THE FUNDAMENTALS OF SPONSORED RESEARCH IN THE UNIVERSITY SETTING

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Sponsored research presents issues unique to higher education law. University research may be sponsored by federal, state or foreign governments, private corporations, or public charities and foundations. Sponsorship is most commonly in the form of money, but may also come in the form of contributions of material, personnel, equipment, space, facilities, or rights to use intellectual property.

Sponsored research creates two sets of legal challenges for the university attorney. The first is structuring and negotiating the sponsorship collaboration. When the sponsor is a corporation, contract negotiations can be difficult. Different perspectives require thoughtful and sometimes tough negotiations over freedom to publish research results, allocation of resulting intellectual property, indemnification and liability, and ownership of research output, to name a few. Foundation grants are simpler, but often also raise issues for negotiation, such as sharing of royalties. Most government funding offers reasonable terms with respect to academic freedom and intellectual property, but federal awards are not usually negotiable, and may also require working through issues pertaining to security measures such as use of foreign nationals or cybersecurity.

The second set of legal challenges arise once the agreement is in place and the research is underway, when a range of compliance obligations arising from the sponsorship relationship,or the nature of the contemplated research must be addressed. Federal sponsorship triggers requirements for compliance regimes to protect human and animal subjects, ensure safety in the context of work with radioactive materials and genetically altered tissues, and conflicts of interest, for example, some of which apply even in the context of non-federally sponsored research. When the sponsorship is in the form of payment for the research, legal issues arise in properly accounting for costs.

As university counsel, you will often sit in the uncomfortable place of resolving the competing interests of the sponsor, the faculty member, and multiple components of your institution. NACUA conferences have produced numerous excellent overviews of some of the subject matter covered here, and there are also comprehensive website resources maintained by the federal agencies that regulate this activity. These materials are collected at the end of this outline. Because the most efficient way to familiarize yourself with the key issues in this area of practice is to examine the actual circumstances under which those issues arise, and the perspectives of the stakeholders in the process, this outline will include an examination of those topics.

I. HOW WILL YOU BE INVOLVED IN SPONSORED RESEARCH ISSUES?

TYPICAL SCENARIOS:

A. A faculty member sends you an industry-generated research contract (or – worse – a purchase order) for "legal review."

B. The Office of Research asks you to develop a standard industry sponsored research contract form.

C. A faculty member wants to form his own company to commercialize his federally funded research, and to provide employment for his graduate students. The faculty member will keep his time with the company to a minimum by having his wife run the company.

D. A professor calls you because a federal investigator has shown up at his graduate student's home demanding to interview him regarding how many hours he worked on the grant that funded his dissertation research.

E. A small, local biotech company wants to sponsor a human clinical trial for their gene therapy product at your institution. The principal investigator is one of the inventors on the technology used to develop the product and serves as a consultant to the company.

F. As part of a push to develop a high tech industry cluster in your town, your university has been asked to provide incubator services to high tech start-ups that originate either from the university or the local community.

G. Your administration asks you to review and revise research policies in light of regulatory changes over the past few years.

H. A student alleges that her faculty advisor stole her ideas and published them without giving her credit.

I. A faculty member asks you to approve an agreement allowing her to receive samples of herpes virus, in connection with her contract from a pharmaceutical company to develop antiviral treatments.

J. You get a call at 8am informing you that federal agents knocked on a graduate research assistant's door early that morning, asking about who is working on which projects at his faculty advisor's lab.

K. The President's Office refers to you a letter from an attorney claiming that your Genomics Center's core assays appear to be covered by several of her client's patents, and advising the President to contact her to discuss a resolution and

license agreement. She indicates that in lieu of payment, her client would be open to an arrangement in which it would receive a percentage of the royalties from any technology that relied in part on analyses performed by the Genomics Center.

II. WHAT ARE THE SOURCES OF APPLICABLE LAW AND REGULATION PERTAINING TO SPONSORED RESEARCH?

This summary list is by no means exhaustive, but it does give you the necessary citations to the major statutes and regulations for the areas listed. For more detailed summaries in the various areas, you may wish to review the resources listed at the end of this outline.

A. The Bayh-Dole Act and Technology Transfer: Pursuant to the Bayh-Dole Act, 35 U.S.C. § 200, *et seq.*, non-profit institutions that make inventions under federal grants may elect to retain title to those inventions and commercialize them by licensing arrangements. The Bayh-Dole Act led to the creation of technology transfer offices in most major research universities. Certain strings attach: the commercialization must favor small businesses and American manufacture, and the federal government retains the royalty-free right to practice the invention. There are also reporting obligations to the federal government. The regulations at 37 C.F.R. Part 401 are an essential read. In light of recent caselaw regarding assignment of inventions, you will want to make sure that your policies regarding university ownership of intellectual property are sufficiently comprehensive, and are backed up with appropriate assignment agreements. Many institutions are monitoring outside activities of their faculty that may affect their right to claim title. *See Stanford v. Roche*, 563 U.S. ___(2011).

For the in-house practitioner, due diligence questions occasionally will arise regarding whether your institution has taken the necessary steps to secure title under Bayh-Dole. As a threshold matter, you will need to ascertain that the invention was "conceived" or "reduced to practice" under a federal funding agreement. Even if your institution has the right to claim title initially, failure to file the necessary election of title within two years of disclosure of the invention to the federal agency will result in the title to the invention reverting to the federal agency.

Where industry is sponsoring research at your institution, industrial sponsors may want assurances that their project will be kept separate from federally funded work, as partial funding or use of equipment funded by federal grant dollars will implicate Bayh-Dole, 37 C.F.R. § 401.1(a). In "exceptional circumstances," a federal agency may determine that restriction or elimination of the right to retain title will better promote the goals underlying the Act. 37 C.F.R. § 401.3(a)(2). In those cases, it is important that your investigators are aware that different intellectual property terms may apply to the results of the research.

