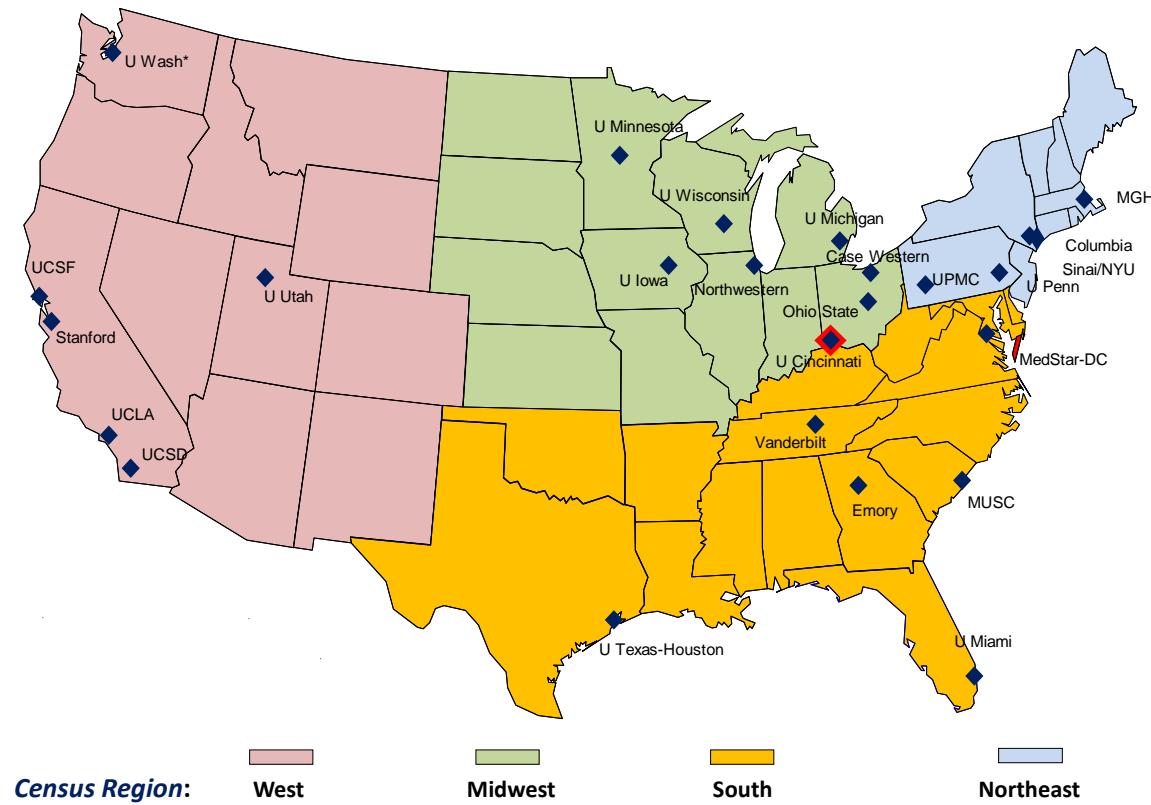


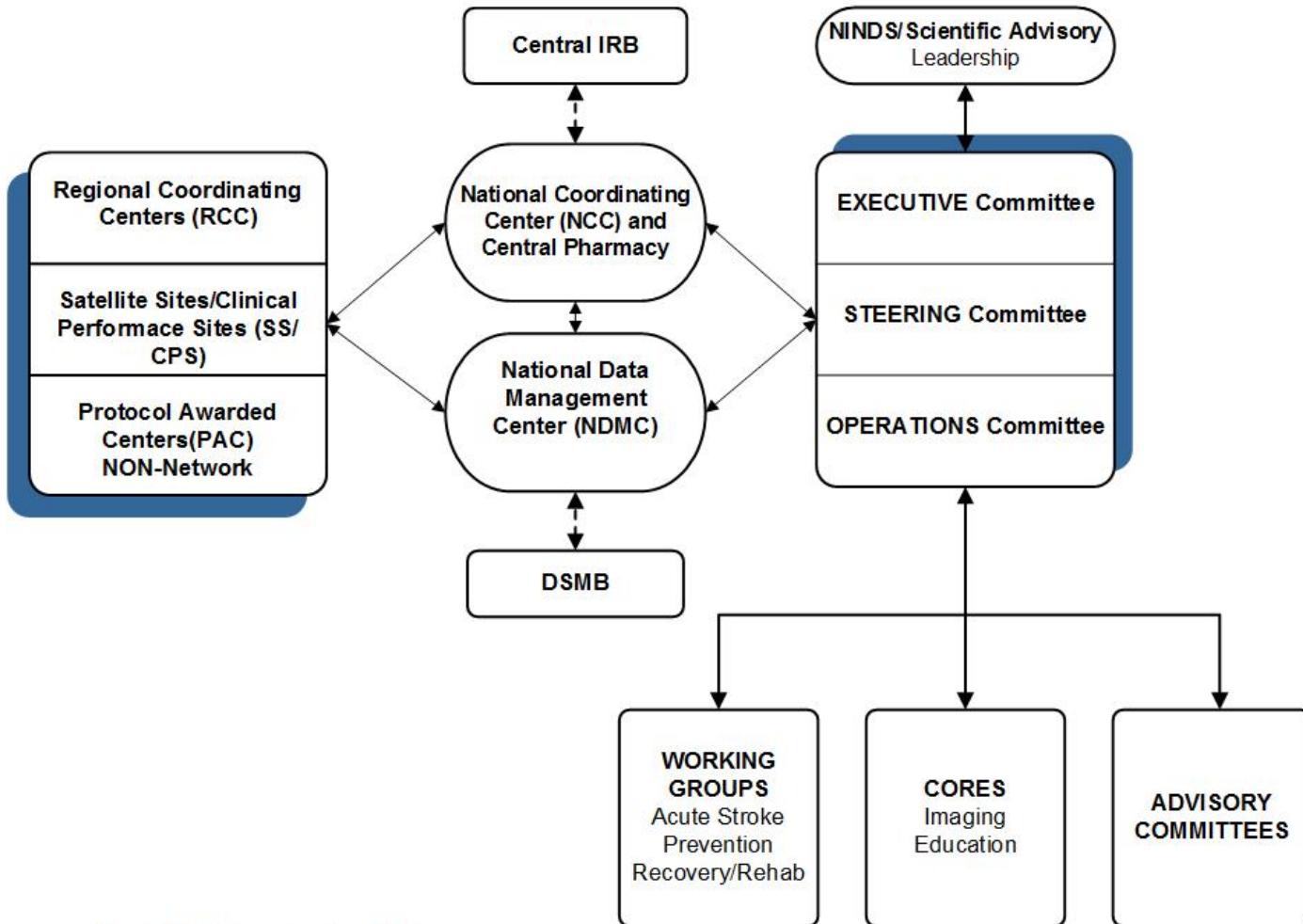


*Maximizing Efficiencies in Cerebrovascular Research*

# “Business End of NIH StrokeNet”

## National and Regional Coordinating Centers





StrokeNet Organizational Figure

# **“Business End of NIH StrokeNet”**

- ▶ NIH StrokeNet (Prevention, Treatment & Rehab)
- ▶ National Coordinating Center (NCC) (UC)
- ▶ Central Institutional Review Board (CIRB) (UC)
- ▶ Data Management Center (DMC) (MUSC)
- ▶ 25 Regional Coordinating Centers (RCC)
- ▶ Satellites (~>300)
- ▶ Clinical Performance Sites

# **“Business End of NIH StrokeNet”**

- ▶ **5 years**
- ▶ **4–5 Phase I & II clinical trials**
- ▶ **2–4 Phase III clinical trials**
- ▶ **Project Source:**
  - PIs in Network;
  - PIs outside Network;
  - NINDS Industry Partners;
  - Current NINDS studies
- ▶ **Drug, Biologic, Device, or other technology**
- ▶ **(NINDS CRADA or 3<sup>rd</sup> Party Agreements)**

# **“Business End of NIH StrokeNet”**

- ▶ RCC Performance Measures:
- ▶ >50% of performance sites FEO Master Trial Agreement w/ NCC
- ▶ >50% of performance sites FEO CIRB Reliance Agreement w/ NCC
- ▶ Standard Operating Procedures (SOPs) of RCC and performance sites submitted to NCC and NINDS
- ▶ Establishment of monthly reports to NCC regarding RCC activities

