Federal Research Funding by Agency for FY2012



Remember

"There is no law that requires you to take money from the Government to support your research but once you do, there are many laws you must follow!"

The Golden Rule: He who has the gold, makes the rules!

We'll be examining these rules in detail over the next few weeks!

COMP 918: Research Administration for Scientists

The Art of Grantsmanship

Tim Quigg, Lecturer and Associate Chair for Administration, Finance and Entrepreneurship
Computer Science Department, UNC-Chapel Hill

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You write a proposal - You receive a grant.
You don't "write a grant!"

- How many of you have written a grant proposal?
- Were any funded? From what agency?
- How did you learn to write grant proposals?

  Your Advisor? Reviewing other proposals? Books or classes? Reading the Instructions? Trial & Error?

You acquired the skill in a past life?

In today's lecture, I will recommend various Grantsmanship strategies and best practices based upon my 40+ years experience. But they are just my opinions. So feel free to disagree (but be prepared to explain why!)

First, let's review the readings!

Summary Concepts "The Art of Grantsmanship" By: Jacob Kraicer

- "Grantsmanship is the art of acquiring peer-reviewed research funding."
- "Good writing will not save bad ideas, but bad writing can kill good ones."
- "The quality of science in applications 10% below the cutoff for funding is not significantly different from that in the 10% just above the cutoff."

Kracier suggests that applicants read the BAA and all agency guidelines carefully to determine if their proposed research:

- Fits? Is it consistent with the BAA objectives? With funding agency goals?
- Ready?
  - Published? – this research, you, the team
  - Pilot studies – preliminary data/results
- Is the budget below the cap? Consistent with the average award size?

"Zen in the Art of Grantsmanship"
By: L. Wade Black

"When I'm on a grants panel, the first thing I look at is the one paragraph summary of the project, then I look at the budget, then I look at the individual's and the organization's past history. These three things strongly influence how I look at the rest of the proposal. They aren't all I consider, but they're very important!"

Ten Tips for Successful Proposal Writing

Lessons I have learned from making almost every imaginable mistake. Maybe you won't have to repeat the same mistakes!

"Great ideas aren't useful until they are written down."

#1: Think, plan, think again. Now write a detailed description of your project.

- Don't worry about format, just write clearly.
- 1st test - Do your ideas make sense when you see them on paper? If not, rewrite until they do.
- 2nd test - Get a trusted colleague to review and comment. If you accept his/her comments, modify and rewrite until you are satisfied.
- This isn't the proposal, but if your ideas don't make sense in this format there won't be a proposal!

Component: Title and Abstract

- Often given too little attention, the title and abstract are the first things read by the Program Manager and are often used to assign the proposal to a Review Panel.
- You want the proposal assigned to the appropriate review panel.
- It is best to write the title and abstract last. At minimum, review and appropriately modify each after the full proposal is written.
- Abstract should contain:
  - Hypothesis to be tested.
  - Brief description of the science and the research plan.
  - Narrative connecting the proposal to the BAA and to the agency's mission/objectives.
  - Description of why the proposal is important, significant and worth supporting.

Component: Proposed Research

- Should be focused, novel, innovative and feasible.
- Should be balanced to include some research activities that are sure and others that are risky.
- Of course, preliminary data/studies should always be included if available.
- Explain what is known, what is not known and why it is essential to investigate the problem.
- Remember - You believe in the importance of the research project, but don't assume its importance is obvious to the reviewers.

You must be an advocate for your research!

Component: Research Design/Methods

- Arrange the aims in logical/sequential order and provide a brief rationale for each.
- Describe the research design and methods you have selected and explain why they are superior to the alternative approaches.
- Provide a timeline for the project: use diagrams and tables as appropriate.

Be sure to document and justify all collaboration arrangements!

"A genius is just a talented person who does his/her homework." Thomas Edison

#2: Learn as much as you can about the agency, program and Program Manager (PM) or Program Officer (PO)!

- Search web sites, ask senior faculty, read
- Be sensitive to "Agency Culture"
  - Terminology
  - Accepted norms
  - Methods of communication
  - Note: Different agencies may interpret the same rules somewhat differently.

Important: Communicate with PM/PO

- Face-to-face is best in the beginning - phone is ok, but don't start with e-mail unless you must.
- Many universities have travel grants to allow junior faculty to visit funding agencies – use them!
- Always make an appointment, even for phone meetings.
- If you call and are fortunate enough to reach the PM, ask for an appointment to discuss the BAA and your ideas – be prepared if he/she says "now is fine."

Preparing for the Meeting

Remember:

- If the PM took the meeting with you, he/she wants to help! This is not an adversarial process. It is in the PM's interest to find "future stars" to fund.
- You only have one chance to make a first impression, so don't blow it!
- Don't hesitate to ask for advice with the grants process. You don't get many shots at "being the new kid," so use the opportunity to your best advantage.

Start the Meeting by:

- Briefly describing your project.
- Be careful not to "run past the sale"- provide additional details of your research based upon the PM's questions and comments.
- Finish before the PM starts looking at the clock. It's usually a good idea to ask about the duration of the meeting before getting started.
- Ask if your ideas fit within the goals of the BAA/program/agency.
- If not, ask if they fit elsewhere in the agency? In another agency? Ask for a referral and a recommendation to another PM.

The pursuit of research funding is a marathon, not a sprint!

Cultivating positive relationships with Program Managers and Program Officers is just one part of your preparation for the race!

"Luck is the place where preparation meets opportunity."

Seneca (Roman Philosopher)

"Goals are dreams with deadlines."

Diana Scharf Hunt

#3: Prepare a detailed proposal development schedule including a timeline and list of responsibilities - then follow it!

- Work backward from the required submission date.
- Assume things will go wrong.
  - Key people might be unavailable (sick, travel, busy).
  - FastLane/Grants.gov might get clogged and delayed.
  - Your campus reviewers/approvers might be busy.
- Schedule for the "inevitable disasters" in your timeline!

Include both proposal preparation tasks and proposal review tasks in your timeline.

- Some tasks can occur in parallel, others must occur sequentially. Be sure to document the "critical path" to proposal submission.
- If you have a sub-awardee, allow time for approval by his/her institutional representatives.
- Note – Your institution's deadlines are important (especially near large agency deadlines), so build them into your schedule to allow adequate time for the Sponsored Research Office (SRO) staff to do their job!

As PI, you must manage the process:

- Set deadlines for drafts/final copy for each component (budget, work scope, attachments)
  - Assign responsibilities
  - Be specific (who, what, when?)
  - Monitor progress – regular feedback/meetings

- Pay special attention to items needed from outside your group (your department/institution, other institutions)
  - Budget
  - Work Scope
  - Letters of support
  - Subcontractor/sub-recipient information

Schedule on-campus review:

- Call ahead - SRO staff are especially busy at proposal deadline. Yours isn't the only proposal!
- Send complicated budgets for early review.
- Discuss any potential "pit-falls."
  - Is cost-sharing documented properly?
  - Are non-standard issues/commitments addressed?

If you need help, ask for it! It's not a sign of weakness to need help, but it is a sign of foolishness to think you know everything!

"Everybody is ignorant, only on different subjects."

Will Rogers

Scientists are taught to "think outside the box." Right?

#4: This may be a good approach when doing science, but when preparing the proposal – learn to "think inside the box!"

- If the instructions ask for "project goals" don't offer "research aims" - even if you prefer that term.
- Follow all proposal guidelines/rules (page limit, type size, font, spacing) precisely.

"Think inside the box"

Follow instructions exactly:

- Don't include appendices if not allowed.
- Avoid abbreviations, acronyms and jargon.
- Proposal must be free of mechanical errors (spelling, typos, grammar).

A messy proposal equals a messy scientist!

"If you can't get the spelling right, how can we expect you to get the research right."

Formula for Success!

- Be creative with the science and
- Be a "good bureaucrat" with the mechanics of the proposal!

Don't prevent a scientifically worthy proposal from being funded because you didn't follow the rules!

"A man who qualifies himself well for his calling, never fails of employment."

Thomas Jefferson

#5: Of course the quality of the science is most important, but ultimately people fund people they know and trust!

- You must "qualify yourself well for your calling", i.e., work to develop the proper skills and reputation.
- The key personnel section of the proposal is vital:
  - Highlight your relevant training/experience and that of the research team.
  - Be honest when describing your strengths – this is not the place for false modesty!

"I not only use all the brains I have, but all I can borrow."

Woodrow Wilson

If you are inexperienced, team up with one or more experienced faculty.

- Be Co-PI with your advisor if necessary - but not for too long.

Work to develop dynamic collaborations.

- **Warning** – You may be a junior partner, but you are still a partner - not an employee. So act accordingly!

Work to become better known through:

- Professional organizations.
- Publication in the best journals.
- Volunteer to be a proposal reviewer. Program Managers are always looking for help!

Imagine what you will learn from reading so many successful and unsuccessful proposals!

Become known by the people doing the "cutting edge" research - benefits include:

- Letters of support
- Future collaborators
- Subcontracting opportunities

Develop a reputation for doing what you are supposed to do!

(Even the little things like submitting progress reports on time.)

Develop a reputation for doing what's right! (particularly in the conduct of your research)

Don't let this be said of you

"**The** President has kept all of the promises he intended to keep."

Clinton aide George Stephanopolous

"He can compress the most words into the smallest idea of any man I know."

Abraham Lincoln

#6: Quality Always Trumps Quantity!

Don't attach "filler information" that is neither necessary to support your presentation nor relevant to the evaluation criteria. If you have adequately "said what needs to be said" with two pages remaining - stop!

- Don't add appendices if they aren't allowed. Reviewers are instructed to ignore them!
- If your proposal references information in an appendix and the reviewers are restricted from reading it, the rest of your narrative might not make sense.

