



Duke University and Health System Research Compliance Seminar

Top Compliance Risks
June 19, 2006

Experience. **Redefined.**[™]

BOSTON
CHARLOTTE
CHICAGO
HOUSTON
LOS ANGELES
NEW YORK
SAN FRANCISCO
WASHINGTON D.C.

Table of Contents

- ◆ **Summary From Compliance Environment Session**
- ◆ **Top Compliance Risks in Research Administration**
 - **Definitions**
 - **Potential Audit Findings**
 - **Methods to Evaluate Institutional Exposure**
- ◆ **Summary**
- ◆ **Contact Information**

Summary from Compliance Environment Session

The following characterize the changing compliance landscape:

- ◆ Research volume and complexity are increasing
- ◆ The number of research constituents is increasing
- ◆ Numerous areas exist for potential non-compliance
- ◆ The risks of non-compliance are high
- ◆ Federal guidelines are getting more rigorous

Result

- ◆ A risk profile that is increasing and should be proactively understood and managed.

Solution

- ◆ A compliance program that contains the key criteria discussed today and/or an assessment that can help you identify and better understand risks as well as prioritize risk management.

Disclaimer

The items identified in this presentation were selected judgmentally based on my experience and the following criteria:

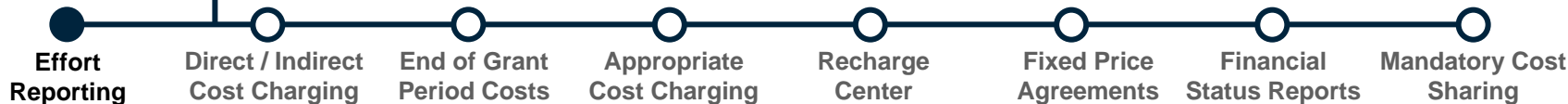
- ◆ **Likelihood of existence in a complex, decentralized research environment**
- ◆ **The extent to which warning signs (i.e. OIG investigations or inquiries) are already evident**
- ◆ **Ease of identification**
- ◆ **Financial ramifications of findings**

Top Compliance Risks in Research Administration

- 1. Effort Reporting**
- 2. Direct vs. Indirect Cost Charging Practices**
- 3. Charging Costs at End of Grant Period**
- 4. Appropriate Charging of Costs to Benefiting Grants**
- 5. Recharge Center / Service Center Rates**
- 6. Fixed Price Agreements**
- 7. Financial Status Reports**
- 8. Mandatory Cost Sharing**
- 9. Protection of Human Subjects**
- 10. Protection and Charging of Animal Subjects**
- 11. Cost Transfers**
- 12. Export Controls**
- 13. Clinical Trial Billing**
- 14. Subrecipient Monitoring**
- 15. Other Support**
- 16. Conflict of Interest**

Effort Reporting

Top RA Compliance Risks



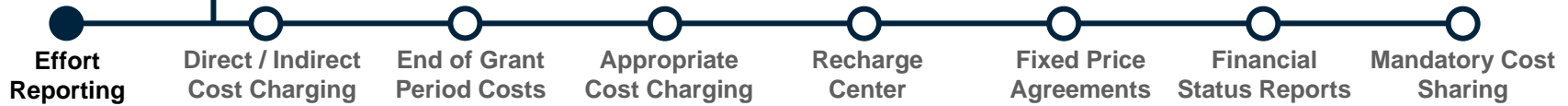
Effort Reporting

Definition

- ◆ **Effort is the proportion of time spent on any activity and expressed as a percentage of the total professional activity for which an individual is employed by the institution.**
- ◆ **OMB Circular A-21, section J.10 requires an effort reporting system that:**
 - **Encompasses all employee activities**
 - **Confirms effort expended after-the-fact**
 - **Requires certification to be performed by an individual with knowledge of all of an employee's activities or suitable means of verification**
 - **Requires certification to be performed regularly**



Top RA Compliance Risks



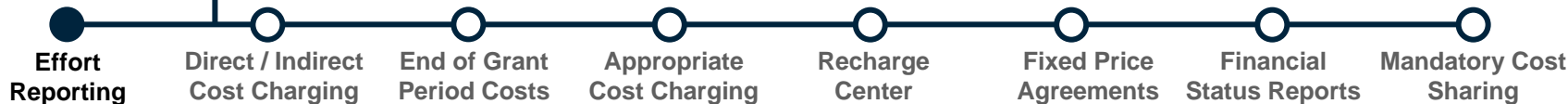
Effort Reporting

Potential Audit Findings

- ◆ Institutional Base Salary (IBS) not clearly defined or consistently applied
- ◆ Faculty members with teaching/admin/clinical responsibilities charging 100% of salary to sponsored projects
- ◆ Effort dedicated to certain “K” awards less than 75 percent of total professional effort
- ◆ Committed cost sharing not reported
- ◆ Effort certified by person without first hand knowledge, and who did not use suitable means of verification
- ◆ Incomplete effort distributions
- ◆ Salary cap not considered
- ◆ Lack of accurate and timely effort reporting (no certifications exist)
- ◆ Significant cost transfers
- ◆ Committed effort is greater than 100 percent



Top RA Compliance Risks



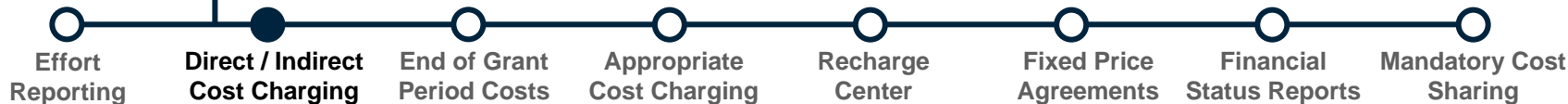
Effort Reporting

Methods to Evaluate Institutional Exposure

- ◆ Compare actual Institutional Base Salary (IBS) to proposed IBS and certified IBS
- ◆ Review effort reports to assess the number of changes noted from payroll distribution
- ◆ Investigate certification and charging of committed cost sharing noted in proposals
- ◆ Compare list of fixed price accounts against activity
- ◆ Review NOGAs to identify greater than 100% committed effort
- ◆ Check for appropriate signatures
- ◆ Talk with investigators about the effort certification process/understanding