B. Research Integrity: Research misconduct is generally defined as "fabrication, falsification, and plagiarism in proposing, performing, or reviewing research, or in

reporting research results." *See, e.g.*, the Public Health Service ("PHS") regulations at 42 C.F.R. §93.103. As the repercussions of a research misconduct finding can include debarment from receiving federal funds, very specific procedures must be followed by institutions investigating such allegations. In December, 2000, the White House Office of Science and Technology Policy ("OSTP") adopted a uniform Federal Policy on Research Misconduct, 65 Fed. Reg. 76260 (December 6, 2000). These regulations have been adopted at least in part by all of the federal granting agencies (including the Departments of Energy, Labor, Transportation, Veterans Affairs, the Environmental Protection Agency, the National Aeronautics and Space Administration, the National Science Foundation, the U.S. Department of Health and Human Services ("DHHS"), and the National Endowment for the Humanities).

The regulations provide definitions of research misconduct, and prescribe a framework for institutional policies requiring two rounds of review of each allegation: an initial inquiry, followed by a more elaborate "investigation," with a separate adjudication phase when the investigation concludes that research misconduct occurred. The regulations generally set a "preponderance of the evidence" standard of proof, and provide criteria for agency review. Because some agencies are deviating slightly from the OSTP standard, it is important that you double check the regulations for the agency funding the research at issue. The DHHS regulations have been promulgated at 42 C.F.R. Part 93, and provide for detailed procedural safeguards for persons accused of research misconduct, as well as protection for the person bringing the allegation. Confidentiality during the internal review is mandatory, 42 C.F.R. § 93.108, although, if research misconduct is found, the finding by the DHHS Office for Research Integrity will be published in the federal register. As debarment (for some period of time) from receiving federal funding is commonly imposed as a penalty, stakes in misconduct investigations are high.

C. Animal Research and the U.S. Department of Agriculture ("USDA"): The Animal Welfare Act is the primary federal statute governing the care and use of animals in research. 7 U.S.C. §§ 2131 –2156. It applies to warm-blooded animals except birds, rats, and mice bred for research. Further guidance is provided in the accompanying regulations at 9 C.F.R., Title 9, Chapter 1, Subchapter A – Animal Welfare. The regulations cover the appropriate standard of care for animals used in research, and require that research involving the use of animal subjects be reviewed by an Institutional Animal Care and Use Committee ("IACUC"). In addition, the PHS Policy on the Humane Care and Use of Laboratory Animals applies additional requirements to all use of live vertebrate animals in PHS-supported research, research training (i.e., educational) or testing activities. The PHS Policy requires that institutions base their program for activities involving animals on the National Academies' Guide for the Care and Use of Laboratory Animals (recently updated in 2011). The requirement for an IACUC is found in Section 13(b) of the Animal Welfare Act, 7 U.S.C. § 2143 and Section IV.A.3 of the PHS Policy. The Office of Laboratory Animal Welfare

("OLAW") is the PHS agency responsible for compliance with these standards. Among other things, the PHS Policy requires any institution using animals in PHS-sponsored research to submit an Animal Welfare Assurance to OLAW, demonstrating the administrative procedures and policies in place to ensure compliance with the Policy by the institution. Further details on the content of an Animal Welfare Assurance can be found at OLAW's website: http://grants.nih.gov/grants/olaw/olaw.htm.

Under federal law, your IACUC must review and approve all grant proposals for PHS-supported activities involving animals. National Institutes of Health ("NIH") Policy permits institutions to submit verification of IACUC approval for competing applications after peer review, but before grant award. This "just-in-time" grant application review policy requires close coordination between your IACUC and research contracting office, to ensure there is appropriate congruence between the research described in the proposal, and the research approved by the IACUC.

The IACUC must review proposed research procedures to ensure they are designed to minimize pain and suffering for animal subjects. The Animal Welfare Act regulations and PHS Policy describe the approval criteria, as well as IACUC procedural requirements. In addition, the regulations include subparts for licensing and registration, standards for research facilities, requirements for attending veterinarians and adequate veterinary care, and recordkeeping and reporting requirements. With the revision of the National Academies' Guide in 2011, social housing of animals is the default expectation for laboratory animals, and any variation from that housing requires special justification from the IACUC.

D. Human Subject Research: Following a series of well publicized scandals involving experimentation on patients, a federal commission in the 1970s issued "The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research," which provided the philosophical framework for the current federal regulatory scheme governing human subject research. The federal regulations, which may be found at 45 C.F.R. Part 46, Subpart A, govern all federally funded research involving human subjects. Under the federal regulations, an institution is engaging in human subject research whenever their employees or agents (i) intervene or interact with living individuals for research purposes; or (ii) obtain, release, or access individually identifiable private information for research purposes. A committee, known as an Institutional Review Board ("IRB") is given the responsibility of prospectively reviewing human subject research protocols.

Each federally funded institution engaged in human subject research must obtain a Federal Wide Assurance ("FWA") from the Office for Human Research Protection ("OHRP"). The required standard terms that OHRP is seeking for all FWAs may be viewed on the OHRP website at:

http://www.hhs.gov/ohrp/humansubjects/assurance/filasurt.htm. Among other things, institutions must assure that their IRB is provided with meeting space and sufficient staff to carry out its duties. FWAs are good for three years, and certain information must be updated on a more frequent basis. IRBs are often internal committees formed by the grant recipient institution, but an institution may chose to rely on an appropriately registered IRB that is based at another institution, or that is completely independent. Increasingly, funding agencies are encouraging the use of a single or central IRB for large, multi-center clinical trials. While such arrangements can streamline the initial approval, there must be an appropriate mechanism to ensure that local requirements are appropriately considered and addressed by the central IRB, and to ensure that on-going monitoring of the trial, and liability issues are addressed.

An institution conducting human subject research must form or contract with an IRB, whose composition is specified in the regulations, to review written protocols for human subject research. The IRB must ensure that research risks are minimized and that research subjects give their written informed consent to participate in the research. What constitutes "informed consent" in a particular setting can be subject to great debate, and, if something later goes wrong in the study, adequacy of the consent will often be an issue. The minimum requirements for informed consent may be found in the regulations at 45 C.F.R. § 46.116, and includes a description of the research, a statement that participation is voluntary, description of risks and benefits, a statement of alternative treatments that are available, and further information. All information in the informed consent must be in clear and understandable language and may not include exculpatory language protecting the institution or the investigator.

Later subparts in 45 C.F.R. Part 46 provide specific requirements for research involving special populations who are perceived to be especially vulnerable (e.g., children, prisoners, and pregnant women, fetuses and neonates), or for treatments that are particularly new and controversial (e.g., gene therapy and xenotransplantation). The IRB will also scrutinize the materials used to recruit subjects, the criteria for determining if patients are eligible for participation in the study, and the type of follow-up that the investigator must conduct.