Always consider the reviewer:

- Assume the reviewer is in a related field, but not an expert in your specific area.
- Often (almost always) reviewers are unpaid.
- Review duties are over and above normal job responsibilities.
- Reviews are often conducted in "bits-and-pieces" (evenings, weekends, between other activities).

Always put yourself in the role of the reviewer and try to make his/her job easier!

"Too much of a good thing is wonderful."

Mae West

(Except with proposal budgets)

#7: Budgets should be the "right size" - neither too large nor too small.

- Remember: Program Managers want to invest their limited resources wisely by funding interesting projects that have a good chance of succeeding.
- If the budget is too small – Project may fail because resources aren't adequate to complete all tasks!
- If the budget is too large – Funds may be wasted!

Important factors PM/POs consider when reviewing proposals

- Research Idea – Is it significant? Innovative? Is it consistent with the agency's goals?
- Research Team – Does the team have the required expertise? Does it have a record of success? As individuals and as a team?
- Facilities/Equipment – Is the required infrastructure (labs, equipment, facilities) available - either budgeted or otherwise available at the institution?
- Budget – Is the budget within the proper range and are the "right" items included?

Budgets must be realistic, with every budgeted expense related to the Scope of Work and the budget must follow all applicable rules!

Budgets must be realistic, with every budgeted expense related to the Scope of Work and the budget must follow all applicable rules!

- **Allocable** – All budget lines are related to the project and necessary to accomplish the work.
- Only the PI can make this judgment.
- Explain each expense, how it was calculated and why it is necessary in the budget justification!

Reviewers should never have to ask:

- Why are five graduate students budgeted, instead of 4 or 6? What portions of the scope of work will be assigned to each student?
- Why is a particular staff member's effort 20%, instead of 10% or 50%?
- How does the travel budget relate to the project?
- Why is all that equipment needed?

It is the PI's responsibility to address the allocability of every budget item and the place to do so is the budget justification!

Budgets must be realistic, with every budgeted expense related to the Scope of Work and the budget must follow all applicable rules!

- **Allowable** – Permitted under the various rules governing the award.
- Is each line item consistent with institutional policy? With funding agency policy? With federal policy (A-21)?

- Every institution has "rule experts" – usually at both the department and institutional level.
- Rely upon their expertise - "make nice" for they will contribute (one way or the other) to your success.
- It is useful for PIs to have a basic understanding of the principles of allowability in federal budgeting as explained in OMB Circular A-21.
- We'll explore A-21 next week, but now let's consider the strategic aspect of budgeting.

Budget novices often make one of two common mistakes by budgeting:

- **Too Little** – Believing the proposal has a better chance of being funded if it is inexpensive.
- **Too Much** – Anticipating the budget will be cut, so the budget is "padded" by the amount of the anticipated cut.

The 1st approach exposes a level of inexperience and the 2nd is simply dishonest!

Budget novices often make one of two common mistakes by budgeting:

- **Too Little** – Believing the proposal has a better chance of being funded if it is inexpensive.
- **Too Much** – Anticipating the budget will be cut, so the budget is "padded" by the amount of the anticipated cut.

Both strategies often backfire because experienced PMs/POs know what resources are required to complete a project!

Dilemma: The PM offers to fund your project, but at a significantly reduced level. What do you do?

After you stop celebrating (enjoy the moment), you only have two choices. Sorry, just saying yes isn't one of them!

Dilemma: The PM offers to fund your project, but at a significantly reduced level. What do you do?

The scope of work should be adjusted consistent with the budget reduction (less work)

or

Either voluntary cost-sharing or "other contributions" should be identified (more resources)!

Dilemma: The PM offers to fund your project, but at a significantly reduced level. What do you do?

To do otherwise casts doubt on the accuracy/integrity of your original budget!

And on you!

"The greatest of all faults is to be conscious of none."

Thomas Carlyle

#8: Criticism from trusted sources can be quite useful!

Get the right colleagues to review and critique your proposal before it is submitted:

- Allow time for this in your proposal timeline.
- Value their input but "Run it through your sifter."
- Remember - It's your proposal!
- Decide whether/how to incorporate their input.

"A good plan executed now is far better than a perfect plan executed next week."

George S. Patton

#9: When the time comes to "push the button", submit your proposal even if it isn't perfect.

Old Saying: If you wait until you can afford to have children, you'll never have them!

"A good plan executed now is far better than a perfect plan executed next week."

George S. Patton

#9: When the time comes to "push the button", submit your proposal even if it isn't perfect.

Likewise, if you wait till your proposal is perfect, you'll never submit one.

"A good plan executed now is far better than a perfect plan executed next week."

George S. Patton

#9: When the time comes to "push the button", submit your proposal even if it isn't perfect.

And, if you never submit one - you dramatically reduce your chances of ever getting one funded!

"Don't push the river. It will flow by itself."

Fritz Perls, Gestalt Therapy

- Be patient, many funding agencies take about six months to complete their review process.
- It is considered inappropriate to contact the agency while a proposal is under review.
- If it's a procurement governed by the FAR, contact of any kind is viewed as an attempt to influence and automatically disqualifies your proposal.
- Just be patient!

You have plenty of other work to do!

However, if the BAA deadline for announcing funding decisions has passed, you may ask for information about the revised schedule.

- Remember - Successful proposals usually get a call from the program officer - People enjoy giving good news!
- Rejections usually come by "snail mail" or e-mail - People don't enjoy giving bad news!

"Failure is the opportunity to begin again, only more intelligently."

Henry Ford

#10: Treat every rejected proposal as an opportunity to learn!

- Many good, otherwise fundable proposals are not funded because the agency ran out of money, not because the proposal was of poor quality.
- Request a copy of the reviewers comments and numeric score where applicable.

Try not to get too defensive, instead accept the review comments as valuable input:

- The reviewers may not have understood your meaning. Why? Rewrite sections that were misunderstood to increase clarity.
- If the reviewers found "holes" in your presentation that you hadn't seen - plug them!
- Share the review comments with a trusted colleague (ideally the one who reviewed the proposal draft) and get his/her view of the criticism.

If after careful consideration, the review comments make little sense, you may have gotten a bad panel – it happens!

Review the title and abstract to see if they properly convey the content of the proposal?

Remember

Proposal writing is an iter

"Life is like riding a bicycle. You don't fall off unless you stop pedaling." Claude Pepper

Remember

Proposal writing is an it

And so is the process of seeking funding for your research. Just don't "stop pedaling."

COMP 918: Research Administration for Scientists

Human Subject Testing: History, Recent Cases, Informed Consent and Institutional Review Boards

Tim Quigg, Lecturer and Associate Chair for Administration, Finance and Entrepreneurship
Computer Science Department, UNC-Chapel Hill

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In one sense, our contemporary approach to the protection of human subjects in research is a reaction to the horrific crimes committed in the guise of scientific research by the Nazis during the Holocaust!

"Laws are often written in response to some terrible crime!"

The Holocaust and the Nuremberg Trials

Millions of Jewish people, gypsies, gay people, Polish Catholic priests, Russian nationals, the mentally ill and political dissidents were victimized by the Nazis by being subjected to atrocious medical experiments as was thoroughly documented at the 1946 Nuremberg Trials (The Doctor's Trial).

The Holocaust and the Nuremberg Trials

The crimes committed by licensed physicians are well-documented and include experiments in:

- ✓ Freezing
- ✓ Malaria
- ✓ Sea water
- ✓ Mustard gas
- ✓ Twin tests
- ✓ Sterilization
- ✓ High altitude/low pressure

The Holocaust and the Nuremberg Trials

"Obviously all of these experiments involving brutalities, tortures, disabling injury, and death were performed in complete disregard of international conventions, the laws and customs of war, the general principles of criminal law as derived from the criminal laws of all civilized nations, and Control Council Law No. 10. Manifestly human experiments under such conditions are contrary to "the principles of the law of nations as they result from the usages established among civilized peoples, from the laws of humanity and from the dictates of public conscience."

Nuremberg Proceedings

The Holocaust and the Nuremberg Trials

How could these atrocities have been committed by Doctors?

Human exploitation is easier when bigotry (often culturally sanctioned) leads one to view the subject as "less than human."

Permissible Medical Experiments

What is permissible? What "principles of the law of nations" are applicable?

The Nuremberg Code is an attempt to answer these questions!

THE NUREMBERG CODE [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S.G.P.O, 1949–1953.]

Permissible Medical Experiments

The great weight of the evidence before us is to the effect that certain types of medical experiments on human beings, when kept within reasonably well-defined bounds, conform to the ethics of the medical profession generally. The protagonists of the practice of human experimentation justify their views on the basis that such experiments yield results for the good of society that are unprocurable by other methods or means of study. All agree, however, that certain basic principles must be observed in order to satisfy moral, ethical and legal concepts:

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Permissible Medical Experiments

The beginning of a definition:

- ✓ reasonably well-defined bounds
- ✓ conforms to the ethics of the medical
- ✓ profession
- ✓ yields results for the good of society
- ✓ and the results are unprocurable by other
- ✓ methods or means of study

Is this enough? Anything missing?

THE NUREMBERG CODE [from Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946–April 1949. Washington, D.C.: U.S.G.P.O, 1949–1953.]

The voluntary informed consent of the human subject is absolutely essential.

This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

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Informed Consent Requires

The research subject must know:

- ✓ the nature, duration, and purpose of the experiment
- ✓ the method and means by which it is to be conducte;
- ✓ all inconveniences and hazards reasonably to be expected
- ✓ the effects upon his health or person which may possibly come from his participation in the experiment.

Later the "assurance of freedom to withdraw without penalty" was added!

Ascertaining Informed Consent is a Serious Matter

"The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."

Permissible Medical Experiments

A more complete definition:

- ✓ reasonably well-defined bounds
- ✓ conforms to the ethics of the medical
- ✓ profession
- ✓ yields results for the good of society
- ✓ and the results are unprocurable by other methods or means of study
- ✓ with the informed consent of subject

Better? Anything still missing?