Direct vs. Indirect Charging Practices



Direct vs. Indirect Charging Practices

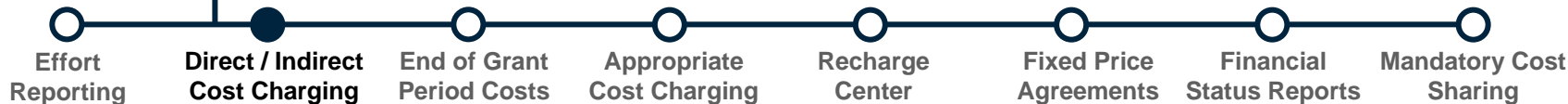
Definition

- ◆ Section D.1 of OMB Circular A-21 states: *Costs incurred for the same purpose in like circumstances must be treated consistently as either direct or indirect costs.*

- ◆ Section F.6.b of OMB Circular A-21 states:
 - *The salaries of administrative and clerical staff should normally be treated as F&A costs. Direct charging of these costs may be appropriate where a major project or activity explicitly budgets for administrative or clerical services and individuals involved can be specifically identified with the project or activity.*
 - *Items such as office supplies, postage, local telephone costs, and memberships shall normally be treated as F&A costs.*



Top RA Compliance Risks



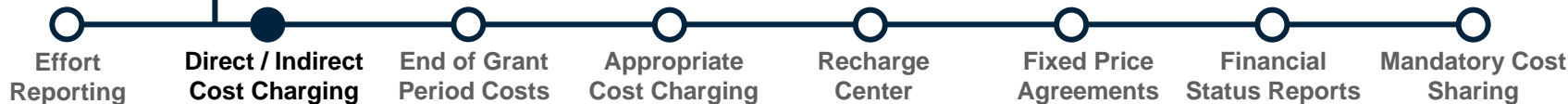
Direct vs. Indirect Charging Practices

Potential Audit Findings

- ◆ **Charges for normal administrative support inappropriately charged as direct costs**
- ◆ **Pens, paper, clerical salary, postage, memberships, etc. are direct charged to grants in normal circumstances as opposed to unlike circumstances**
- ◆ **Departmental charges distributed to multiple grants**
- ◆ **Departmental or institute business manager allocated to multiple grants**
- ◆ **Large research centers/institutes do NOT distinguish unlike circumstances and charge administrative costs direct**



Top RA Compliance Risks



Direct vs. Indirect Charging Practices

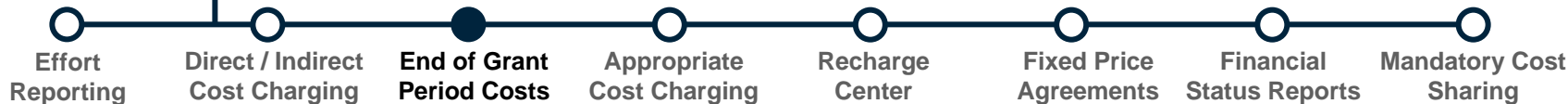
Methods to Evaluate Institutional Exposure

- ◆ Interview people with administrative type job titles who are direct charged
- ◆ Identify list of typically indirect type transactions and determine whether circumstances are unlike (usually requires review of proposal and an interview)
- ◆ Investigate allocation method for supplies with joint use



Charging Costs at End of Grant Period

Top RA Compliance Risks



Charging Costs at End of Grant Period

Definition

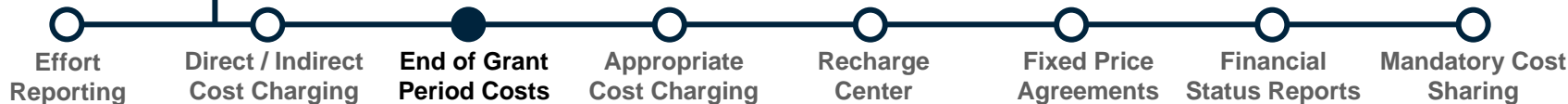
- ◆ **Charges incurred near the expiration date of an award often warrant increased scrutiny. In addition, charges made after the expiration date of an award shortly before the FSR is issued should be evaluated closely.**

Potential Audit Findings

- ◆ **Charges do not benefit the project being charged**



Top RA Compliance Risks



Charging Costs at End of Grant Period

Methods to Evaluate Institutional Exposure

- ◆ Investigate large cost transfers performed near the grant end date
 - Move from one overspent federal award to one with a surplus.
- ◆ Look for large charges (such as equipment) in the final months of a grant period
 - Large equipment should only be charged if the project will benefit from the equipment.
- ◆ Investigate charges incurred shortly before and after the grant end date for allowability and allocability



Appropriate Charging of Costs to Benefiting Grants

Top RA Compliance Risks



Appropriate Charging Costs to Benefiting Grants

Definition

- ◆ OMB Circular A-21 Section B.3 describes *allocation* as:
The process of assigning a cost, or a group of costs, to one or more cost objective, in reasonable and realistic proportion to the benefit provided or other equitable relationship.
- ◆ OMB Circular A-21 requires costs *directly* charged to a sponsored project to be:
 - Allocable; provides direct benefit
 - Allowable; per university or sponsor policy or OMB Circular A-21
 - Reasonable and necessary
 - Consistently treated throughout the institution
 - Available within the budget for the award



Top RA Compliance Risks



Appropriate Charging Costs to Benefiting Grants

Potential Audit Findings

- ◆ **Costs charged based on funding availability**
- ◆ **Costs allocable to a particular sponsored agreement have been shifted to other sponsored agreements:**
 - **In order to meet deficiencies caused by overruns or other fund considerations**
 - **To avoid restrictions imposed by law or by terms of the sponsored agreement**
 - **Or for other reasons of convenience**
- ◆ **Items charged to grants do not benefit the scope of work. Examples of these type of items might include:**
 - Books
 - Bottled Water
 - Ergonomic chairs
 - Coffee Services
 - Meals
 - Flowers
 - General Use Computers
 - Birthday Cakes
 - Software (MS Excel or MS Word)



Top RA Compliance Risks



Appropriate Charging Costs to Benefiting Grants

Methods to Evaluate Institutional Exposure

- ◆ Investigate cost transfers to identify inappropriate transfers
- ◆ Review grant transaction samples for unusual items
- ◆ Conduct periodic random samples