The Health Insurance Portability and Accountability Act ("HIPAA") was enacted in 1996 and applies to institutions that obtain and transmit individuals' personal health information ("PHI") in connection with electronic billing for insurance reimbursement. The Health Information Technology for Economic and Clinical Health (HITECH) Act was signed into law on February 17, 2009, and added significant increased penalties and enforcement for violations of the Privacy Rule. While HIPAA was designed to address confidentiality in the provision of health care, it has had far-reaching effects on the conduct of human subject research. The Privacy Rule Regulations under HIPAA, 45 C.F.R. Parts 160 and 164, set limitations on research institutions' ability to use, receive, and transmit PHI to third parties. Before PHI may be collected or used for research, an investigator

must have a signed HIPAA authorization from the research subject. A HIPAA authorization is similar to, but not exactly the same as, an informed consent document. In most cases, the informed consent document and the HIPAA authorization may be combined into a single document, although there are mandatory elements to a HIPAA authorization that must be reflected in the combined document. 45 C.F.R. § 164.508(b)(3). When researchers need to access PHI without prior written authorization from the individual, the data must either be: 1) de-identified, which requires the removal of 18 specific identifiers, 2) released as a limited data set – which requires removal of a smaller set of identifiers, but also requires execution of a Limited Data Set Agreement, or 3) covered by an IRB waiver under the Privacy Rule's restrictive standards. Further information on the implementation of HIPAA may be found at the website of the PHS Office of Civil Rights, at http://www.hhs.gov/ocr/hipaa/privacy.html.

E. Clinical Trials and New Drug and Device Studies: While the OHRP regulations cover all types of federally funded research involving humans (including psychological testing), the Food and Drug Administration ("FDA") regulates a specific subset of research involving new drugs (including new dosages or uses of already approved drugs) or new medical devices. *See* 21 C.F.R. Part 50. Before a new drug may be marketed, the FDA requires that the sponsor establish that the drug is safe and effective through properly designed and controlled clinical trials. There are generally three phases of clinical trials: a phase I trial assesses toxicity of the drug in humans and attempts to determine a safe dosage; a phase II trial assesses efficacy of the drug and further refines dosage; and a phase III trial tests the drug in a large population to confirm efficacy, note side effects, and compare the effectiveness of the new drug with other treatments. A sponsor must submit an investigational new drug application ("IND") before commencing a study. *See* 21 C.F.R. Part 312.

For device studies, an investigational device exemption ("IDE") and IRB approval will be required for any device that is considered a "significant risk device." The FDA regulations define such devices as presenting a potential for serious risk to the health, safety or welfare of a research participant, and includes such items as implants and cardiac devices. *See* 21 C.F.R. Part 812. Non-significant risk devices include things like daily wear contact lens and foley catheters. Studies involving non-significant risk devices require IRB approval, but no IDE filing. There is a third category of devices that are exempt from the IDE requirements, including certain kinds of diagnostic tests, and devices used within their approved labeling, 21 C.F.R. § 812.2(c). Your IRB will often need to be involved in assessing the risk level of devices in studies, and the FDA has issued guidance documents that can help guide that decision-making. *See* Information Sheet Guidance for IRBs, Clinical Investigators and Sponsors: Significant Risk and Nonsignificant Risk Medical Device Studies, January 2006, *available at* http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM126418.pdf.

As phase I trials may be sponsored by the federal government or the institution (because the therapy is not yet proven), often your faculty member is the holder of the IND or the IDE. This will obligate your investigator and your institution to comply with whatever terms are set forth in that IND or IDE. The FDA will generally provide audit results and notices of violations only to the IND/IDE holder (i.e., your faculty member); therefore, it is important that you have internal policies requiring faculty to copy the IRB on all FDA correspondence. For later phase studies, often a pharmaceutical company is the sponsor of the research and the holder of the IND or IDE.

Certain types of studies, which involve ionizing radiation in humans, will also be subject to Nuclear Regulatory Commission ("NRC") regulations. Your institution will have an NRC license which will specify applicable standards for handling, use and disposal of such materials, including stringent requirements for ensuring the security of such materials. In many institutions, a separate Radiation Safety Committee will review proposed human studies involving ionizing radiation to ensure compliance with these regulations.

Generally speaking, radioactive drugs are subject to the same IND requirements as any other drug, except for those cases in which radioactive isotopes are used in basic research and administered under the conditions set forth in radioactive drug research committee ("RDRC") program. See 21 C.F.R. § 361.1. Under these regulations, use of radioactive isotopes in basic research may occur without the filing of an IND where: 1) the research is basic research, intended to gain knowledge about the metabolism of the radioactive drug or human physiology, pathophysiology or biochemistry; 2) the radioactive drug is not intended for immediate therapeutic or diagnostic purposes; 3) the radioactive drug's safety and efficacy is not being assessed; 4) the use of the radioactive drug has been approved by an RDRC meeting the FDA regs, and the RDRC has assessed the protocol in accordance with the FDA requirements; 5) the dose of the radioactive drug to be administered is not known to have any clinically detectable pharmacologic effects in humans; and 6) the radioactive dose is justified based on the legitimate study needs and is below FDA set limits. Your institution's RDRC must be registered with the FDA, 21 C.F.R. § 361.1(c)(4), and your RDRC and IRB reviews should be coordinated.

In 2007, the Public Health Service Act was amended to add a requirement that most FDA-regulated clinical trials be registered in Clinical Trials.gov, and that the results of those trials be made public through the same web portal. If your institution is considered the sponsor of the clinical trial, your institution will be responsible for ensuring that this disclosure of results is made. In some cases, where designated by the study sponsor, the Principal Investigator may be responsible for registration. In either case, penalties for failure to register can be serious. See 42 U.S.C. § 282(j) and 21 U.S.C. § 331(jj).