## **“Business End of NIH StrokeNet”**

- ▶ RCCs chose which trial they or their Satellites will participate in.
  - Said RCC may pass but have one or more of its Satellites participate.
  - RCC may participate but none of its Satellites will participate.
  - RCC participates and all of its Satellites participate
  - Combination

# “Business End of NIH StrokeNet”

- ▶ Performance Measures:
- ▶ CIRB review < 2months NINDS Council approval of protocol
- ▶ 1<sup>st</sup> 3 trials start-up < 6 months from NGA to 1<sup>st</sup> patient/visit
- ▶ 1<sup>st</sup> 3 trials 50% of RCCs initiate study < 4 months from NGA \*\*PTAs\*\*
- ▶ Evidence that the **RCC is sustaining an average monthly enrollment** of at least one participant per Stroke Network study conducted at this RCC over a consecutive three month period prior to the November 1, 2015 Administrative Continuation submission.
- ▶ Evidence that the RCC has collaboratively **participated in** development of at least one Stroke Network clinical trial protocol that has been submitted as a new grant application to the NINDS

# "Business End of NIH StrokeNet"

## ► Agreements

- ❖ Master Trial Agreement (MOU & \$0) – RCCs & Satellites – **from the NCC**
- ❖ Reliance Agreement (CIRB) – RCCs & Satellites – **from the CIRB**
- ❖ Protocol Trial Agreements – Participating RCCs & Satellites – **from the NCC**
- RCCs – NINDS – NO SUBAWARDS – NINDS NO \$25K



# “Business End of NIH StrokeNet”

- ▶ RCC MTA turnaround



- 4 days to 60 days with an average of 29 days

- ▶ RCC Satellite MTA turnaround

- FEOs to date 9, PEOs 44, numerous 3B attachments

# **“Business End of NIH StrokeNet”**

## ► Subaward numbering:

- 008822 (UC Coeus #)-Vendor Number for each RCC or RCC Satellite



## ► Site Numbers:

- RCC – R01, R02, etc. (alphabetical)
- Satellites – R01-S01, R01-S02, R02-S01, etc.

## ► Subject lines on e-mails:

- #RCC & Name of RCC
- #RCC–Satellite & Name of Satellite

# **“Business End of NIH StrokeNet”**

## ► **Protocol Trial Agreements (PTAs)**

- Each PTA agreement will be individual stand-alone with a new NINDS grant number
- Trial specific
- Different types of trials = Different PIs
- Trial budgets will be in place prior to the PTAs going out.
- PTAs can be sent to RCCs and the Satellites that have signed an MTA.
- Payments to Clinical Performing Sites by RCC and Satellites from their PTA by Purchase Order.

# “Business End of NIH StrokeNet”

## ► PAYMENT

- PTAs represent mechanism through which sites will be paid.
- Payment will occur on a per patient, trial-specific basis.
  - For each trial – patient payment parameters/milestones/intervals will be programmed into the webDCU.
  - Auto-generated message is sent to the NCC that payment to X Institution in the amount of \$Y is due.
  - NCC will generate the invoice, submit to UC Accounts Payable, and payment will be scheduled for payment 30 calendar days from date of invoice submission.
  - PTA PI and PTA Study Coordinator will be notified via email of pending payment.
    - NOTE – UC is requiring ALL payees to enroll for Electronic Funds Transfer (EFT) payment. The NCC is working to ensure that your institution has enrolled for EFT prior to when StrokeNet trials are actively enrolling.
- Payments from the RCC or Satellite level to their Clinical Performance Sites will be via Service Agreements or Purchase Orders.

# **“Business End of NIH StrokeNet”**

**NCC**

**U01 – Research Project Cooperative Agreement** – Supports discrete, specified, circumscribed projects to be performed by investigator(s) in an area representing their specific interests and competencies.

Used when substantial programmatic involvement is anticipated between the awarding Institute and Center.

One of many types of cooperative agreements.

No specific dollar limit unless specified in FOA

# **“Business End of NIH StrokeNet”**

**RCC**

- ▶ **U10 – Cooperative Clinical Research-- Cooperative Agreements** – To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and are usually conducted under established protocols.
  