But the forces that lead to unethical medical experimentation were not left at the Nazi doorstep…

nor did the problem even originate in Germany!

Tuskegee Syphilis Experiments

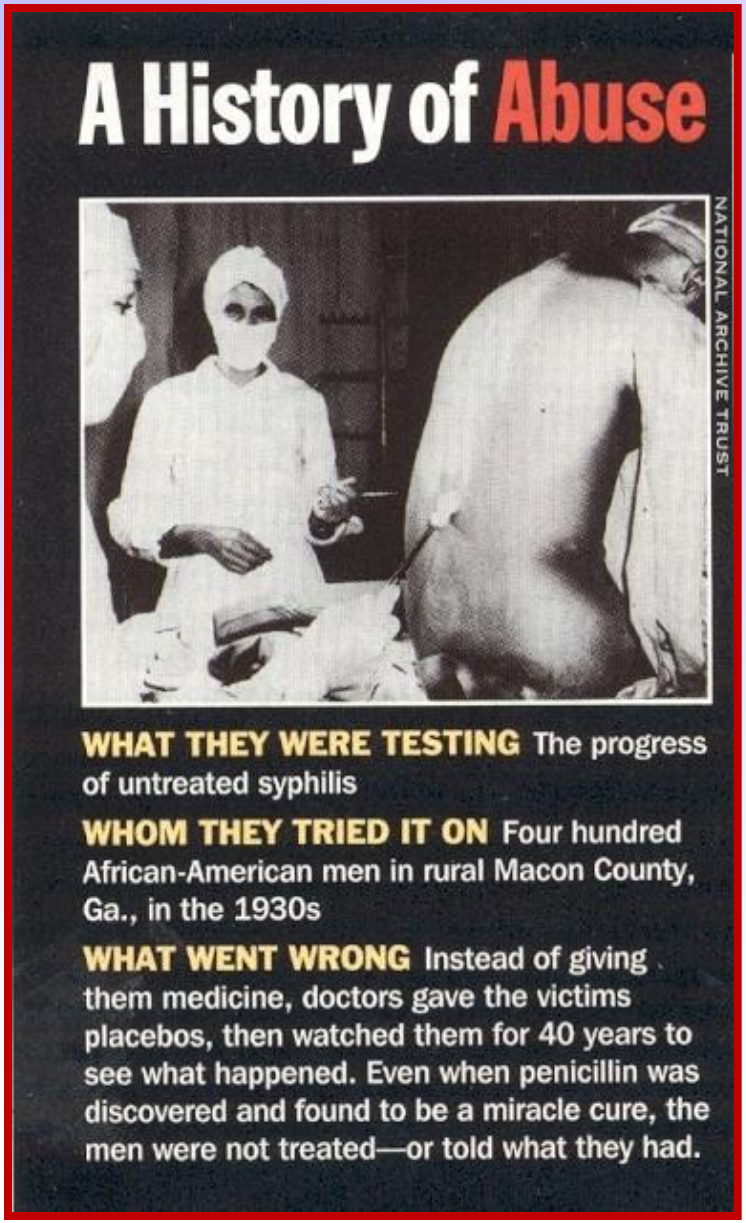
From 1932 to 1972, the U.S. Public Health Service conducted an experiment in Macon County, Alabama to determine the natural course of untreated latent syphilis in black males. Treatment was withheld even after the onset of penicillin therapies became commonplace in the 1940s.

Tuskegee Syphilis Experiments

- ✓ 400 poor, illiterate African-American sharecroppers infected with latent syphilis were enrolled in a study and were offered free health care, meals and burial insurance from the U.S. Government.
- ✓ They were never told they had syphilis, nor were they ever treated for it. Rather they thought they had "bad blood" - a local term that included multiple ailments.

Tuskegee Syphilis Experiments

- ✓ Government officials went to great lengths to insure that no therapy was received; even after the use of penicillin as a cure became the standard treatment in 1947.
- ✓ Medical research staff lied to patients and even actively worked to prevent them from accessing programs available to others.
- ✓ The withheld treatment caused needless suffering and eventual death.



"The longest non-therapeutic experiment on human beings in medical history."

July 26, 1972
New York Times

Tuskegee Syphilis Experiments

"The study continues to cast a long shadow over the relationship between African Americans and the bio-medical professions; it is argued that the study is a significant factor in the low participation of African Americans in clinical trials, organ donation efforts, and routine preventive care."

Syphilis Study Legacy Committee
May 20, 1996

Finally, on May 16, 1997 President Bill Clinton Spoke for the Nation and Apologized for the Ugly Reality of our Government's Involvement!

"The eight men who are survivors of the syphilis study at Tuskegee are a living link to a time not so very long ago that many Americans would prefer not to remember, but we dare not forget. It was a time when our nation failed to live up to its ideals, when our nation broke the trust with our people that is the very foundation of our democracy."

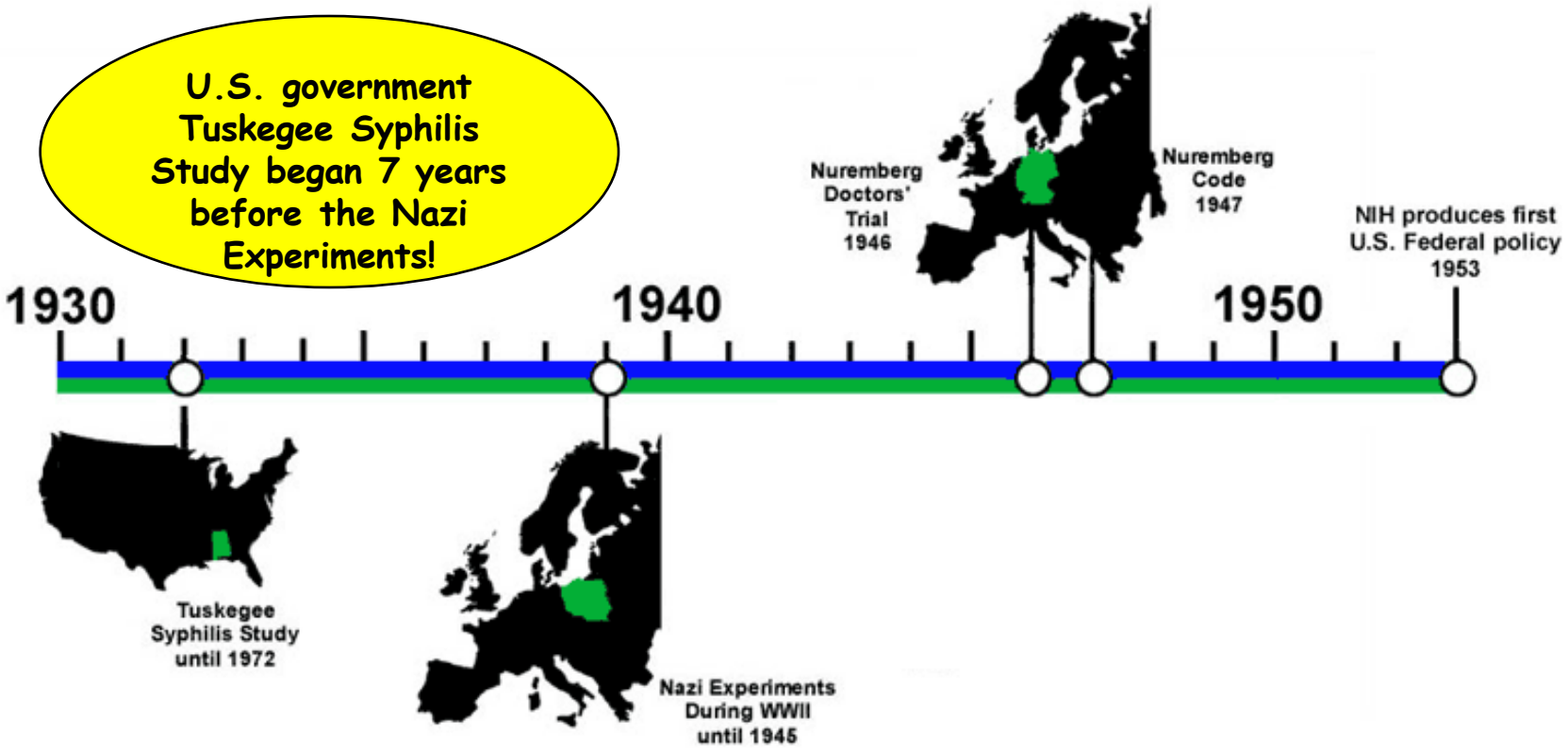
"To the survivors, to the wives and family members, the children and the grandchildren, I say what you know: No power on Earth can give you back the lives lost, the pain suffered, the years of internal torment and anguish. What was done cannot be undone. But we can end the silence. We can stop turning our heads away. We can look at you in the eye and finally say on behalf of the American people, what the United States Government did was shameful, and I am sorry."

Lessons Learned From Nuremberg and Tuskegee

- Science without ethics can (and often does) lead to abuse.
- Societal problems (racial, gender, social and economic bigotry) can erode medical ethics.
- In order to prevent abuse, we must have:
    - Independent, external review of all research involving human subjects.
    - Commonly accepted (and enforced) standards.
    - Rigorous rules for obtaining informed consent!