F. Conflicts of Interest in Research: The Public Health Service ("PHS") and the National Science Foundation ("NSF") both have express regulations on Objectivity in Research: the PHS regulations are found at 42 C.F.R. Part 50, Subpart F, and the NSF requirements are found at NSF Proposal and Awards Policies and Procedures Guide 13-1, Part II, Section IV.A. At one time, these regulations mirrored each other but, following a series of high profile cases in which PHS funded researchers were found not to have disclosed outside interests, plus a growing body of science establishing that even modest payments to medical professionals may affect prescribing behavior, the PHS revamped their regulations in 2011. Both require adoption of institutional procedures that require faculty to disclose to the institution outside financial interests above specified thresholds when those interests would likely be affected by the research. Beyond that, the requirements are now quite different.

The PHS regulations require that investigators disclose all outside interests meeting the specified threshold levels, and the institution is responsible for determining whether those interests may be related to funded research. This requirement applies to any investigator on the project responsible for the design, conduct, or reporting of the research, and includes not just PIs, but may also include other faculty, staff, post-docs, and students. The definition of reportable financial interests include: remuneration from a public company, when aggregated with any equity interest in that company, in excess of $5,000 in the preceding 12 month period; or any equity interest in a non-public company or remuneration in excess of $5,000 from the nonpublic entity in the preceding 12 months; and interest in any intellectual property rights upon receipt of $5000 associated with those rights (other than royalties received through the investigator's current institution). 42 C.F.R. § 50.603. The investigator must report his/her interests, plus the interests of his/her spouse and dependent children. In addition, investigators must report reimbursed or sponsored travel expenses, unless the payment is provided by a government agency, an institution of higher learning, non-profit hospital or non-profit research institute. While it is not express in the regulations, the NIH has issued guidance suggesting that the $5,000 reporting threshold may be applied to reimbursed or sponsored travel, if the institution has defined that reporting level in its institutional policy. See NIH Notice NOT-OD-13-004 (October 18, 2012), available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-004.html. The disclosures must be reviewed by a designated institutional official (which could be a Dean, a committee, or a compliance officer) who will have to determine if the reported interest constitutes a "financial conflict of interest" with a PHS grant. That determination, which requires only a reasonable basis, has two parts: 1) the financial interest must be related to a NIH-funded research project (e.g. the grant might be evaluating a company product) and; 2) must be a type that could directly and significantly affect the design, conduct or reporting of the NIH-funded research. If a financial conflict of interest is identified, the institution must manage, reduce, or eliminate it, before federal funds are expended, and report the details to the PHS.

Under the NSF requirements, somewhat different standards and generally higher thresholds apply. Unfortunately, some interests that are excludable under NSF rules are reportable under PHS rules, and vice versa. The NSF defines a significant financial interest as "significant" if it amounts to more than ten thousand dollars ($10,000) per year in expected outside income from an entity or involves equity either worth more than ten thousand dollars ($10,000) or equity representing more than five percent (5%) of the outstanding equity in a company that would "reasonably appear" to be affected by NSF funded work. Any intellectual property interest, such as ownership of a patent, constitutes a significant financial interest (except royalties received through the the investigator's current institution). Income from seminars or lectures, income from royalties received through the applicant institution, and income from service on advisory panels for public or nonprofit entities is excluded from the definition of a significant financial interest. The investigator is required to report such significant interests to a responsible institutional official. The institution is required to assess whether the significant financial interest presents an actual conflict of interest, which will exist where the institution reasonably determines that the significant financial interest could "directly and significantly affect the design, conduct, or reporting" of NSF-funded work.

In addition to the PHS and NSF requirements, the FDA requires additional disclosures in connection with clinical trials, although this reporting is made to the IND or IDE holder, rather than to the institution. It is important to note that the threshold reporting level for financial conflicts of interest under the FDA regulations is higher than either the PHS/NSF regulations: $25,000 per year for consulting, and a market value of $50,000 for equity in public companies. On the other hand, the FDA also considers unrestricted grants in excess of $25,000 to investigators' institutions for the benefit of the investigator, any equity in non-public companies, or an interest by the investigator in the drug or device (i.e., rights in a patent) to constitute a reportable conflict. *See* 21 C.F.R. § 54.2. It is important that your institutional policies consider all of the possible applicable standards—and that appropriate training is provided to investigators so that they know what to report and to whom.

Given the potential for harm to human subjects when an investigator may have a significant financial interest in a clinical trial sponsor, the NIH has issued guidance entitled, "Financial Relationships and Interests in Research Involving Human Subjects: Guidance for Human Subject Protection," available at http://www.hhs.gov/ohrp/humansubjects/finreltn/fguid.pdf (May 5, 2004). Further guidance can be found in the report of a joint advisory committee of the Association of American Medical Colleges and the Association of American Universities entitled "Protecting Patients, Preserving Integrity, Advancing Health: Accelerating the Implementation of COI Policies in Human Subjects Research," (February 2008) (available at http://www.aau.edu/research/Rpt_AAU-AAMC_COI_208.pdf), which provides comprehensive recommendations for the management of both individual and institutional conflicts of interest.

G. Tax Implications of Corporate Sponsored Research: Corporate sponsored research can destroy the tax-exempt status of bonds that finance the buildings in which the research is conducted. Generally, if the research facilities were constructed with tax-exempt bond money, you are limited in the rights you can grant to the sponsor in any technology resulting from the research. This means, for example, that you may not assign the sponsor outright ownership or exclusive rights in any inventions resulting from the research without rendering the agreement "private business use" of the facility. You may, however, give the sponsor first rights to negotiate an exclusive license with an arms-length royalty rate at the time the technology is ready for licensing. The Internal Revenue Service ("IRS") has recently liberalized its interpretation of private use, to expressly recognize that non-exclusive grants of rights to inventions resulting from federally funded or multiple-party funded research will not be considered "private business use," provided that certain provisions are met.

However, public institutions do have a ten percent (10%) allowance to accept contracts that avoid this requirement. Private institutions have a smaller allowance – five percent (5%) minus the costs of issuance, resulting in a net allowance that is usually in the two to three percent (2% to 3%) range. When multiple bond issues were used to fund multiple buildings, the allocation of private business use to particular bond issues becomes complicated, and IRS regulations provide conflicted guidance. New regulations are due out in 2008.

The IRS has recently stepped up enforcement in this area. It is requiring institutions to have well documented procedures to demonstrate that they keep private business use below the permissible thresholds, and to preserve records, such as research agreements, in order to prove compliance. *See* IRS Revenue Procedure 2007-47, Internal Revenue Code regulations (26 C.F.R.) § 1.141-1, *et seq*. *See also* Ben Griffiths' excellent NACUA outline: *Industry Sponsored Research and University/Industry Relations,* Narrative Outline (November 2000 CLE, 20 pp.).