- ▶ **NOA Issue** –
  - Administrative vs Human Subject Research

# “Business End of NIH StrokeNet”

- ▶ RFAs – Released Wed 5/14/2014
- ▶ PAR-14-220: NIH StrokeNet Clinical Trials and Biomarker Studies for Stroke Treatment, Recovery, and Prevention (**U01**)
  - <http://grants.nih.gov/grants/guide/pa-files/PAR-14-220.html>
- ▶ Application Receipt Date(s): **July 15, 2014**; subsequently, beginning with October 5, 2014; Multiple dates, see announcement.

# “Business End of NIH StrokeNet”



- ▶ **Rock Talk** *Helping connect you with the NIH perspective*
- ▶ Posted on March 14, 2014 by Sally Rockey
- ▶ **Federal Agencies and Research Organizations Working In Partnership**
- ▶ There are many ways my NIH colleagues and I keep up with the concerns of the research community, but one way that I have not discussed in depth on the blog is the Federal Demonstration Partnership or FDP. The FDP is a forum of federal agencies and funding recipients, sponsored by the Government, University, Industry, Research Roundtable of the National Academies, that comes together to work on identifying, testing, and implementing effective processes and systems for the management of federal government-supported research and education. What started out in 1986 as an experiment between the Florida State University System, the University of Miami, and 5 federal agencies, including NIH, has evolved into an organization of 120 research institutions and 10 federal agencies that work together on efficient support of extramural research.
- ▶ NIH, and my office in particular, is very active with the FDP. Michelle Bulls, the head of the NIH Office of Policy for Extramural Research Administration within the Office of Extramural Research, is a longstanding member of the FDP Executive Committee, which provides overall direction to the entire partnership. Several NIH leaders also serve as co-chairs of FDP subcommittees that are convened to discuss important topics in depth, such as conflict of interest and the outcomes of scientific investments.
- ▶ The FDP has contributed to a number of significant improvements to the grants process, helping to identify and promote changes such as allowance of no cost extensions, increased budget flexibility, allowing pre-award costs, and more. One particularly important FDP initiative is quantifying how the administrative tasks associated with federal grants affect time spent on research. ...
- ▶ Wondering if your institution or agency is part of this group? Current FDP member organizations are listed on the FDP website. Every six years the FDP enters a new phase to identify priority areas, and they are now accepting applications through March 28 for new organizations to join the upcoming phase. ...

[http://nexus.od.nih.gov/all/2014/03/14/federal-agencies-and-research-organizations-working-in-partnership/?utm\\_source=nexus&utm\\_medium=email&utm\\_content=nihupdate&utm\\_campaign=mar13#sthash.dZRk8IEu.dpuf](http://nexus.od.nih.gov/all/2014/03/14/federal-agencies-and-research-organizations-working-in-partnership/?utm_source=nexus&utm_medium=email&utm_content=nihupdate&utm_campaign=mar13#sthash.dZRk8IEu.dpuf)

# “Business End of NIH StrokeNet”

- ▶ Benefit of the FDP Subaward template
- ▶ Federal agency acceptance
- ▶ Standardization of template and attachments
- ▶ Ease of review of Special Terms and Conditions (The only place for revisions!)
- ▶ Delegated signature authority
- ▶ Quicker turnaround



# **“Business End of NIH StrokeNet”**

- ▶ Academic site vs. a clinical performing site
- ▶ Academic site is the university, the school of medicine.  

- ▶ Clinical performing sites are places where patients are enrolled in a trial, and or treated and or data is entered into WebDCU.  


# “Business End of NIH StrokeNet”

- ▶ If patients are being recruited and or treated and or data entered into WebDCU from a facility **not listed** on the RCC or the RCC Satellite MTA agreements, an amendment needs to be completed to add the clinical performing sites to ensure MUSC has a complete listing of the clinical research centers for reporting purposes.
- ▶ WebDCU™ is a web based clinical trial data management system developed by the Data Coordination Unit at MUSC (Medical University of South Carolina). <https://webdcu.musc.edu/>



# “Business End of NIH StrokeNet”

## ► Information Collected

- DUNS #



- Congressional Districts



- Zip + 4



## ► Taxpayer \$\$

- Congress and consumer interest groups want to know

## **“Business End of NIH StrokeNet”**

- ▶ FFATA – Federal Funding Accountability and Transparency Act of 2006 – ensures that the public can access information on all entities and organizations receiving Federal funds.
- ▶ Central to the law was the development of [www.USASpending.gov](http://www.USASpending.gov), a publically available website with searchable information on each Federal grant and contract over \$25,000.