Recharge Centers / Service Center Rates

Top RA Compliance Risks



Recharge Centers / Service Center Rates

Definition

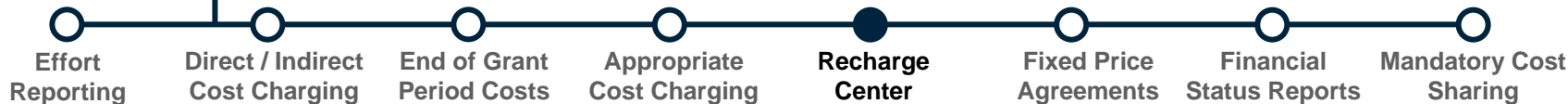
- ◆ ***A recharge center or service center is an internal operation that charges users for services or materials provided.***

Examples include:

- ***Machine shop***
 - ***Glass blowing***
 - ***Animal care***
- ◆ ***Recharge centers must use consistent and equitable cost accounting practices to ensure compliance with federal regulations. OMB Circular A-21 mandates that service center rates be:***
 - **Based on actual or projected costs**
 - **Reviewed and recalculated periodically**
 - **Inclusive of all expenses related to the provision of service/product**



Top RA Compliance Risks



Recharge Centers / Service Center Rates

Potential Audit Findings

- ◆ Recharge center charged more than total cost of providing the service/product (surplus)
- ◆ Recharge center billing rates not based on actual cost
- ◆ All users not charged for services
- ◆ Recharge center not billing all users consistently
- ◆ Recharge center billing rates include unallowable costs in billing rates
- ◆ Rates not reviewed periodically
- ◆ Rates include cost of capital equipment



Top RA Compliance Risks



Recharge Centers / Service Center Rates

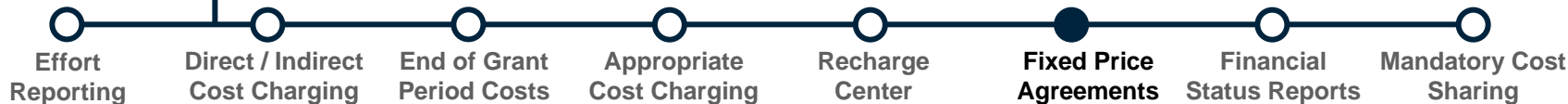
Methods to Evaluate Institutional Exposure

- ◆ Review billing rate calculation
- ◆ Investigate recharge centers with large surplus or deficit balances
- ◆ Review service center charges for inconsistent rates
- ◆ Test the accuracy of rate calculation and distribution of costs between different services to make sure cross-subsidies do not exist



Fixed Price Agreements

Top RA Compliance Risks



Fixed Price Agreements

Definition

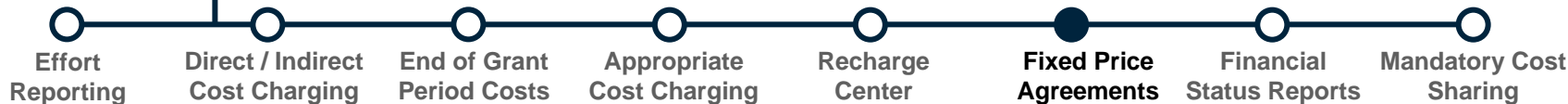
- ◆ ***Fixed price agreements provide a predetermined award amount to accomplish specific objectives during a specific timeframe. Fixed fee agreements are paid per deliverable or test performed. Over expenditures are the responsibility of the university; unused balances do not revert to the sponsor.***
- ◆ **Residual (unspent) balances on fixed price research awards often become discretionary funding for the PI and/or department.**

Potential Audit Findings

- ◆ **Cost- reimbursable award overcharged**



Top RA Compliance Risks



Fixed Price Agreements

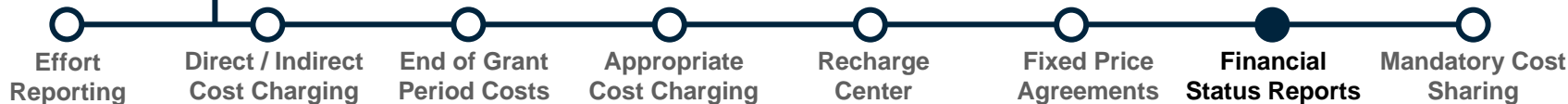
Methods to Evaluate Institutional Exposure

- ◆ Investigate expenses on fixed price awards nearing grant expiration date
- ◆ Obtain list of all active awards by investigator; compare expenses on fixed price vs. cost reimbursable awards for reasonableness
- ◆ Investigate fixed price awards with extended end dates



Financial Status Reports

Top RA Compliance Risks



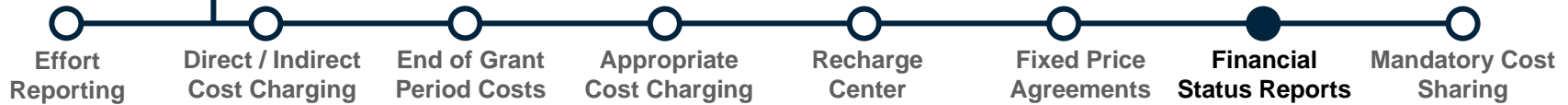
Financial Status Reports

Definition

- ◆ ***A Financial Status Report (FSR) is a statement of financial expenditures of a grant or contract. Sponsors normally require FSR submission 90 days after the budget and project periods. FSRs must cover any authorized extension of time in the budget period and should specify the amount to be carried over to the next budget period, if applicable.***



Top RA Compliance Risks



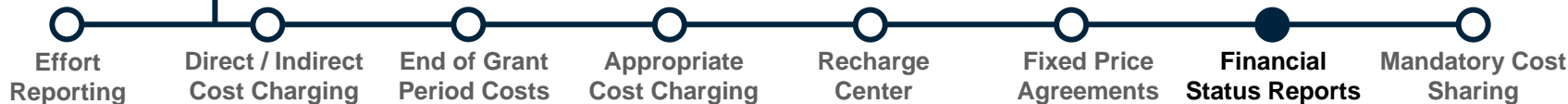
Financial Status Reports

Potential Audit Findings

- ◆ **FSRs are not submitted on time**
- ◆ **FSRs contain invalid information**
 - **Costs that are not allowable per federal guidelines**
 - **Cost sharing is not captured or reported accurately**
 - **Subcontract costs are not reported accurately**
 - **Program income is misstated**
 - **Indirect Costs (IDC) incorrectly charged and reported**



Top RA Compliance Risks



Financial Status Reports

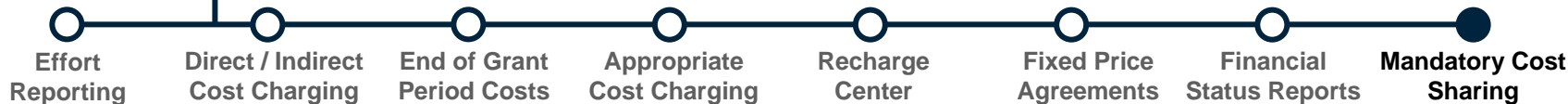
Methods to Evaluate Institutional Exposure

- ◆ Obtain a list of closed awards that require FSRs and confirm that FSRs were completed.
- ◆ Review expenditure report to ensure that the final expenses reconcile with those reported on the FSR. Ensure that the detail does not include any unallowable transactions.
- ◆ Of FSRs required, determine how many FSRs have been revised. Note the reasons why the FSRs were revised and document trends.
- ◆ Analyze trends and revise current business processes for FSR preparation.