H. Cost Reimbursement and Financial Requirements: Federally sponsored grants and cooperative agreements are governed by agency regulations based on Office of Management and Budget ("OMB") Circulars. The two with which counsel need to be familiar are Circulars A-21 and A-110. A-21 provides the rules for cost reimbursement; A-110 covers a panoply of other terms and conditions. OMB has recently proposed sweeping changes in both of these circulars, with an aim towards simplifying and streamlining compliance. 78 Fed. Reg. 7282 (Feb. 1, 2013). Depending on the outcome that that proposed rulemaking, numerous policies at your institution may need to be revised.

Cost reimbursement issues are divided into two main categories: allowability and allocability. Allowability pertains to whether a particular reimbursement request is of a type that is permitted. Certain expenses are prohibited, and some

categories of expenses are governed by ambiguous rules, such as legal expenses or secretarial costs. Allocability relates to whether a particular expense, or an employee's time for a particular task, may be charged to a particular contract. Some universities have recently been challenged on allocability issues by federal investigators, resulting in multi-million dollar settlements.

In addition to the issues related to the charging of direct costs, OMB Circular A-21 addresses calculation and charging of indirect costs and sets forth in some detail what may be included in an indirect rate. The specific indirect rate for your institution is negotiated with the federal government and applies to all federal grants received by your institution. Pursuant to OMB Circular A-21, "[e]ach institution's [indirect] cost rate process must be appropriately designed to ensure that Federal sponsors do not in any way subsidize the [indirect] costs of other sponsors, specifically activities sponsored by industry and foreign governments." Thus, you cannot negotiate or waive the indirect rate for industrial sponsors without jeopardizing your ability to collect these indirect costs from the federal government.

Some tricky financial issues you might encounter are program income and cost-sharing, both governed by OMB Circular A-110. Program income involves any revenues generated by grant activities, such as conference fees or revenues from the sale of a CD-ROM. Cost-share means funds or resources contributed by your institution as a condition of receiving the grant (including funds contributed by nonfederal sponsors). Both program income and cost-share are considered the legal equivalent of federal funds, and all the rules governing those funds apply to program income and cost-share as well.

For the in-house practitioner, negotiating appropriate payment terms for clinical trials involves multiple accounting standards. While the OMB Circular A-21 model is how institutions cost their externally sponsored research, industry sponsors prefer to simply pay per procedure or milestone on clinical trials. There are two aspects to this issue. First, as some of the procedures carried out in the course of a clinical trial may primarily be part of the standard of care for management of that disease (for example, a CT scan of an oncology patient), care must be taken to ensure proper budgeting and billing. The Centers for Medicare and Medicaid Services ("CMS") issued in 2000 a Final National Coverage Decision, addressing what claims CMS deems suitable for billing as standard of care which is available at: https://www.cms.gov/Medicare/Coverage/ClinicalTrialPolicies/downloads/finalnationalcoverage.pdf.

The second aspect relates to compensation for subject harm. As industry has attempted to limit the claims it may face from research subjects who allege harm from participation in the research protocol, it has become common to see industry attempting to limit its obligation to pay to claims that are not otherwise covered by insurance. CMS quickly became alert to the possibility that medical bills for

harm resulting from an industry sponsored trial may be submitted to CMS for payment, rather than the industry sponsor. In 2010, CMS issued an alert notifying industry sponsors of clinical trials that, under the Medicare Secondary Payer Mandatory Reporting Provisions in Section 111 of the Medicare, Medicaid, and SCHIP Extension Act of 2007, CMS considered a promise to make payments to research subjects for injury arising from the trial to be an offer of liability insurance. Industry sponsors offering compensation for subject harm sustained in a clinical trial would thus be required to register with CMS as a secondary payer for claims. As a result of this alert, a number of industry sponsors have substantially scaled back what they are willing to offer in the way of compensation for subject harm in clinical trial agreements. As providing at least emergency care (without charge) for harm resulting from participation in a clinical trial is generally considered ethically required (as well as sound risk management), institutions must take care to insure that they are not left holding the financial responsibility for an industry sponsored trial.

I. Export Controls – the EARs and ITARs: The Export Administration Regulations ("EARs"), 15 C.F.R. §§ 730-774, administered by the U.S. Department of Commerce, and the International Traffic in Arms Regulations ("ITARs"), 22 C.F.R. §§ 120-130, administered by the U.S. Department of State, are increasingly being applied to university research activities. Both sets of regulations restrict the export of certain goods, technologies and information. Under the EARs and ITARs, you may "export" regulated technologies without ever leaving the country, by disclosing specific information or providing specific services to foreign nationals in academic and research settings on your campus, such as to foreign students or visiting faculty ("deemed export"). Sharing information about equipment, technology, biological materials, or software, for example, may be restricted.

Both EARs and ITARs provide for an exemption for information arising out of "fundamental research," where universities perform research that is carried out without restriction on publication or dissemination of research results. The exemption applies only to deemed exports within the United States. Export of covered technologies (e.g., equipment, software, biomaterials, or data) out of the country imposes tough compliance and licensing obligations.

Even on campus, the exemption is limited. It does not apply to confidential information, or to information subject to restrictions on publication in sponsored research contracts or grants. In any of these situations, information about regulated technologies must be restricted based on the nationality of the students and faculty involved. Violations of the export control rules are criminal, a fact often missed by faculty. One faculty member was sentenced to four years in jail for ITAR violations. *See United States v. Roth*, 628 F.3d 827 (6th Cir. 2011).

The Council on Governmental Relations has produced a publication, "Export Controls and Universities: Information and Case Studies," (February 2004) to

provide practical guidance (http://www.cogr.edu/docs/Export%20Controls.pdf).

A related set of requirements are the embargoes imposed by various sources of law, and generally reflected under the Office of Foreign Asset Controls ("OFAC") regulations. For several countries (Syria, Sudan, Myanmar, Cuba, North Korea and Iraq, as of March 2013)), a many types of transactions are prohibited, including otherwise benign activities such as exporting furniture, transferring biological samples, hiring translators, or answering questions at a conference. Licenses for such activities may sometimes be obtained, but not always, and generally not without some period of delay. Institutions must closely monitor all travel to these countries, and interactions with individuals located in these countries to shield themselves and their researchers from criminal liability.