Human Subjects in Research

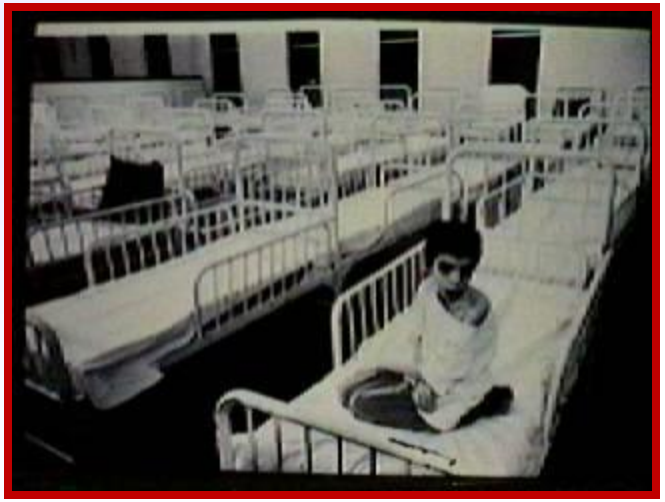
Timeline of Events



From NIH – Human Participant Protections Education for Research Teams

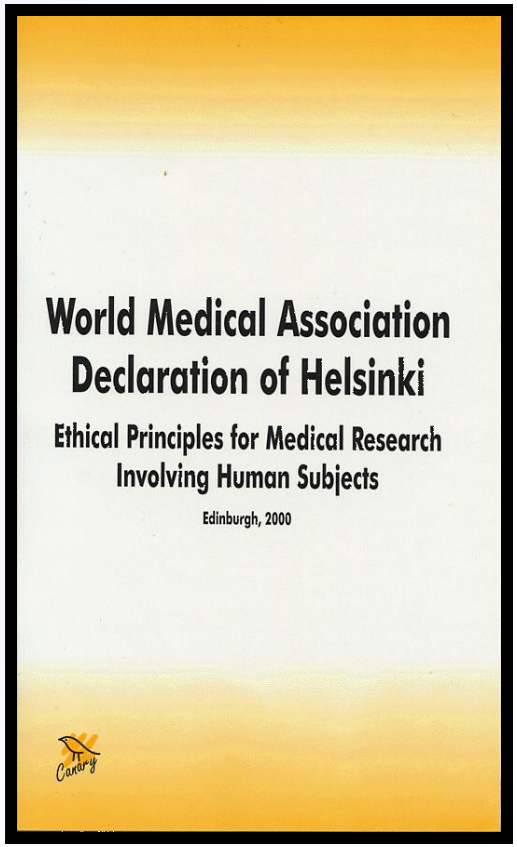
The Willowbrook Study

- New York institution for "mentally defective" children with a reputation for providing quality care.
- From 1963-1966 a study was conducted to gain an understanding of the natural history of infectious hepatitis.
- Newly admitted children were deliberately infected.
- Willowbrook closed its doors, however, the hepatitis study continued for several more years.



Declaration of Helsinki

- 1964 (revised October 2002)
- Distinguished between therapeutic activities and non-therapeutic research.
- Informed consent was the central requirement.
- It allowed (for the 1st time) surrogate consent for the:
  - Physically incapacitated,
  - Mentally incapacitated and
  - Children.



Federal Protections Began

- National Research Act of 1974
  - It codify policy for the protection of human subjects (45 CFR 46).
  - Established Institutional Review Board as authorizing body for human subjects research.
  - Formed National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.
- Only applied to federally funded or FDA regulated research.

Belmont Report

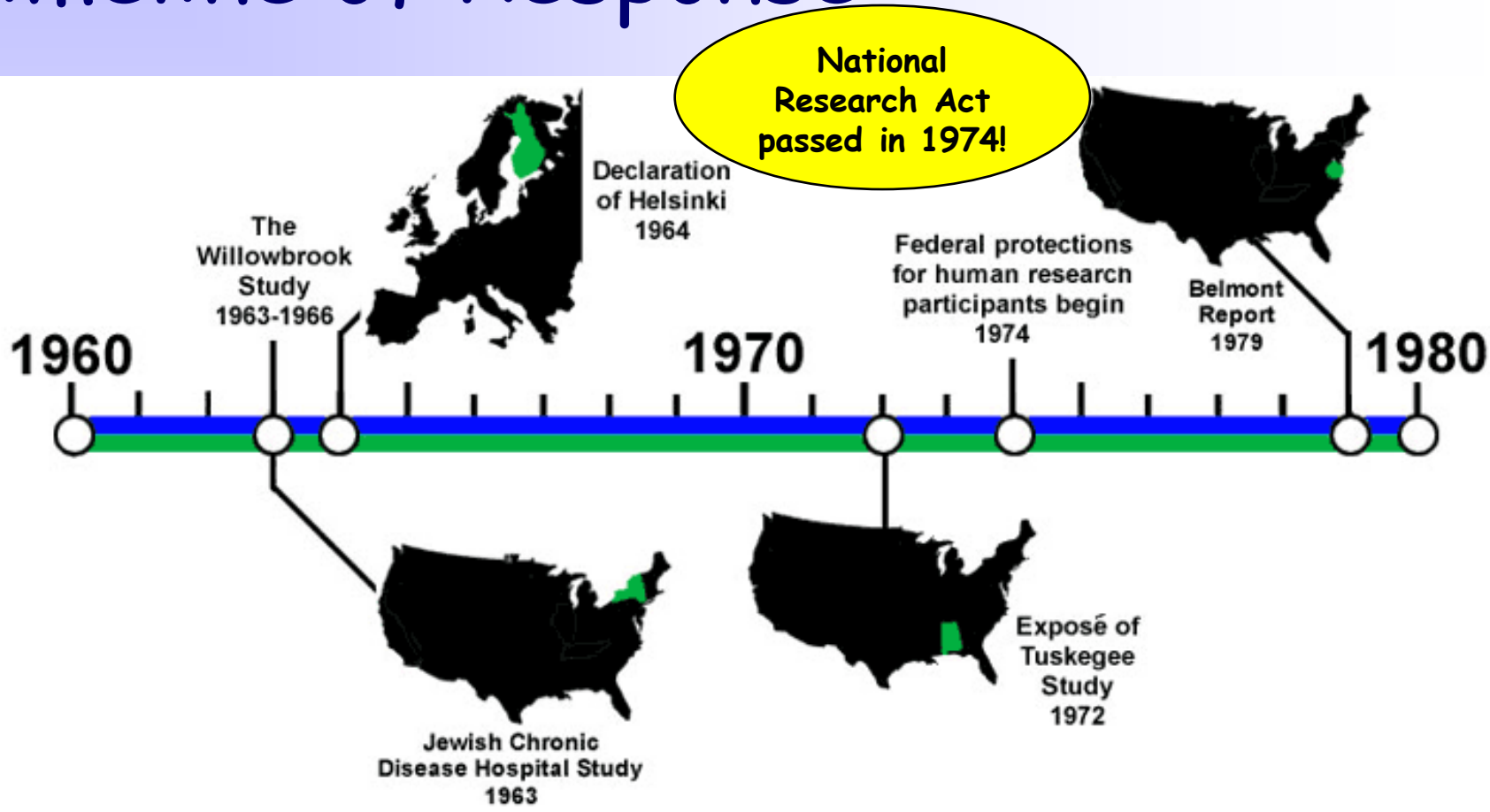
- "Ethical Principles and Guidelines for the Protection of Human Subjects" was published in 1979 by the U.S. DHEW.
- The report listed three ethical principles upon which federal regulations would be based:
  - Respect for Persons
  - Beneficence
  - Justice

Belmont Report: Cornerstone of Ethical Principals

- Respect for Persons – People should be given all necessary information to make truly informed decisions.
- Beneficence – Maximizing benefits while minimizing harm.
- Justice – Treat all people as equals.

Human Subjects in Research

Timeline of Response



From NIH – Human Participant Protections Education for Research Teams

Recent Case: Jesse Gelsinger

- Jesse had Ornithine Transcarbamylase (OTC) deficiency of the liver – a condition that prevents the metabolism of ammonia. The disease is usually fatal at birth, but his condition was not inherited, rather it resulted from a genetic mutation after birth. He was able to survive on a restricted diet and medicine.
- In September 1999, 18 year old Jesse volunteered in a gene therapy clinical trial at the University of Pennsylvania, Institute for Gene Therapy.
- He was injected with an experimental adenoviral vector carrying a corrected gene.
- He died four days later from a massive immune response resulting in multiple organ failure and brain death which was triggered by the vector.

Important information was withheld from Jesse and his family!

- The lead doctor treating Jesse was also PI of the study.
- He held one-third of the shares in the company that was developing the drug.
- The company was funding the clinical trial at the University.
- The University also held equity in the company!

Anything about this trouble you? Your thoughts?

Each of the primary elements of a serious conflict of interest was present!

- The lead doctor treating Jesse was also PI of the study.
  (Conflicting clinical and research roles)
- He held one-third of the shares in the company that was developing the drug.
  (Personal financial conflict of interest)
- The company was funding the clinical trial at the University.
  (Personal financial conflict of interest)
- The University also held equity in the company!
  (Institutional conflict of interest)

Recent Case: Ellen Roche

- Two Johns Hopkins University asthma researchers hypothesized that in people without asthma, lung inflation protects airways from obstruction through some unknown neural messaging mechanism and that this mechanism is somehow disabled in asthmatics.
- They designed a clinical study to test their hypothesis and got approval from the appropriate IRB.
- Their study design involved administering methacholine (a substance that mimics the symptoms of asthma) to healthy individuals.

Recent Case: Ellen Roche

- A group of participants would subsequently be given a dose of hexamethonium, a ganglionic blocker that would prevent one of these neural messaging mechanisms from functioning.
- Ellen, a 24 year old employee at the Asthma and Allergy Center responded to a flier and signed a "Clinical Investigation Consent Form" which did not include all relevant information on the risks involved with inhaling hexamethonium.
- Ellen was either motivated by altruistic desires to help people with asthma or by the $365 fee!

Recent Case: Ellen Roche

On May 4, 2001 she received 1g of hexamethonium by inhalation, developed a dry cough the next day and by May 9 she was hospitalized with fever, hypoxia and various chest abnormalities. Her conditioned worsened and on June 2, 2001 she died of progressive hypotension and massive organ failure.