- ▶ Subawards = RCC PTAs and RCC Satellite PTAs

# “Business End of NIH StrokeNet”

- ▶ FSRS.gov – The Federal Subaward Reporting System collects data on executive compensation and first-tier subawards.



- ▶ Report must be filed within 30 days after full execution of agreement
- ▶ A Grant can be accessed only once per month
- ▶ [http://grants.nih.gov/grants/public\\_accountability/ffata.htm](http://grants.nih.gov/grants/public_accountability/ffata.htm)

# **“Business End of NIH StrokeNet”**

- This award does not have automatic carryover, must be requested annually from the GMB office at NINDS.
- Must have a FFR filed each year with NIH.
  - FFR = Federal Financial Report. NECESSARY to have been received and accepted in order for an institution to request carryover.
- RCC Year 1 funds withheld pending completion of project milestones: **This money will be available whenever your RCC reaches the milestones required for release of this money, regardless of the year in which your RCCs milestones are met.**
  - For example, if it takes until project year 3 (8/1/2015 – 7/31/2016) for an RCC to achieve MTA & RA execution by 50% of identified performance sites, the funds originally withheld will still be available and can be requested at that time and provided that the other milestones had been achieved.

# “Business End of NIH StrokeNet”

- ▶ For Profit determination:
- ▶ State Secretary of State
  - Search engine “Corporations (name of the state) searchable database
- ▶ SAM.gov
  - Entity Structure
    - Corporate Entity (Not Tax Exempt)
  - Profit Structure
    - For Profit Organization
  - Entity Type
    - Business or Organization
  - Purpose of Registration
    - All Awards

# “Business End of NIH StrokeNet”

## ► Practice Groups

- ▶ 1. They have to be in SAM.gov. They have to have a DUNS #.
- ▶ 2. They have to realize they may be federally audited.
- ▶ 3. UC will require the practice group's private audit report for subrecipient monitoring (If they do not have one, that should be a red flag.)
- ▶ 4. Know the practice group can/will bill CMS for routine patient care services.
- ▶ 5. Know that if the practice group does the “study” work too it will be paid for these services by NIH through the PTAs.
- ▶ 6. **We have heard** (and are not the legal expert or giving legal opinions) practice groups are unable or unwilling to sign an MTA because: If the practice does the study work and gets paid by NIH and does the clinical care and gets paid by CMS (both payers are the US government) the burden of proof for not double billing will be on that group, its accounting practices and its accountants.
- ▶ 7. However, if the practice group have a separate corporate “research group” within their practice, the practice groups are more inclined and eager to participate.
- ▶ 8. In your meetings, the decision may be the practice group's as to what the practice group is willing or able to do.



# **“Business End of NIH StrokeNet”**

## NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards

### **15 CONSORTIUM AGREEMENTS 15.2.6 Audit**

- The grantee must require **consortium participants** to comply with the requirements of Office of Management and Budget (OMB) Circular A-133 or 45 CFR part 74.26(d) (**for profit**), as applicable, for audit of NIH grant funds expended by consortium participants.
- Regardless, if a **non-profit consortium participant** meets the OMB Circular A-133 threshold criterion of aggregate annual expenditures of \$500,000 or more under applicable Federal awards, the grantee must receive a copy of that organization's A-133 audit and take appropriate action based on any findings that relate to the consortium agreement. If a consortium participant will not reach that expenditure threshold, the grantee is responsible for monitoring the organization's activities to ensure compliance with NIH requirements. The grantee may not require a consortium participant to have an audit and charge the audit costs to NIH grant funds unless required or authorized by OMB Circular A-133 or 45 CFR part 74.26(d).