J. Biosafety and Biosecurity: Numerous federal regulations and requirements govern various aspects of biosafety. Most important for biomedical research are the NIH's Recombinant DNA (rDNA) Guidelines, available at http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html, which are incorporated contractually into all NIH research grants. The Guidelines require that institutions establish an Institutional Biosafety Committee ("IBC") to review all rDNA research conducted on campus, regardless of the source of funding for the research, for safety and environmental concerns. Some rDNA research requires prior NIH approval as well.

The federal government has also designated certain potentially harmful biological materials as "select agents." These select agents consist of certain viruses, bacteria, toxins, and related genetic materials that are harmful to humans, animals or plants, or all three and might be of use to bioterrorists. The DHHS's Centers for Disease Control and Prevention ("CDC") and the USDA's Animal and Plant Health Inspection Service ("APHIS") have regulations for the possession, use and transfer of these select agents, which implement the USA PATRIOT Act of 2001, Public Law 107-56 (Oct. 26, 2001), and the Public Health Security and Bioterrorism Preparedness Response Act of 2002. While the CDC and APHIS maintain their own lists of select agents, 42 C.F.R. § 73.3 (for the CDC list), and 7 C.F.R. § 331.3 & 9 C.F.R. § 121.3 (for the APHIS list), there is also an "overlap" list of agents that pose risks to both human, and animal/plant products. 42 C.F.R. § 73.4. Access to select agents requires both registration of the facility, 42 C.F.R. § 73.7(a); 7 C.F.R. § 331.7, 9 C.F.R. § 121.7, and a security risk assessment for the individuals working with the agents, 42 C.F.R. § 73.10, 7 C.F.R. § 331.10, 9 C.F.R. § 121.10. All aspects of security of the facility, including physical security, IT security and biosafety features must be described to, and approved by, the responsible agency, and access must be restricted to personnel who have cleared mandatory FBI background checks.

Since March 22, 2008, all universities have been required to comply with the Department of Homeland Security ("DHS") Chemical Facility Anti-Terrorism Standards ("CFATS"). That means that institutions must inventory the amounts

on campus of 325 Chemicals of Interest ("CoI"), and determine whether those amounts are above the threshold limits for reporting. If CoI are reported, DHS may then require the institution to prepare a Security Vulnerability Assessment and to develop and implement a Site Security Plan. This requirement applies to the entire campus, such as the physical plant, not just the research components, but the impact on laboratories is significant. The CFATS regulations, at 6 C.F.R. Part 27, and Appendix A, set forth detailed rules for determining CoI amounts, addressing situations such as how to assess quantities when the chemicals are in mixtures or solutions or are kept in various types of containers. Institutions have flexibility in that they can assess threshold amounts institution-wide, or by campus, by groups of buildings, or even for each building individually.

In addition to the more specialized laws applicable to biosafety and biosecurity in the research setting, the Occupational Health and Safety Act, 29 U.S.C. § 651, *et seq.* (2012), governs the safety of workers in laboratory settings, including university laboratories. For an excellent overview of the OSHA structure, standards and their application in university setting, *see* David Monz and Patrick Schlesinger's NACUA outline, *Laboratory Safety (and Liability) in the Research Environment*, Narrative Outline, (November 2012 CLE).

K. Human Embryonic Stem Cell Research: Human embryonic stem cell research is governed by a patchwork of partially consistent state laws, nonbinding national norms, and federal funding requirements. State laws may specifically regulate the creation of human embryonic stem cells (hESCs), including the donation of the relevant predecessor biological materials. In some states, laws designed to discourage abortion may introduce other issues, including, in some states, making it illegal to destroy an embryo for research purposes. They may speak to the permissibility of reimbursement to the donors, and may specify requirements of informed consent for the donors. They often impose the same or similar requirements for hESCs imported into the state for research purposes. An overview of existing and proposed state laws in this area as of 2006 is available from the National Conference of State Legislatures at : http://www.ncsl.org/programs/pubs/summaries/0166608-sum.htm.

Like much biomedical research in the United States, federal rules related to the types of research that can receive federal funding support have shaped what research is being done. NIH Guidelines on Human Stem Cell Research, July 7, 2009, *available at*, http://stemcells.nih.gov/policy/pages/2009guidelines.aspx, specify that only hESCs that are contained in an NIH registry (with specific ethical and scientific requirements for inclusion) may be used in research proposed for NIH funding.

In addition to the funding and state law issues, any derivation of hESCs will likely involve human subject research, and will therefore require prospective IRB review and compliance with the Common Rule.

III. KEY CONTRACTING ISSUES IN INDUSTRY SPONSORED RESEARCH CONTRACTS

Industry support for university research can come in several forms, including straight funding agreements, material transfer agreements for the supply of research reagents or study compounds, loans of equipment, or some combination of all three. While less common, collaborative research agreements can include active participation by industry partners, or work conducted partially in and by the university, and partially in or by the industry partner. Clinical trial agreements present special issues as well, and university counsel should be sure to understand all of the potential risks and relationships in approaching an agreement. Negotiating these agreements is important to protect the institution's resources, to safeguard the researchers' academic freedom, and to ensure your institution's ability to use the results of the research. The brief summaries below highlight the most common areas of contention.

Note too that sponsorship agreements with foundations and with government agencies often require counsel input as well, although usually on a much smaller scale, as the dimensions for negotiation are more limited, and many government contracts are constrained by law or regulation. Federal grants are governed by agency rules and regulations, and federal contracts come under the Federal Acquisition Regulations.

A. Indemnification

Two sets of indemnification issues arise in industry sponsored research contracts. First, the sponsor may want the institution to indemnify it for liability arising from the conduct of the research. In some cases this may be reasonable, such as where a corporation or foundation is providing proprietary materials (e.g., experimental molecules or plasmids) to the university researcher, with little potential for benefit to the provider, and where the industry sponsor has not participated in the design of the research protocol. Even then, however, many institutions, especially state institutions, are restricted from indemnifying, and may need to object, or else forego the material. In other cases, however, the corporate partner does seek to benefit from the research, and it is more appropriate for each side to bear its own liability risk. Most universities avoid indemnifying corporate sponsors where possible, but may indemnify governmental or charitable sponsors in some cases.