What's wrong here? Your thoughts?

Let's analyze this case using the three principles from the Belmont Report.

Belmont Report: Cornerstone of Ethical Principals

- Respect for Persons – People should be given all necessary information to make truly informed decisions.

Was this principle followed? If not, how was the principle violated?

Belmont Report: Cornerstone of Ethical Principals

- Beneficence – Maximizing benefits while minimizing harm.

Was this principle followed? If not, how was the principle violated?

Belmont Report: Cornerstone of Ethical Principals

- Justice – Treat all people as equals.

Was this principle followed? If not, how was the principle violated?

The Investigation: Three agencies conducted investigations

Federal Food and Drug Administration (FDA)

Found five violations including failure to submit Investigational New Drug application for the use of hexamethonium as an inhalant, report adverse effects from the experience of the earlier subject, and advise participants that use of drug was experimental.

The Investigation: Three agencies conducted investigations

Johns Hopkins University Internal Review

Criticized both the investigators and the IRB for failure to obtain FDA approval to use hexamethonium as an inhalant and ignoring respiratory problems experienced by the first participant.

The Investigation: Three agencies conducted investigations

Office of Human Research Protection (OHRP)

- Harshest criticism of the three reports! They suspended all research using human subjects pending full compliance by University.
- Found "widespread noncompliance to federal guidelines of research involving human subjects."
- Stopped $301 million in federal research projects involving 2,400 investigators.
- University came into compliance in 3 days.
- Reached an out-of-court financial settlement with Ellen Roche's family.

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AUGUST/SEPTEMBER 2001, VOL. 33, NO. 5

Human Research Subject Protections at Issue

By Peter Melkonian

Ellen Roche, 24, volunteered for an asthma experiment whose main purpose was to find out how a normal lung reacts to irritants. Scientists at Johns Hopkins University had Roche and other healthy volunteers inhale a drug called hexamethonium to provoke airway constriction. The scientists did not alert participants that the chemical can carry significant risk, yet Roche became ill almost immediately. After inhaling the drug, Roche began to cough and feel short of breath. Her lungs and kidneys failed within weeks. On June 2, Roche died of acute respiratory distress syndrome. This tragedy and other human research experiment tragedies have put the issue of human research subject protections into the spotlight.

In July, the OHRP stopped virtually all of Johns Hopkins U.S.-supported research.

The federal Office for Human Research Protections (OHRP) concluded that the Hopkins researchers did not obtain information on hexamethonium and lung toxicity. The drug is not approved for human use and the review board never asked for information on the safety of the drug in humans. The consent form signed by Roche also did not state that hexamethonium was not approved by the Food and Drug Administration (FDA).

In some cases, Hopkins acknowledges, minutes of particular review board meetings were not typed and recorded. In others, research proposals may have been voted on simultaneously or board meetings not properly convened. The federal agency also faulted the University on numerous other points, including situations where board members participated in reviews with conflicting interests. An internal investigation by Johns Hopkins University found fault with the principal investigator and the institution's review board for inadequately examining the risks of the drug and not warning volunteers about the risks. A 1998 report conducted by the inspector general of the Department of Health and Human Services found that institutional review boards "review too much, too quickly and with too little expertise."

Dr. Wendy Baldwin, Deputy Director for Extramural Research at the National Institutes of Health (NIH), believes every university needs to look at how they have organized their human research subject protections. She states "We cannot solely rely on IRBs. IRBs have a critical role but there are data safety monitoring boards, the FDA, and the NIH who also monitor human

continued on page 5

Inside...

Selected Cases:

- Duke University – Allegations of wide-spread noncompliance.
- NIH – Children enrolled in a study involving "greater than minimal risk."
- Fred Hutchinson Cancer Center – Allegations of significant conflict of interest.

Why do these problems persist?

- Financial pressures to obtain/keep research funding
- The rise of corporate-sponsored research
- Conflicts of Interests – both personal and institutional

Science without Ethics can lead to abuse!

Human Subjects in Research

"The first two questions the IRB faces is whether the activity involves research and second, whether it involves human subjects."

Office for Research Protections,
DHHS IRB Review Book

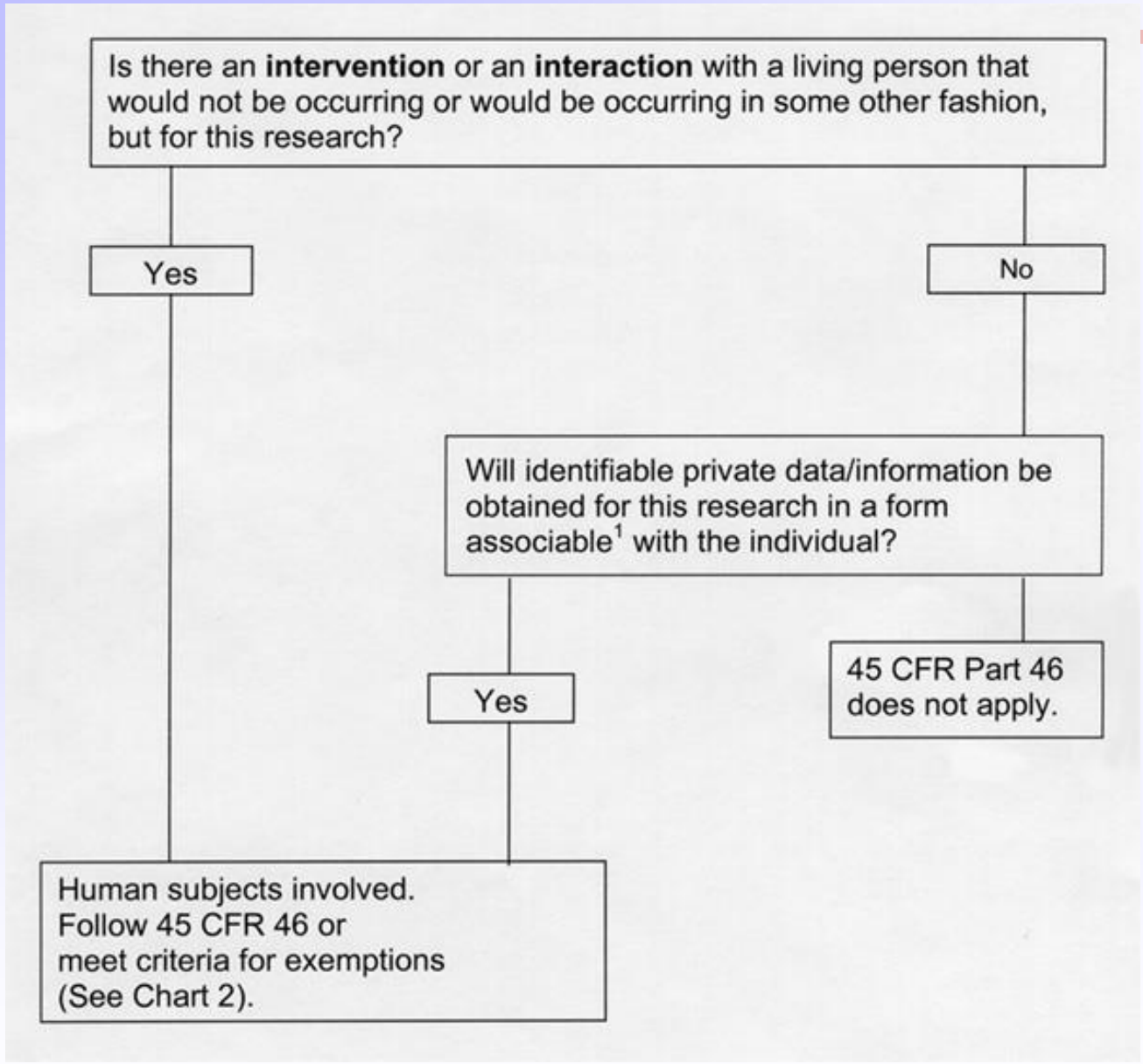
- ✓ What constitutes research?
- ✓ What is a human subject?

The answers may seem obvious, but we must carefully define each of these terms.

"Research is defined by the regulations as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge."

"Human subjects are defined by the regulations as living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) with identifiable private information."

Office for Research Protections, DHHS IRB Review Book



Is it human subject research?

Examples of studies with humans that require IRB review?

- ✓ Clinical trial of investigational drug
- ✓ Comparison of educational methodologies
- ✓ New virtual reality program - testing undergraduate students wearing headgear
- ✓ Chart review of patient data with no patient contact
- ✓ Quality of life study of community housing residents
- ✓ Venous blood samples from volunteers

Examples of studies with humans exempt from IRB review

- ✓ Educational (classroom) strategies
- ✓ Use of educational tests
- ✓ (Re) study of existing data with no identification of participants
- ✓ Study or evaluation of public benefit programs
- ✓ Taste and food quality evaluation (if consumption is otherwise safe)

Best Practice: Always submit to the IRB and let them determine if approval is required!

It is always better to be safe than sorry!

Informed Consent

Information: Informed consent must provide clear information regarding the research study, location, procedures to be followed, potential risks, possible benefits, duration of the study, alternatives, confidentiality provisions, contact information, and assurance of freedom to withdraw without penalty.

Informed Consent

Comprehension: Informed consent must be obtained in a way that is intelligent, rational and respective of the maturity of enrollees. Consent documents must be written in the native language of enrollees, and in a way that is non-technical/non-scientific. The informed consent process and informed consent forms are not for the benefit of the scientist or the lawyers.

Informed Consent

Voluntariness: Informed consent must preclude any element or even the appearance of coercion or undue influence.

Institutional Review Boards (IRBs)

- ✓ Institution-based
- ✓ Peer review
- ✓ Prior review, approval and/or modification

Public Involvement began in the 1960's!