Mandatory Cost Sharing

Top RA Compliance Risks



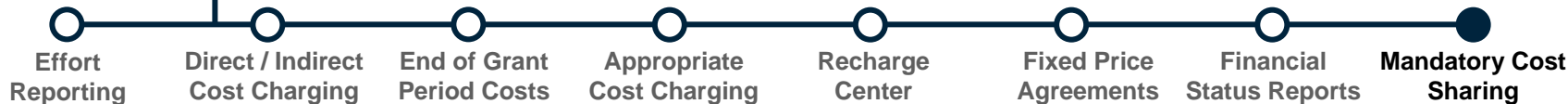
Mandatory Cost Sharing

Definition

- ◆ ***Cost sharing is a commitment of university (or third party) resources or funding that supplements externally sponsored project funding. Mandatory cost sharing occurs when the sponsor has required cost sharing as a prerequisite to apply for and receive an award.***



Top RA Compliance Risks



Mandatory Cost Sharing

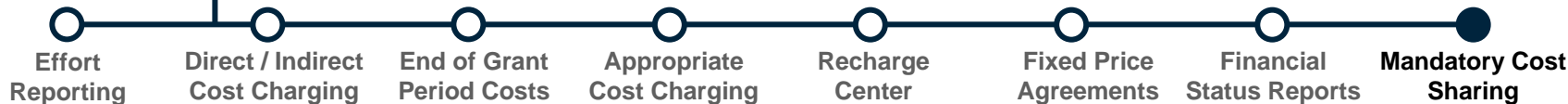
OMB Circular A-110 mandates the cost sharing contributions and the documentation of required cost sharing. Section B.23.a establishes the following criteria for determining whether a contribution is eligible for cost sharing.

Cost Sharing Contributions Must:

- ◆ **Be verifiable from the recipient's records**
- ◆ **Not be included as contributions for any other federally-assisted project or program.**
- ◆ **Be necessary and reasonable for proper and efficient accomplishment of project or program objectives.**
- ◆ **Be allowable under the applicable cost principles.**
- ◆ **Not be paid by the Federal Government under another award, except where authorized by Federal statute to be used for cost sharing/matching.**
- ◆ **Be provided for in the approved budget when required by the Federal awarding agency.**
- ◆ **Conform to other provisions of [OMB Circular A-110], as applicable.**



Top RA Compliance Risks



Mandatory Cost Sharing

Potential Audit Findings

- ◆ **Mandatory cost sharing commitments are not met**
- ◆ **Unallowable/inappropriate charges used to meet cost sharing commitments**
- ◆ **Effort certification system does not verify cost sharing charges**
- ◆ **University does not record and maintain documentation for reporting the cost sharing to the funding agency**

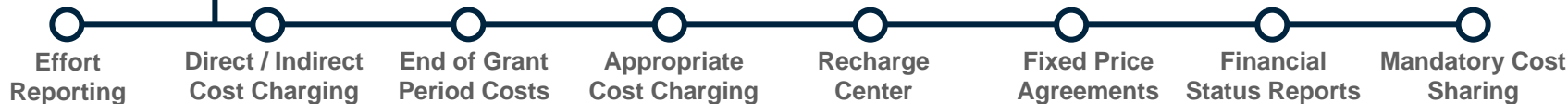
Methods to Evaluate Institutional Exposure

- ◆ **Investigate university's method and process for tracking and reporting cost sharing**
- ◆ **Review award documents including cost sharing; obtain accounting information and effort reports for the life of award**



Protection of Human Subjects

Top RA Compliance Risks



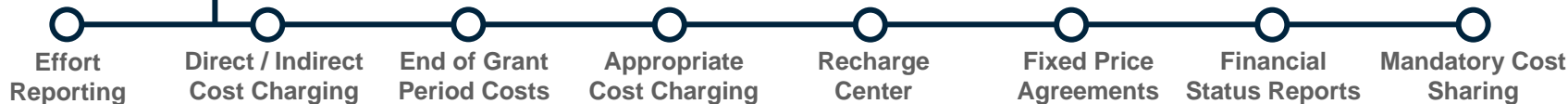
Protection of Human Subjects

Definition

- ◆ **University that perform research on human subjects are required to obtain the review and approval of the university's Institutional Review Board (IRB)**
- ◆ **The IRB approves the protocol, which is the outline or plan for use of an experimental procedure or experimental treatment. Review and approval must include all protocols involving humans, including externally and internally-funded research**
- ◆ **Regulations are codified at 45 CFR Part 46**



Top RA Compliance Risks



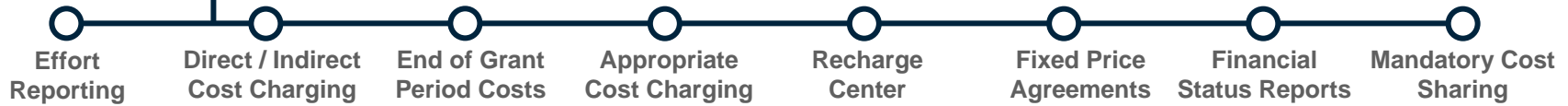
Protection of Human Subjects

Potential Audit Findings

- ◆ **Protocols for continuing research not reviewed and approved at least once per year**
- ◆ **Quorum is not present at meetings**
- ◆ **Mandatory training for key research personnel not performed**
- ◆ **Protocols for externally or internally funded research involving human subjects not reviewed**
- ◆ **Documentation of IRB policies and procedures not sufficient**
- ◆ **Informed consent forms confusing or unused**
- ◆ **Meeting minutes incomplete**
- ◆ **Inadequate HIPAA compliance**
- ◆ **Inadequate consideration of special populations (children, prisoners)**