Secondly, Universities may seek indemnification from the industry sponsor. One scenario where the university may seek indemnity is where the industry sponsor is providing a material, drug, device or other item for use in the study, and liability may result from that item. A strong case for indemnification can be made where the protocol for the study (for example- a clinical trial) has been written by the sponsor.

Indemnification of the university is especially important when the sponsorship agreement itself provides for any sponsor use of the research results, such as research & development use of resulting data or materials. In such cases, the

agreement should provide for up-front indemnification of the university for liability resulting from that use.

Indemnification clause negotiations can create tensions among everyone involved. The parties may be far apart in their positions, and indemnification is often the last issue to be resolved. Faculty may be quite frustrated if a technical issue of low concern to them is holding up their research, and they may not understand why university counsel is being so insistent, especially if the underlying contract appears low risk, such as a no-money material transfer agreement. As the liability for third party claims will fall to the institution's, and not the individual faculty member's, budget, the risk may not be as immediate to that faculty member.

B. Confidentiality & Publication Clauses

Corporate sponsorship agreements generally provide that sponsor-provided confidential information must be kept confidential. The battle lines usually form around the duration of the confidentiality period, whether each employee receiving the information must sign a document committing to confidentiality, and, most significantly, whether and how the confidential information will be identified. Corporations often want to mandate confidentiality for any information they provide that is inherently confidential. Universities want confidential information clearly marked so that their researchers have fair warning and don't disclose or publish information that they didn't realize was intended to be confidential. Care should be taken to ensure that the definition of "confidential information" is not defined so broadly as to encompass the results of the research, even if it was collaboratively generated by the sponsor and labeled Confidential.

While the corporate sponsor's confidential information may be necessary for the research, it is important to ensure that confidentiality clauses do not inappropriately restrict the faculty member's ability to publish the resulting research. While universities' publication clauses routinely do provide the sponsor the right to receive manuscripts in advance, with an opportunity for the sponsor to object to release of any confidential information, and to arrange for intellectual property protection, the sponsor must not be provided rights to control, edit, or approve resulting publications beyond removing their own confidential information. Any additional rights would infringe on academic freedom. Beyond that, restrictions on publication can expose the university to the deemed export rules by destroying the fundamental research exclusion (see Section II (I) on Export Controls).

C. Intellectual Property

The standard intellectual property ("IP") provision for corporate sponsored research agreements is for the university to own its employees' resulting inventions, and provide the corporation an option to negotiate for a license to them at fair market value. This reflects the university position that it is not

performing fee-for-service activities, but engaged in industry supported basic research, with the university retaining control over the products of that research. Ceding ownership of intellectual property to the sponsor can result in tax implications, and can further result in the faculty member being blocked from continuing their own line of research. In order to balance the needs of the university and the sponsor, most universities' will grant the sponsor an option to license any resulting IP, and often the corporation will also receive a nonexclusive royalty-free right to use the inventions for internal research purposes only.

Corporate sponsors will sometimes seek some pre-negotiated royalty rate for future inventions, but universities generally resist, especially if the research is being conducted in facilities built with tax exempt bonds. Pre-set royalty rates make the research private business use (see Section II(G)).

Difficult negotiations can arise from conflicting needs of the parties. When sponsors provide intellectual property of their own, such as genetically altered materials, or software, or drug precursors, it will be very important to them to ensure that they own or control any university improvements to their IP. Otherwise, their development of their own IP would be "blocked" by university patents. And universities' negotiators must watch out for the possibility that inventions will arise from research supported by different sponsors, including the federal government, all with conflicting claims to the IP.

It should be mentioned that in research grants from Foundations, intellectual property issues also can dominate the negotiations. Sponsors often want a share of the university's ensuing royalties, and often start by demanding 100% of the net proceeds allocable to inventions resulting from their sponsorship. Needless to say, universities resist these demands, but often compromise on some formula for equitable sharing.

D. Termination Clauses

Most contracts will provide for termination for various reasons, ranging from breach by one of the parties to at-will termination. They often set out procedures for pre-termination notice, and an opportunity to cure any breach. Watch out for clauses that would allow the company to terminate on short notice, and leave the university on the hook for committed expenses. In cost-reimbursement contracts, universities generally insist upon provisions providing for payment of noncancelable expenses, such as pre-committed leases, and salary expenses for post-doc salaries when the post-doc has been hired specifically for the project.

IV. WHAT ARE SOME PRACTICE POINTS THAT MAKE UNIVERSITY COUNSEL'S LIFE EASIER?

A. Dealing with Industry – It is important that you be able to clearly articulate the mission and values of the university in dealing with industry. Universities are not

contract research organizations, and issues such as intellectual property ownership, publication rights, confidentiality, and the charging of indirect rates are common areas for friction.

1. Recognize that economic development may be a small part of your overall mission, but that a basic commitment to research and teaching is primary.

2. When human subjects are involved, the highest concern and attention should be focused on the protection of those subjects in research. This means attention to the specifics of the regulations and the formalities of IRB review and approval, as well as promotion of human research subject protection as a value of equal or greater weight than the interests of the sponsor or commercial success. The failure to attend to this matter with the appropriate commitment can result in suspension of all federally financed human subject research at your institution.

B. Conflicts of Interest

1. Conflicts of interest usually arise from complicated fact patterns. Your conflicts of interest committee or other decisionmaker will need help focusing on the research conflicts issues – does the outside financial interest create a risk of bias in the conduct of the research? You will need to make sure that other issues are routed to the appropriate decisionmaker. Other issues often linked with conflicts of interest include conflicts of commitment, nepotism, procurement code violations (publics), diversion of intellectual property, theft of institutional corporate opportunity, and improper use of institutional resources.

2. Conflicts of interest often occur in connection with faculty start-ups. The institutional conflicts decisionmakers may find themselves in opposition to administration and community support for tech transfer efforts. It is valuable to make sure the upper administration is well-briefed on conflicts issues, the federal regulations, and the institution's obligations. It is even more valuable to make sure that the folks working on tech transfer understand the issues, and design start-ups accordingly, so as to minimize conflicts in the first place.