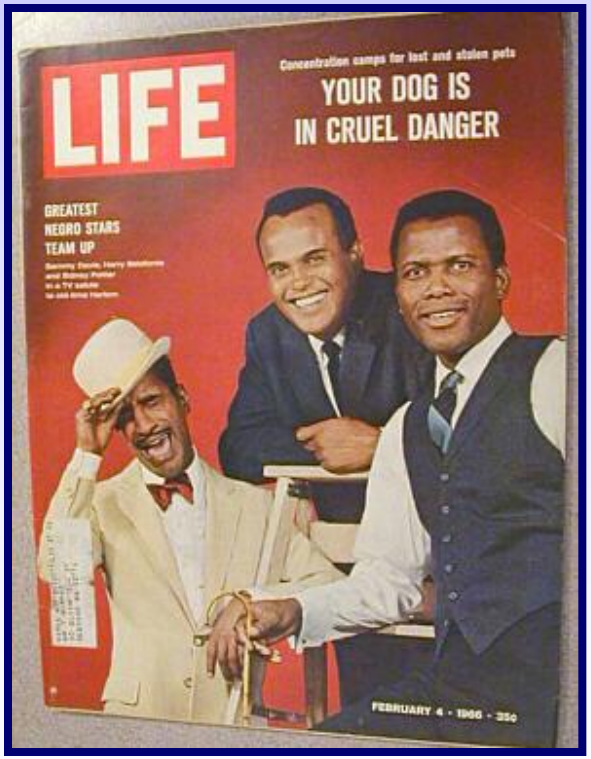
1962 – *Silent Spring*, by Rachel Carson

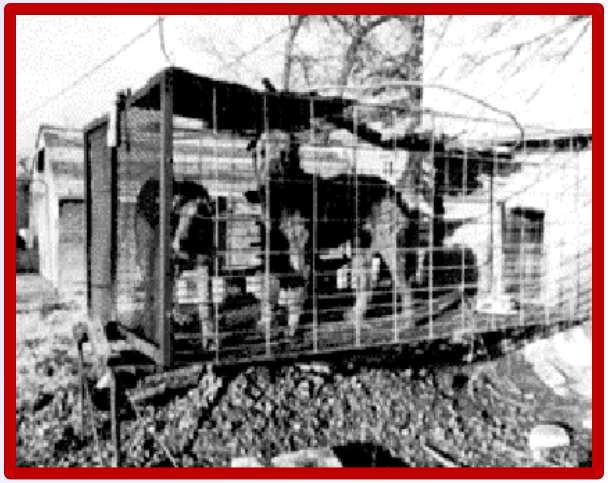
Carson argued that uncontrolled and unexamined pesticide use was harming and even killing not only animals and birds, but also humans. She accused the chemical industry of spreading disinformation and public officials of accepting industry claims uncritically.

The title "Silent Spring" was meant to evoke a spring season in which no bird songs could be heard, because they had all vanished as a result of pesticide abuse!

Public Involvement

1966 – LIFE magazine article

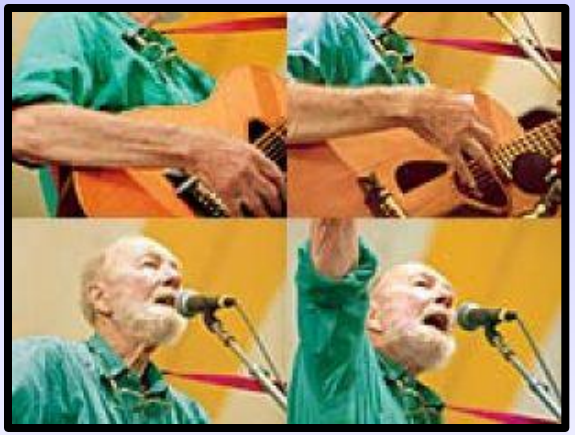




The **Animal Welfare Act** was signed into law by President Lyndon B. Johnson on August 24, 1966. It is the only Federal law in the U.S. that regulates the treatment of animals in research and exhibition.

Public Involvement

1969 – Greenpeace founded



1975 – *Animal Liberation*, by Peter Singer

1982 – "Silver Spring Monkeys"
17 macaque monkeys from the Philippines used in experiments at the Institute for Behavioral Research from 1981-1991.

"Silver Spring Monkeys"

- The monkeys were used as research subjects by Dr. Edward Taub, a psychologist who cut their "different ganglia" which supplied sensation from the brain to their arms.
- He then used arm slings to restrain either the good or deafferented arm to train them to use the limbs they could not feel.
- In May of 1981, Alex Pacheco (PETA) began working undercover at the lab and alerted police to what he consider unacceptable living conditions for the monkeys.
- This resulted in the 1st police raid against an animal researcher in U.S. history!

Pacheco's description of the laboratory

"No one bothered to bandage the monkeys' injuries properly (on the few occasions when bandages were used at all), and antibiotics were administered only once; no lacerations or self-amputation injuries were ever cleaned. Whenever a bandage was applied, it was never changed, no matter how filthy or soiled it became. They were left on until they deteriorated to the point where they fell off the injured limb. Old, rotted fragments of bandage were stuck to the cage floors where they collected urine and feces. The monkeys also suffered from a variety of wounds that were self-inflicted or inflicted by monkeys grabbing at them from adjoining cages. I saw discolored, exposed muscle tissue on their arms. Two monkeys had bones protruding through their flesh. Several had bitten off their own fingers and had festering stubs, which they extended towards me as I discreetly took fruit from my pockets. With these pitiful limbs they searched through the foul mess of their waste pans for something to eat."

"Silver Spring Monkeys"

- Police entered the Institute, removed the monkeys, and charged Taub with 17 counts of animal cruelty and failing to provide adequate veterinary care.
- Litigation continued for several years until the case reached the U.S. Supreme Court in July 1991.
- PETA's application to the Supreme Court for custody of the monkey's was rejected and days later the remaining monkeys were killed.
- While not successful, the custody dispute saw celebrities and politicians campaign for the monkeys' release and brought the matter of cruelty in animal research into the public consciousness.
- This event put PETA on the map!

Last April, People for the Ethical Treatment of Animals (PETA) announced that one of its employees had been working in a laboratory at UNC, secretly videotaping mice, researchers, and staff. Some of PETA's claims were alarming. But were they true? After months of internal investigation and two independent reviews, here's what we've learn

During the early afternoon of April 18, 2002, I stood with reporters and photographers outside the Thurston-Bowles Building and heard the university administrators say, over the growl of buses climbing Manning Dr UNC-Chapel Hill had nothing to hide in its animal-research facilities. No, we not retaliate against People for the Ethical Treatment of Animals (PETA) for planting a spy in our midst for six months or for secretly videotaping our researchers and animal-husbandry staff. No, we had no plans to conduct background checks on prospective employees to weed out the spies. And yes, members of the press could come inside our animal facilities and have a look around.

Then, with the cameras rolling, Tony Waldrop, vice chancellor for research and graduate studies, made a promise that in one breath appropriated several

In 2002, PETA infiltrated UNC labs and documented problems with the procedure for killing mice!

thousand hours from dozens of faculty, administrators, and staff. "We will," he said, "investigate every aspect of every allegation."

Six months later, as I write this, we have honored that promise. Our investigators have conducted dozens of interviews, reviewed hundreds of records, endured 40-some hours of murky videotape, and we have submitted our reports. Here's the bottom line: There were some problems, a few of them serious. The university suspended the animal-research privileges of two researchers. Two others received probation, and several more have been required to modify their procedures or undergo additional training. One animal-facility manager has resigned. One new laboratory technician has been hired. We have turned over hundreds of pages of documents requested under North Carolina's public-records law, to PETA. Two separate review teams have come to campus and independently put us under the microscope. And we have shipped a report of our findings to the Office of Laboratory Animal Welfare (OLAW) in the National Institutes of Health (NIH).

Is that the end of the story? No. It will take time to upgrade staff and facilities, refine our new procedures, conduct new training, and confirm that our safeguards are working. And even though we have answered hard questions from reporters, from PETA, and from OLAW, we have not yet put our answers on the record for the people who support this university and its research. That's what this story is intended to do.

Improbable Ally

Photo by Neil Caudle click to enlarge

The story begins, improbably enough, with Senator Jesse Helms. The University of North Carolina at Chapel Hill has not, in the past, been one of Senator Helms' favorite institutions. But in the case of the Helms Amendment to the 2002 Farm Bill, university officials were squarely on his side. The amendment was intended to prevent provisions of the Animal Welfare Act (AWA) from being extended to mice, rats, and birds. Like other research universities accredited by the

Government Involvement

- 1962 – NIH issued the first *Guide For the Care and Use of Laboratory Animals*
- 1966 – Laboratory Animal Welfare Act
  - Covered warm blooded animals used in teaching, research and testing
  - Excluded rats, mice and birds
  - Enforced by the USDA
  - Annual Inspections were required

Government Involvement

- 1970 – Animal Welfare Act
  (updated in 1976, 1985, 1990)
- 1973 – Public Health Service Policy
  (updated in 1979, 1985)
- 1985 – PHS Health Research Extension Act
  - Covered live vertebrate animals when PHS funds are involved.
  - Enforced by the Office of Laboratory Animal Welfare (OLAW), NIH.

Government Involvement

- Both PHS Policy and the AWA established the Institutional Animal Care and Use Committee (IACUC) as the authorizing body
- Membership
  - Representative of entire institution
  - One non-scientist
  - Community representative out-side of university

COMP 918: Research Administration for Scientists

Research Ethics: Misconduct in Science, Authorship, Peer Review and Data Rights/Ownership

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Science is a Community Based on Trust

"Most Americans see strong science as essential to a successful future. Yet that generous social support is based on the premise that **science will be done honestly** and that mistakes will be routinely identified and corrected."