Top RA Compliance Risks



Protection of Human Subjects

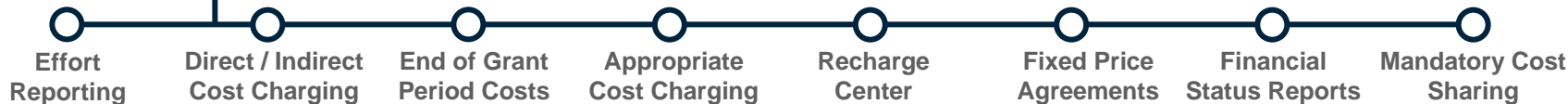
Methods to Evaluate Institutional Exposure

- ◆ Review documentation and procedures for protocol approval and renewal (including sample meeting minutes)
- ◆ Investigate selection of awards to ensure protocols approved
- ◆ Review sample of informed consent forms
- ◆ Review sample projects to ensure compliance with approved protocol



Protection and Charging of Animal Subjects

Top RA Compliance Risks



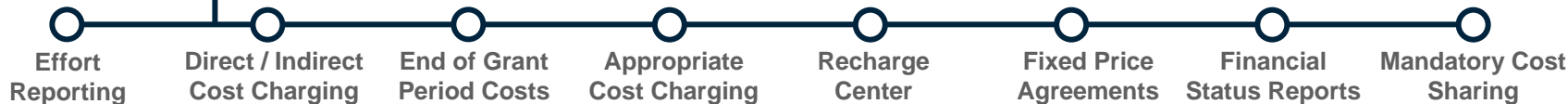
Protection and Charging of Animal Subjects

Definition

- ◆ Universities that perform research on animal subjects are required to obtain the review and approval of the university's Institutional Animal Care and Use Committee (IACUC).
- ◆ University animal facilities are responsible for the compliant purchasing and supplying of research animals, the care of the research animals, and the fiscal management for animal related charges including purchase of animals (usage), husbandry services (per diem), and labor (i.e. surgical procedures).
- ◆ Regulations codified 9CFR, Chapter 1, Subchapter A – Animal Welfare



Top RA Compliance Risks



Protection and Charging of Animal Subjects

Potential Audit Findings

- ◆ Protocols for continuing research not reviewed and approved when required
- ◆ Animal research taking place without protocol approval
- ◆ Documentation of IACUC policies and procedures not sufficient
- ◆ Animal charges not properly allocated to benefiting research projects
- ◆ Animal per diem rates not representative of the actual cost

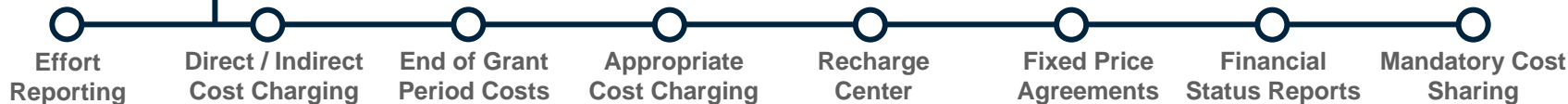
Methods to Evaluate Institutional Exposure

- ◆ Review calculation of per diem billing rates
- ◆ Compare animal charge on a project to the protocol
- ◆ Review documentation and procedures for protocol approval and renewal
- ◆ Investigate selection of awards to ensure that protocols are active



Cost Transfers

Top RA Compliance Risks



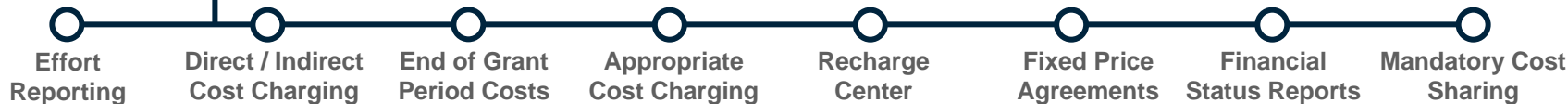
Cost Transfers

Definition

- ◆ **A cost transfer is an after-the-fact reallocation of the cost associated with a transaction from one activity/account to another.**
- ◆ **NIH Grants Policy Statement - “Cost transfers to NIH grants by grantees, consortium participants, or contractors under grants that represent corrections of clerical or bookkeeping errors should be accomplished within 90 days of when the error was discovered. The transfers must be supported by documentation that fully explains how the error occurred and a certification of the correctness of the new charge by a responsible organizational official of the grantee, consortium participant, or contractor. An explanation merely stating that the transfer was made “to correct error” or “to transfer to correct project” is not sufficient. Transfers of costs from one project to another or from one competitive segment to the next solely to cover cost overruns are not allowable.”**



Top RA Compliance Risks



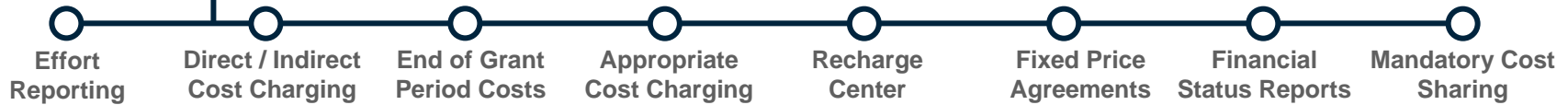
Cost Transfers

Potential Audit Findings

- ◆ **Insufficient documentation for cost transfers**
- ◆ **Significant number of late cost transfers (greater than 90-120 days after original charge)**
- ◆ **Costs transferred from an account in overrun status to an account with large balance**
- ◆ **Significant number of cost transfers from departmental account to sponsored accounts**



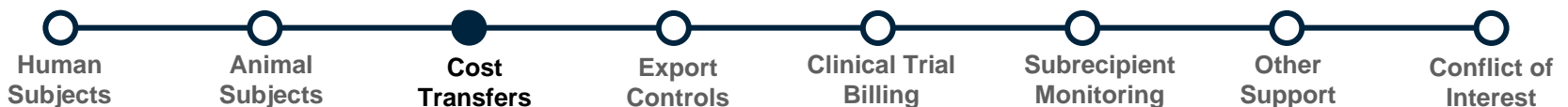
Top RA Compliance Risks



Cost Transfers

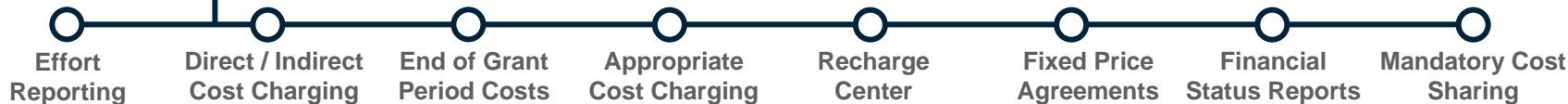
Methods to Evaluate Institutional Exposure