# “Business End of NIH StrokeNet”

- ▶ NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards
- ▶ 18 GRANTS TO **FOR-PROFIT** ORGANIZATIONS
- ▶ 18.4.5 Audit
  
- ▶ The requirements for non-Federal audits of for-profit organizations are specified in 45 CFR 74.26(d). A for-profit organization is required to have a non-Federal audit if, during its fiscal year, it expended a total of \$500,000 or more in Federal awards. 45 CFR 74.26(d) incorporates the thresholds and deadlines of OMB Circular A-133 but provides for-profit organizations two options regarding the type of audit that will satisfy the audit requirements. The grantee either may have (1) a financial-related audit (as defined in, and in accordance with, the Government Auditing Standards (commonly known as the "Yellow Book"), GPO stock 020-000-00-265-4, of a particular award in accordance with Government Auditing Standards, in those cases where the recipient receives awards under only one HHS program, or (2) an audit that meets the requirements of OMB Circular A-133.
  
- ▶ OMB Circular A-133 is available electronically at  
[http://www.whitehouse.gov/sites/default/files/omb/assets/a133/a133\\_revised\\_2007.pdf](http://www.whitehouse.gov/sites/default/files/omb/assets/a133/a133_revised_2007.pdf).
  
- ▶ The Government Auditing Standards are available electronically at  
<http://www.gao.gov/govaud/ybk01.htm>. Audits must be completed and submitted to the National External Audit Review Center within 30 days after receipt of the auditor's report(s), or 9 months after the end of the audit period, i.e., the end of the organization's fiscal year, whichever is earlier. The address is found in Part III.
  
- ▶ For-profit organizations expending less than \$500,000 a year are not required to have an annual audit for that year but must make their grant-related records available to NIH or other designated officials for review or audit.



# **“Business End of NIH StrokeNet”**

- ▶ Neurology Now April/May 2014
  - American Academy of Neurology
- ▶ [www.neurologynow.com](http://www.neurologynow.com)
- ▶ “The more sites the more possibility of increased enrollment and meeting the trial enrollments sooner than later.”

# **“Business End of NIH StrokeNet”**

- ▶ **NIH StrokeNet Unique features:**
- ▶ **Regional** Coordinating Centers
- ▶ NO Subawards, no \$25K, NO Subawards
- ▶ VA Medical Centers and their Non-profits
  - [http://www.research.va.gov/programs/nppo/npc\\_locator.cfm](http://www.research.va.gov/programs/nppo/npc_locator.cfm)
- ▶ Indian tribe(s)
- ▶ Rehabilitation inpatient and outpatient facilities
- ▶ Out-patient Clinics
- ▶ MUSC compiling a list of clinical performing sites and enrollments from the clinical performing sites.

# **“Business End of NIH StrokeNet”**

- ▶ Questions???



- ▶ Further Information:
- ▶ 1-855-472-0072 NCC Phone Tree
- ▶ [www.nihstrokenet.org](http://www.nihstrokenet.org)
- ▶ **NO SUBAWARDS – NO SUBAWARDS**

# **“Business End of NIH StrokeNet”**

- ▶ Where to go for help:
- ▶ Institution: your grants and contracts or sponsored programs office
- ▶ Hospitals: Business office or the institutional CFO office, research department
- ▶ Private businesses: CFO office, COO office

# “Business End of NIH StrokeNet”

- ▶ [www.SAM.gov](http://www.SAM.gov) “Search Records”
- ▶ fCOI compliance – FDP Clearinghouse
- ▶ [http://nrc59.nas.edu/pub/fcoi\\_home.html](http://nrc59.nas.edu/pub/fcoi_home.html)
- ▶ FWA Federal-wide Assurance
- ▶ <http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc>
- ▶ Federal Audit Clearinghouse A-133 Audit Reports
- ▶ <https://harvester.census.gov/fac/dissem/disclaim.html>
- ▶ Zip+4
- ▶ <http://www.zip-codes.com/free-zip-code-tools.asp>
- ▶ Provides the zip+4, the county, and if you click on “More on Zip Code XXXXX, the entire demographics including the Congressional District

# “Business End of NIH StrokeNet”

- ▶ Assistance vs. Acquisition
- ▶ Grants and Cooperative Agreements
- ▶ OMB Circular A-21 ⇒ **2CFR**, Part 220
- ▶ OMB Circular A-110 ⇒ **2CFR**, Part 215
- ▶ <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>
- ▶ Contracts
- ▶ **48** CFR, Part 52 and Part 300 (DHHS)
- ▶ <http://www.ecfr.gov/cgi-bin/ECFR?page=browse>