Bruce Alberts, President,
National Academy of Sciences,

"The right to search for truth implies also a duty; one must not conceal any part of what one has recognized to be true."

- Albert Einstein

"The only ethical principle which has made science possible is that the truth shall be told all the time…"

C.P. Snow "The Search" 1959

Three Important Themes in Science

- ✓ Trust
- ✓ Truth telling
- ✓ Ethics

Trust is dependent upon truth-telling!

Three Important Themes in Science

- ✓ Trust
- ✓ Truth telling
- ✓ Ethics

If society no longer believes scientists are telling the truth, trust (and support) for science will be lost!

Three Important Themes in Science

- ✓ Trust
- ✓ Truth telling
- ✓ Ethics

We rely upon "ethics" to keep scientists trust worthy!

Three Important Themes in Science

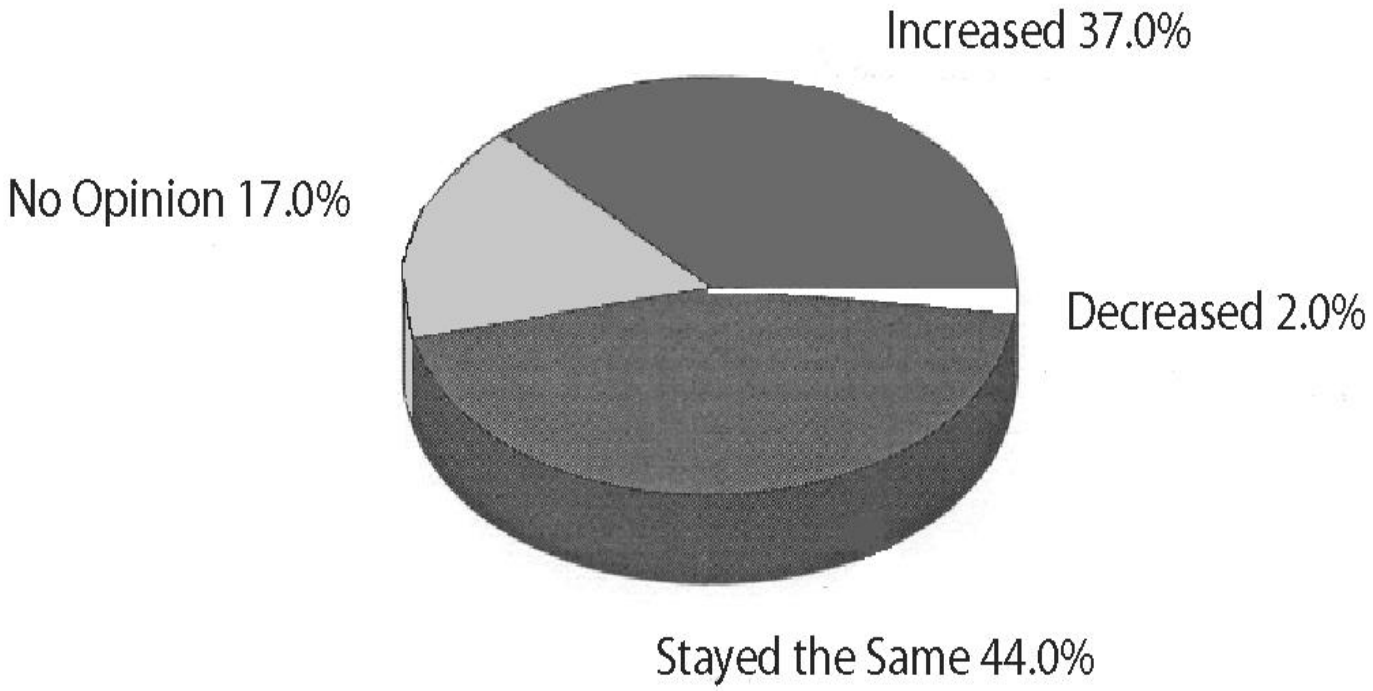
- ✓ Trust
- ✓ Truth telling
- ✓ Ethics

But what exactly does the term "ethics" mean?

Three Inter-Related Aspects of Ethics

- A set of principles of right conduct.
- The formal rules and standards that govern the conduct of an individual or the members of a profession.
- Behavior expected of all faculty, students, and staff to conduct research with the highest standards of integrity!

Principles – Rules - Behavior



Scientific Fraud and Misconduct Frequency Over the Past 10 Years

Institutional Compliance

This concern for fraud along with the conflicts of interest posed by the commercial opportunities for patenting and licensing university inventions have made it necessary for universities to develop comprehensive systems to monitor and manage ethics at the individual and the institutional level!

Four Areas of Concentration for Institutional Compliance Systems

- Proper fiscal management of public funds.
- Protection of human and animal research subjects.
- Proper use and disposal of hazardous materials.
- Preventing research misconduct through strict adherence to the scientific method and truth telling.

Federal Definition Research Misconduct

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results is research misconduct. It does not include honest error or differences of opinion.

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Use in Any Research Proposal!

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Use in the Conduct of Research!

Federal Definition Research Misconduct

Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results is research misconduct. It does not include honest error or differences of opinion.

Use in Formal Peer Review or Any Other Review of Research Results!

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Use in Project Reports or Any Publications!

Fabrication, Falsification of Medical Research Data

By Gary Schwitzer, January 25, 2012

The British Medical Journal reports:
"More than one in ten (13%) UK-based scientists or doctors have witnessed colleagues intentionally altering or fabricating data during their research or for the purposes of publication, while 6% say they are aware of possible research misconduct at their institution that has not been properly investigated, reveals a *BMJ* survey published today which attracted over 2,700 responses.

Dr. Fiona Godlee, *BMJ* Editor in Chief, said: "While our survey can't provide a true estimate of how much research misconduct there is in the UK, it does show that there is a substantial number of cases and that UK institutions are failing to investigate adequately, if at all. The *BMJ* has been told of junior academics being advised to keep concerns to themselves to protect their careers, being bullied into not publishing their findings, or having their contracts terminated when they spoke out."

Disgraced Cloning Expert Convicted in South Korea

The New York Times October 26, 2009

SEOUL, South Korea – Hwang Woo-suk, a disgraced cloning expert from South Korea who had claimed major breakthroughs in stem-cell research, was convicted Monday of falsifying his papers and embezzling government research funds. A judge sentenced him to a suspended two-year prison term, saying Dr. Hwang had shown remorse and had not taken research money for personal use.

Dr. Hwang was once hailed as a national hero in the South. His school, Seoul National University, disowned him in 2005, saying that he had fabricated the papers he had published to global acclaim.

Former Harvard professor Marc Hauser fabricated, manipulated data

The New York Times

September 5, 2012

Marc Hauser, a prolific scientist and popular psychology professor who last summer resigned from Harvard University, had fabricated data, manipulated results in multiple experiments, and described how studies were conducted in factually incorrect ways, according to the findings of a federal research oversight agency posted online Wednesday.

The report provides the greatest insight yet into the problems that triggered a three-year internal university investigation that concluded in 2010 that Hauser, a star professor and public intellectual, had committed eight instances of scientific misconduct. The document, which will be published in the Federal Register Thursday, found six cases in which Hauser engaged in research misconduct in work supported by the National Institutes of Health. One paper was retracted and two were corrected, and other problems were found in unpublished work.

Cases of Plagiarism Handled by the United States Office of Research Integrity 1992-2005

By Alan R. Price, Associate Director for Investigative Oversight
Office of Research Integrity

ORI Definition of Plagiarism : As a general working definition, ORI considers plagiarism to include both the theft or misappropriation of intellectual property and the substantial unattributed textual copying of another's work. It does not include authorship or credit disputes. . . . Many allegations of plagiarism involve disputes among former collaborators who participated jointly in the development or conduct of a research project, but who subsequently went their separate ways and made independent use of the jointly developed concepts, methods, descriptive language, or other product of the joint effort. The ownership of the intellectual property in many such situations is seldom clear, and the collaborative history among the scientists often supports a presumption of implied consent to use the products of the collaboration by any of the former collaborators. For this reason, ORI considers many such disputes to be authorship or credit disputes rather than plagiarism. Such disputes are referred to PHS agencies and extramural institutions for resolution (ORI, 1994).

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Kowalski - He was an instructor in medicine at the Dana Farber Cancer Institute, after completing his residency and postdoctoral work in pathology at Harvard Medical School. He took with him an NIH grant application on the immune response to HIV/AIDS glycoprotein by his mentor, focusing on an area in which the respondent had not worked nor written for that laboratory (thus, he was not a collaborator on the source application). He copied essentially the whole application of his former mentor for use as his own NIH grant application, as alleged by a reviewer who had seen the original application at NIH. He was not debarred, but in 1993 he was given a 3-year certification and prohibition from PHS service period.

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Imam - He was an associate professor of pathology at the University of Southern California who copied almost all of a grant application on human DNA telomerase enzyme to a state agency, which had been given to him in confidence by a peer reviewer. The respondent used it in his own NIH grant application, as alleged by a reviewer, who was the original applicant. In 1997, he was debarred for 3 years as well as prohibited from PHS advisory service.

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Farooqui - He was a research associate professor of dermatology at the University of Cincinnati, who plagiarized material on hormone expression in human skin from the significance section of a National Science Foundation (NSF) grant application, as alleged by a reviewer for NSF, which the respondent had obtained from another confidential reviewer and used in his NIH grant application. After ORI imposed on him in 1996 a 3-year certification and non-service period, NSF OIG expanded the case, finding more of the same plagiarism in NSF applications, so NSF debarred him for an additional period.

Institutional Responsibility

Awardee institutions have primary responsibility for the prevention and detection of research misconduct and for the inquiry and investigation of alleged research misconduct.

Laboratory Notebook!