- ◆ Evaluate the number of both salary and non-salary cost transfers
- ◆ Review the documentation for a sample of cost transfers to ensure it includes
 - Description of the error
 - Description of how the cost benefits the project it is being moved to
 - Certification of transfer by responsible organizational official
- ◆ Review the documentation for a sample of late cost transfers to ensure it includes an explanation for the lateness of the cost transfer request
- ◆ Review advance account policy and procedures to ensure they are effective in getting investigators to set up advance accounts



Export Controls

Top RA Compliance Risks



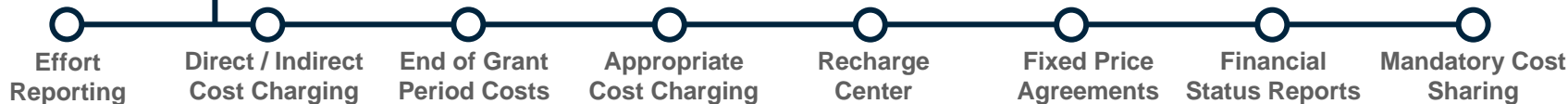
Export Controls

Definition

- ◆ Regulations that prohibit the sharing of certain information (e.g. military technology, technical data, trade secrets, etc.) with other countries and foreign nationals
- ◆ Applies not only to disseminating information outside borders (e.g., shipping equipment, lecture in foreign country) but also to transferring knowledge to a foreign national in the United States (“deemed export”)
- ◆ Three government agencies regulate export controls:
 - 1) State Department regulates military technologies
 - International Traffic in Arms Regulations (ITAR)
 - 2) Commerce Department regulates non-military technologies
 - Export Administration Regulations (EAR)
 - 3) Treasury Department bans or tightens controls on certain countries, including, Iran, Cuba, North Korea, Syria and Sudan.



Top RA Compliance Risks



Export Controls

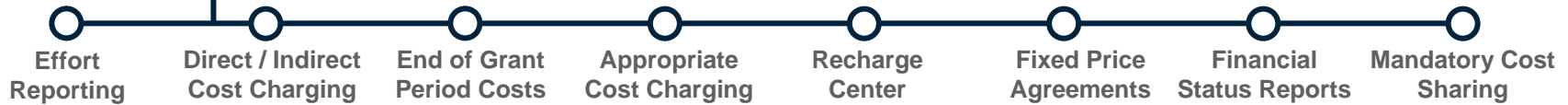
Potential Audit Findings

- ◆ **Transferring equipment, technology, or something of value (could be physical or intellectual) that is export controlled without first applying for a license* may carry significant penalties, including both civil and criminal, for the institution and the individual who ships the item.**

*** Many universities contend that the majority of information shared during research, education, and other activities does not require an export control license because of the “Fundamental Research Exclusion” or “Education Exclusion”. These exclusions primarily impact “deemed exports.” Export controlled equipment and technology that is shipped outside the United States is NOT covered by these exclusions.**



Top RA Compliance Risks



Export Controls

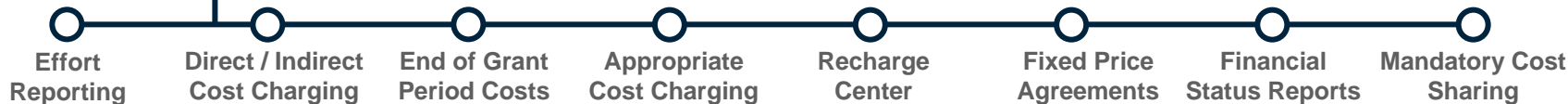
Methods to Evaluate Institutional Exposure

- ◆ Evaluate institutional awareness regarding export control regulations
- ◆ Review policies, procedures and assigned responsibilities
- ◆ Determine if export controlled risks are likely to be identified
- ◆ Determine if restrictions that can abrogate the fundamental research exclusion are effectively negotiated out of grants and contracts
- ◆ Review the Export Control Management System used to document and track decisions related to export controls and Foreign National Control Plan (requirement when applying for certain types of export control licenses)
- ◆ Determine if highest risk areas related to export controls have been identified and mitigated



Clinical Trial Billing

Top RA Compliance Risks



Clinical Trial Billing

Definition

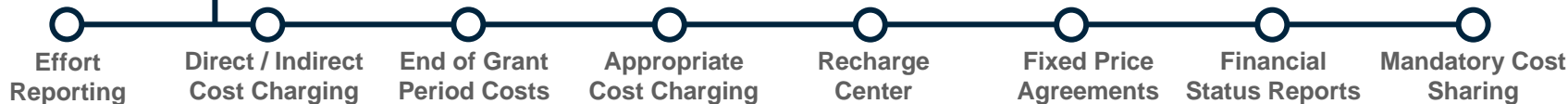
- ◆ **Standard of Care = Care that a patient would normally receive**
- ◆ **Research = Care specifically supporting a research protocol**

Goals

- ◆ **All clinical or research services are identified**
- ◆ **Each clinical or research service is assessed to determine whether government programs or private insurance will cover the service based on accurate understanding of coverage rules/state mandates**
- ◆ **Costs of any services unlikely to be covered by third party payors are calculated**
- ◆ **Sponsor payment covers the calculated cost of the uncovered services**
- ◆ **Sponsor agreement clearly identifies which services are covered by the sponsor payment and which services are not**
- ◆ **Informed consent form notifies subjects of co-pay and deductibles and about any other costs not covered by insurance or sponsor**
- ◆ **Subjects receiving clinical trial services are appropriately identified in billing systems and costs of clinical trial services are allocated to appropriate payor**



Top RA Compliance Risks



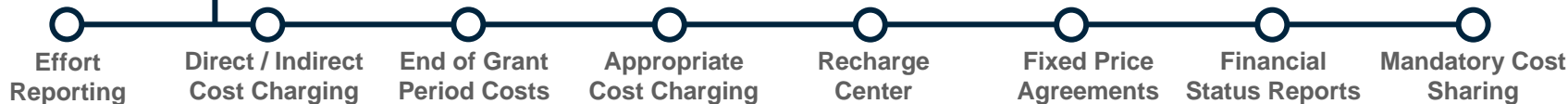
Clinical Trial Billing

Potential Audit Findings

- ◆ **Billing for certain physician professional services and hospital inpatient and outpatient services that are not reimbursable under the Centers for Medicare & Medicaid Services' (CMS) national coverage decision (NCD) on clinical trials.**
- ◆ **Billing both the third-party insurance company and the research sponsor for the same service.**
- ◆ **Subjects receiving clinical trial services are not appropriately identified in billing systems and costs of clinical trial services are not allocated to appropriate payor.**
- ◆ **Insufficient patient tracking systems, clinical trial management systems, or other IT tools that can help an institution follow a patients charges and ensure that they are being dropped to the right account**
- ◆ **Clinical trials costs inappropriately charged and billed to Medicare or Medicaid instead of to research account.**



Top RA Compliance Risks



Clinical Trial Billing

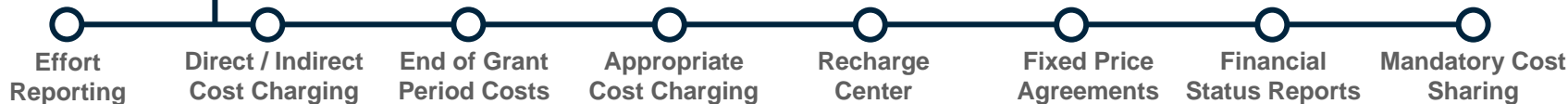
Methods to Evaluate Institutional Exposure

- ◆ Review policies and procedures related to clinical trial billing, including the procedures for developing research budgets and the procedures for identifying research participants when they present for services during registration/scheduling.
- ◆ Review roles and responsibilities for PI, study coordinator, office of research, registration personnel, and billing staff.
- ◆ Conduct reviews and ongoing audits (by patient, by trial, spot checks).



Subrecipient Monitoring

Top RA Compliance Risks



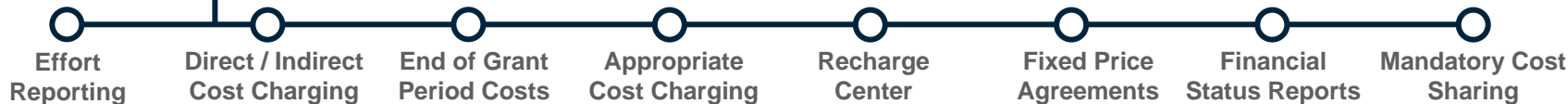
Subrecipient Monitoring

Definition

- ◆ **OMB Circular A-110 mandates that federal grant recipients monitor each program, function, or activity funded with federal grant awards – including subawards**
- ◆ **Subrecipient Monitoring is the process of providing oversight to subawards throughout their lifecycle including:**
 - **Obtaining the appropriate information prior to submitting the proposal (statement of intent, accurate budget, statement of work)**
 - **Reviewing appropriateness of subawardee**
 - **Executing an agreement consistent with A-133 requirements**
 - **Acquiring signed A-133 certification statements (from other A-133 institutions)**
 - **During the award monitoring**



Top RA Compliance Risks



Subrecipient Monitoring

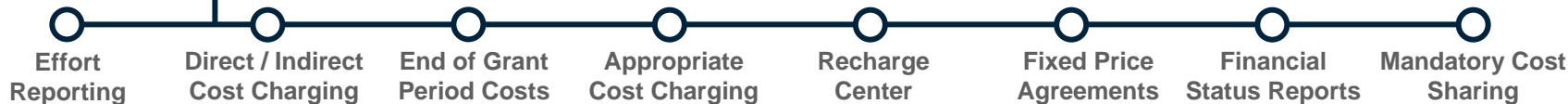
Potential Audit Findings

- ◆ Lack of internal controls related to subawards
- ◆ Lack of A-133 certification documentation
- ◆ Unallowable costs or lack of cost sharing documentation on subawards

** In the 2006 work plan published by the Office of Inspector General (OIG), subrecipient monitoring was listed as one of the items that will receive increased attention and be targeted during audits.*



Top RA Compliance Risks



Subrecipient Monitoring

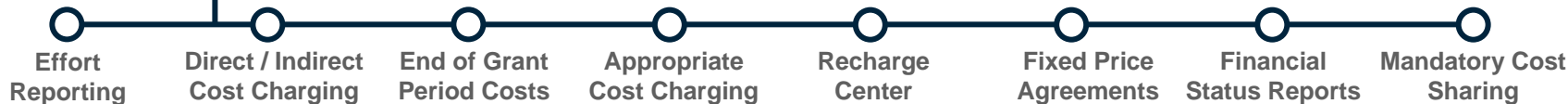
Methods to Evaluate Institutional Exposure

- ◆ Review policy or procedures for sub-recipient monitoring
- ◆ Ensure 100% completion of A-133 audit certifications
- ◆ Confirm subcontract template meets A-133 requirements
- ◆ Review process to pre-qualify sub-recipients
- ◆ Determine if roles and responsibilities for pre-award, post-award and department levels are clearly defined
- ◆ Determine if sub-recipient monitoring uses a risk-based approach (which is a preferred industry practice)
 - A-133 institutions may need less overall monitoring
 - Desk audits for some sites
 - Smaller, less savvy institutions might merit increased oversight
- ◆ Review the process used to monitor sub-recipient performance
 - Approval of invoices by the PI
 - Review of invoices and reports by research accounting



Other Support

Top RA Compliance Risks



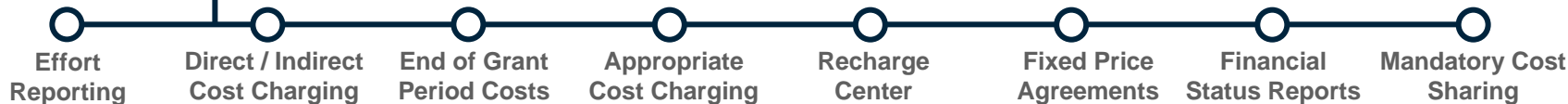
Other Support

Definition

- ◆ **According to the NIH, other support includes all financial resources, whether Federal, non-Federal, commercial or institutional, available in direct support of an individual’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, and/ or institutional awards. Training awards, prizes, or gifts are not included.**
- ◆ **Applicants must submit complete and up-to-date other support information for key personnel before an award is made. Pursuant to NIH’s “just-in-time” procedures, other support information is submitted upon the request of NIH staff when the application is under consideration for funding. Once an award is funded, grantees must report any changes in other support for key personnel as part of the annual progress report to NIH.**