Yes, the laboratory notebook (real or virtual) is still the "gold standard" and final authority on data collection, manipulation, and presentation. It should contain:

- All the information on an experiment's design and execution.
- The original data - preferably as the raw data output.
- Calculations and data reductions.
- Conclusions and interpretations.

Courts have favored paper over electronic!

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- Conclusions and interpretations.

Should be signed, dated and witnessed!

Who owns data?
PI, institution or funding agency?

- **It Depends!**
- If created under a sponsored research agreement, the terms (FAR clauses) are authoritative.
- Remember, all agreements are between the university and the funding agency in the name of a PI, so any obligation to deliver data rest with the university.
- What is the university's data rights policy?

Case Study: Data Ownership

- A graduate student has just defended her dissertation and is leaving for a post doctoral position at another university.
- While packing up her office, her mentor refuses to allow her to take the laboratory notebooks which contain her research data.
- The mentor won't even allow her to take copies.
- Who do you think owns the research data?
- Should the student have been allowed to take the results of her labors? How about a copy?
- Would your view be different if the student was going to a competitor's laboratory? How about into industry?

Federal Definition Research Misconduct

Fabrication: Making up data or results and recording or reporting them.

Case Study: Data Fabrication

You believe the work of a fellow student assigned to your lab is forged. The data are too clean, the student isn't in the lab often enough to support the amount of data generated, and sufficient reagents are not being consumed consistent with the research.

- Is there enough "evidence" to allege data fabrication?
- Let's say you report your suspicions to the PI and are simply told to "mind your own business" - What would you do?
- Is reporting your concern to the PI sufficient? Do you have additional ethical responsibilities? When have you adequately fulfilled your ethical responsibilities?

Federal Definition Research Misconduct

Falsification: Manipulating research materials, equipment, or processes, or changing or omitting data or results such that the research is not accurately represented in the research record.

Case Study: Data Falsification - 1

- You are a junior member of a research team using an autoanalyzer to test the effects of radioprotective agents on prostaglandin production. Only six of the ten assays demonstrate protection.
- A senior researcher (not the PI) suggests the lack of observed response in the other four assays was due to "equipment failure."
- Is this assessment valid? Should it be accepted, rejected or questioned?
- How might the assessment be tested?
- If the ambiguity persists, how should you proceed?
- Is leaving responsibility with the senior investigator enough? Would it matter if the PI agreed with the senior investigator?

Case Study: Data Falsification - 2

- You prepare a scatter-graph that demonstrates a time-dependent effect. Unfortunately, several points do not closely follow the relationship.
- Your advisor suggests dropping the lowest points because "the cells were obviously dead" and the highest point because "it is an obvious outlier."
- Is the suggested method for determining which points to exclude acceptable?
- If you are not satisfied with the instructions from your advisor, what other course(s) of action are open to you in this situation?
- In general, how would you approach your advisor when facing any issue involving proper ethical behavior?

Federal Definition Research Misconduct

Plagiarism: The appropriation of another person's ideas, processes, results, or words without giving appropriate credit.

Case Study: Plagiarism

You are reviewing a paper for a journal and recognize a significant portion of the text. After checking, you confirm that the paper indeed incorporates entire passages from other works without attribution.

What Action Should You Take?

- Immediately report your concerns to the Journal? Or would you contact the author first? Would knowing the author influence your actions?
- If you spoke with the author would any of these explanations cause you to be more lenient:
  - The author said it was simply a careless oversight.
  - The author is a first year graduate student with little experience.
  - The author comes from a country with different standards for citations.

Authorship

Authorship of a scientific paper should be limited to those individuals who have contributed directly to:

- the design and execution of the experiments and
- participated in the preparation of the manuscript.

There may be some variation by discipline!

Is "and" right or should it say "and/or?"

Case Study: Authorship

A paper is being prepared concerning the metabolism of sulfites. Which of the following should be included as authors?

- Toxicologist who provided previously published information on animal models.
- Wildlife specialist who provided information on breeding mice.
- Technician who helped develop assay and wrote the methods section.
- Another scientist who helped design experiments and edited the final draft.

Peer review is the process used within the scientific community where scientists evaluate their colleagues' grant applicants for possible funding and their scientific papers for possible publication.

Two guiding principles:

- Fairness
- Confidentiality

Case Study: Peer Review

A faculty investigator who is also a consultant to a biotech company serves on an NIH study section. He reviews a grant proposal which contains information demonstrating that his current work (both academic and corporate) is headed down a blind alley.

How should he proceed?

Case Study: Peer Review

- What issues of confidentiality and conflict of interest are involved?
- "Once the bell has been rung, it can't be unrung!" Now that he has the knowledge, he can't just forget it!
- How might this situation have been avoided?

False Claims Act Whistleblowers

A good faith allegation is made with the honest belief that research misconduct may have occurred. An allegation is not in good faith if it is made with reckless disregard for or willful ignorance of facts that would disprove the allegation.

False Claims Act
Qui Tam Provisions

- "He who sues on behalf of the King as well as for himself."
- Allows private parties to sue entities and individuals that have submitted false claims to the Government.
- The person must have actual knowledge of allegedly false claims to the Government to file a lawsuit on behalf of the Government.

False Claims Act
Qui Tam Provisions

- If the Government receives a monetary settlement from the defendant, the Act allows the person bringing the suit to receive a portion of the settlement.
- Individuals seeking whistleblower status must first meet several criteria defined in the Act.

Check to be certain you qualify for whistleblowers status before proceeding!

False Claims Act
Qui Tam Provisions

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- Individuals seeking whistleblower status must first meet several criteria defined in the Act.

Whistleblowers status affords some legal protection against retaliation!

False Claims Act Recovery

- In 2008, the Government recovered approximately $1.3 billion through False Claims Act suits.
- 90% of the recovered funds came from health care and pharmaceutical companies.
- For 2009, Congress allocated an additional $25 million to combat fraud and abuse in the Medicaid Program alone.

False Claims Act
University of Georgia

This 2006 suit alleged that University of Georgia researchers committed violations of the False Claims Act by receiving more than $1 million in Environmental Protection Agency grants based upon published research that had used manipulated data which discounted the toxicity of the tested sewage sludge.

False Claims Act
University of Georgia

The suit was filed by the Government on behalf of *qui tam* (whistle-blower) plaintiffs David L. Lewis, an adjunct senior research scientist at UGA (and a former microbiologist at the Environmental Protection Agency), and two farming families who alleged the sludge contained harmful chemicals that resulted in the death of cattle on their farms.

False Claims Act
University of Georgia

The suit specifically alleged that sludge samples were:

- not included from farms that reported animal deaths and
- were taken only during drought periods when toxin levels would be lowest.

Results of litigation sealed!

False Claims Act
St. Louis University

This suit was brought by whistleblower and former Dean, Andrew Balas. It alleged the SLU School of Public Health overstated time spent by faculty members on CDC grants, resulting in significant overpayment.

The investigation identified numerous examples of NIH and HUD grants being charged for these "phantom faculty work hours" resulting in similar overpayments.

False Claims Act
St. Louis University

SLU's Defense: A good faith effort had been made to comply with "highly complicated cost accounting principles governed by regulations that are hundreds of pages long." Any mistakes made were simply that – unintentional mistakes!

This is the "don't blame me" defense! It's the Government's fault for making the rules so darn hard to follow!

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St. Louis University

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SLU settled for $1 million.

The whistleblower received $190,000 as his share of the recovery!

False Claims Act
Weill Medical College, Cornell

The whistleblower was:

- The PI's senior administrative assistant.
- She had worked at Cornell for 11 years before resigning 2002.

She filed the suit in April 2004.

False Claims Act
Weill Medical College, Cornell

The lawsuit alleged that the PI misrepresented which researchers were working on particular grants; misapplied and fraudulently accounted for grant funds; falsified data from research; and submitted the same projects multiple times even if funded by other agencies.

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$2.6 million settlement!

False Claims Act
Yale University

Yale researchers allegedly spent down remaining grant funds near the expiration dates via cost transfers that were deemed not "allocable", i.e., the costs did not relate to the work of that specific project.

Note: Federal regulations require that unspent fund balances at the end of a grant be returned to the Government.

False Claims Act
Yale University

- $7.6 million final settlement - $3.8 million actual plus $3.8 million punitive damages.
- No criminal charges were brought.
- The Government acknowledged Yale's cooperation in the investigation and its ongoing efforts at reform.
- It is likely that Yale's consulting & legal fees exceeded the final settlement amount.

False Claims Act Suits Involving Falsified Effort Reporting

Many False Claims Act suits allege that:

- Researchers spent less time working on grants than the proposal promised or
- The grant was charged for someone who didn't work on the grant.

Resulting in overstatement of effort!

False Claims Act: Selected University Settlements

- Northwestern - $5.5m (Feb. 2003)
- Johns Hopkins - $2.6m (Feb. 2004)
- Alabama-Birmingham - $3.4m (April 2005)
- Cornell - $4.4m (June 2005)
- University of Connecticut - $2.5m (Jan. 2006)
- Harvard - $2.4m (June 2004)

Effort Reporting Case Study

- Physician Scientist Dr. E. Coli
- 2 NIH grants - 25% effort
- 3 days/week in clinic
- Directs Infectious Diseases medical curriculum
- Lectures to medical students three times per week, and
- Serves on the institutional promotion and tenure committee.

Any cause for concern with Dr. Coli's effort?

Federal Investigative Agencies for NIH and NSF

- Office of Research Integrity in the DHHS, promotes integrity in biomedical and behavioral research supported by PHS. ORI monitors institutional investigations of research misconduct (www.ori.hhs.gov)
- Office of the Inspector General in the NSF is responsible for preventing, detecting, and handling cases involving research misconduct (www.nsf.gov/oig)

ORI

National Science Foundation
WHERE DISCOVERIES BEGIN