Top RA Compliance Risks



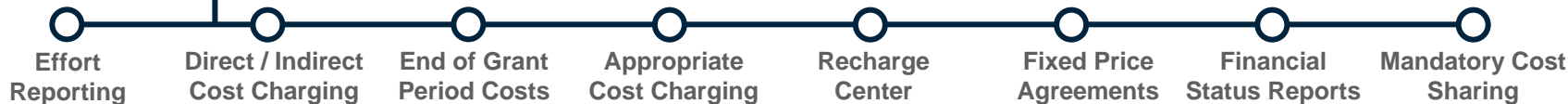
Other Support

Potential Audit Findings

- ◆ **Other support not complete and up-to-date**
- ◆ **Other support only includes support from Federal Sources**
- ◆ **Other support indicates budgetary, commitment or scientific overlap**
- ◆ **Other support does not list support where key personnel are spending time but not receiving salary support**
- ◆ **Other support does not list support that key personnel are receiving through their appointment at other institutions.**
- ◆ **Clinical trial awards not listed as other support**



Top RA Compliance Risks



Other Support

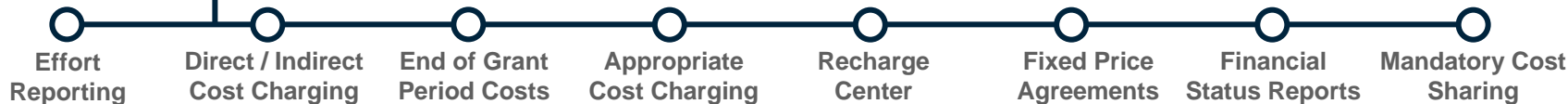
Methods to Evaluate Institutional Exposure

- ◆ Review policy and procedures for completing other support documentation.
- ◆ Review roles and responsibilities for completing other support documentation to determine if they are well defined and understood by all parties.
- ◆ Interview a sample of heavily-funded faculty members to determine their process for completing other support documentation.
- ◆ Review other support documentation for a sample of faculty members and compare with their salary charges, effort statements and outstanding proposals to determine if they are appropriately including all other support in the award documentation.



Conflict of Interest

Top RA Compliance Risks



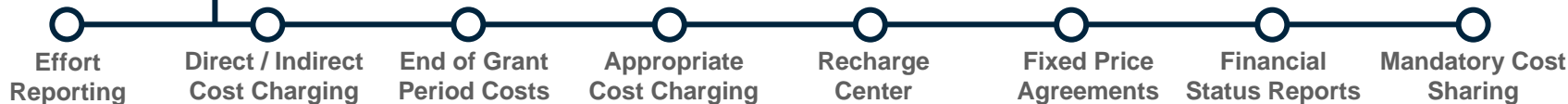
Conflict of Interest

Definition

- ◆ **The term "conflict of interest" refers to situations in which financial or other personal considerations may compromise, or have the appearance of compromising, an employee's professional judgment with regard to the research they are conducting.**
- ◆ **Under 42 CFR Part 50, institutions must certify that they maintain a "written, enforced policy" on conflicting interests. Under the regulations, institutions must also report to NIH the existence of any conflicting interests and assure that the interest has been "managed, reduced, or eliminated."**



Top RA Compliance Risks



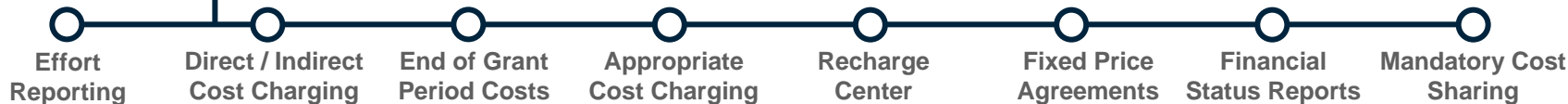
Conflict of Interest

Potential Audit Findings

- ◆ Institution does not have a conflict of interest policy or procedures.
- ◆ Institution does not have effective procedures for reviewing the financial conflict of interest disclosures received from the investigators.
- ◆ Institution does not properly maintain records of all financial disclosures and all actions taken by the Institution with respect to each conflicting interest for at least three years from the date of submission of final expenditures report.
- ◆ Conflicts were not appropriately identified and communicated to the sponsor.
- ◆ Conflicts were identified and communicated but were not properly managed.



Top RA Compliance Risks



Conflict of Interest

Methods to Evaluate Institutional Exposure

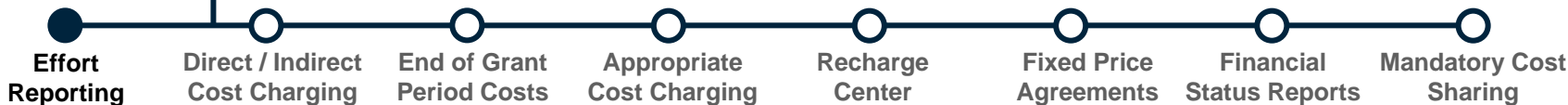
- ◆ **Review Conflict of Interest policy and procedures.**
- ◆ **Review roles and responsibilities related to identifying, communicating and managing conflicts of interest to ensure all individuals involved in the process have a clear understanding of their roles and responsibilities.**
- ◆ **Meet with a sample of faculty members to determine their understanding of the institution's conflict of interest policy and procedures.**
- ◆ **Review a sample of identified conflicts and review the institution's handling of those conflicts to determine if they were appropriately managed, reduced or eliminated.**



Top Compliance Risks in Research Administration

- 1. Effort Reporting**
- 2. Direct vs. Indirect Cost Charging Practices**
- 3. Charging Costs at End of Grant Period**
- 4. Appropriate Charging of Costs to Benefiting Grants**
- 5. Recharge Center / Service Center Rates**
- 6. Fixed Price Agreements**
- 7. Financial Status Reports**
- 8. Mandatory Cost Sharing**
- 9. Protection of Human Subjects**
- 10. Protection and Charging of Animal Subjects**
- 11. Cost Transfers**
- 12. Export Controls**
- 13. Clinical Trial Billing**
- 14. Subrecipient Monitoring**
- 15. Other Support**
- 16. Conflict of Interest**

Top RA Compliance Risks



Contact Information

For additional information please contact:

Shandy Husmann

Managing Director

Higher Education and Healthcare Practice

Huron Consulting Group

shusmann@huronconsultinggroup.com

312-583-8757