3. Conflicts of interest carry the greatest risk in the context of clinical trials. The American Association of Medical Colleges ("AAMC") and other organizations recommend that institutions go beyond minimum federal conflict of interest requirements for human subjects research. The potential for appearance of conflict is high in the event of patient injury. Make sure that your institution's process provides especially careful scrutiny of potential conflicts in clinical settings.

C. Research Misconduct

1. Research misconduct may arise through a formal complaint, or may lurk hidden in an employment dispute or student disciplinary action. Make sure that research misconduct allegations are identified and treated separately under regulations that conform to federal requirements. Resolution of the underlying employment or student grievance does not satisfy federal requirements for handling research misconduct.

2. Know the scope of research misconduct. It does not include financial improprieties. Administrators who are unhappy with faculty conduct in research activities may be searching for a preexisting mechanism to handle other allegations; do not let the overly prescriptive research misconduct regulations become a dumping ground for other problems.

3. You or your clients should maintain affirmative contact with witnesses and complainants to make sure they are not experiencing retaliation, and to ensure that the institution learns of any new evidence.

D. Contracting

1. If you are working with a contracting administrator, make sure the faculty member is involved. The publications clause or confidentiality provisions that may be acceptable to you legally, and acceptable to the administrator, may impose impossible obstacles to the researcher.

2. If you are working with the faculty member, make sure the contracting administrator is involved. The billing or reporting requirements that are acceptable to the faculty member may impose impossible obstacles to the administration.

3. Make sure that compliance obligations are identified while you are working on the contract, especially prior reviews by internal compliance committees such as the IRB, Conflict of Interest Committee ("COIC"), IACUC or IBC. Little irritates a faculty member more than to work with counsel on a months-long negotiation and come to the close only to find out that there are several more sets of internal requirements before the research can proceed. Faculty members sometimes think that counsel are "handling" these requirements for them.

4. Before starting serious work on a contract, be it reviewing a proposed contract or drafting one, find out about any other contracts, past or present, involved in the research. Research can often involve multiple sponsors, providers of biological materials, employees loaned from outside entities, donations of equipment, etc. You cannot analyze confidentiality clauses, intellectual property rights, or data sharing obligations with one outside party without considering the corresponding clauses, rights and

obligations of the other parties.

E. Reporting to the Federal Government

1. Many areas of research compliance are overseen by federal government agencies. Institutions are required to report many instances of noncompliance, and, especially in the context of human or animal subject research, certain unanticipated events (which may also be adverse events) not involving noncompliance.

2. Your IRB and IACUC should have written policies regarding when and how they will report unanticipated events or noncompliance. Similarly, your research integrity officer should have policies regarding reports to the Office of Research Integrity. You should understand these policies, and make sure that these committees are reflecting in their minutes the basis for their determination of whether or not to report an incident.

3. A common mistake is to wait to report until all the facts are clear – a process that often takes much longer than originally contemplated. If a reporting obligation pertains, it is usually better to report the partial facts promptly, in order to obtain the enforcement agency's trust. You should be clear that you are still investigating, and will follow up with a fuller report later.

V. WHO ARE THE STAKEHOLDERS IN VARIOUS SPONSORED RESEARCH SITUATIONS?

A. The High Tech Start-up Company

1. Your University Office of Technology Transfer – This is the organization charged with negotiating a commercially reasonable license to the technology, which may include an equity position for the university. They are interested in extracting fair market value for the technology. They want to ensure the start-up will actually commercialize the invention, and want your advice on including minimum royalty requirements, and rescission rights if patenting milestones are not met. If equity is involved, you will likely be consulted about liquidation priorities and anti-dilution protection. These specialized provisions may require consulting outside counsel.

2. Your Research Office – There is likely to be a sponsored research contract from the start-up to the university, which may include sticky negotiations over ownership of intellectual property, the role of the faculty-inventor of the technology, and the indirect rate.

3. Your Faculty Member – Who is the inventor of the technology around which the start-up was formed, who also has a large equity position in the

company, and who wants to sit on the board of directors. She also wants to obtain either a research or a consulting contract from the company.

4. Your Local Economic Development Folks – Who are trying to create a high tech hub for the region and want to see if they can "facilitate" negotiating the appropriate agreements for the start-up company.

5. The Investors – Who want all the red tape to vanish as quickly as possible, and who likely have close connections to your President and Regents.

6. Outside Counsel for the Sponsoring Company – Who have associates burning the midnight oil, and expect 24-hour turnaround on all contract review.

7. Your Conflicts of Interest Committee – Which identifies difficult conflicts, and wants your advice on developing a management plan that will mitigate those conflicts.

8. Your Vice President – Who wants the legal office to expedite deals like this.

B. The Clinical Trial Sponsored by Big Pharma

1. Your research office – Pharmaceutical companies generally take an aggressive position with respect to clinical trials agreements. Expect them to offer only a per-patient payment, to demand a complete waiver of intellectual property rights, and to seek to own the data and control the publication. They will likely set strict time limits on your decision as to whether to accept the contract.

2. Your IRB – The pharmaceutical company may have drafted the protocol, or your faculty member may have been involved. In either case, the protocol must be reviewed, may be altered and the appropriate informed consent documents must be generated.

3. Your Faculty Member – Where human subject research is involved, the FDA and the NIH require disclosure of "significant financial interests." If your faculty member owns $5,000 worth of Big Pharma stock, or receives more than $5,000 per year of consulting fees from Big Pharma, or has an interest in intellectual property involved in the trial, disclosure (at a minimum) and conflict of interest management must be addressed.

4. Your Conflicts of Interest Committee – It will want time to gather all the facts and deliberate carefully before negotiating a management plan with the faculty member.

C. Research Misconduct Allegations

1. The Accuser, who may or may not also be a faculty member – She wants vindication of her position. She will also want to be privy to all aspects of the process. She may also claim that her reputation has been damaged by the accused, and may seek employment-based recompense.

2. The Accused – He wants assurances that he is innocent until proven guilty. He is unhappy that the investigation is taking time away from his work, and may want employment-based recompense for the damage to his reputation from the allegations, from the fact that the university is taking them seriously, and from the fact that his productivity is suffering as a result. If the accuser is under his direct supervision, he may take actions against the accuser which appear to be retaliatory.

3. The Sponsor – If the sponsor is a federal agency, you may have reporting obligations, and the risk that your procedures and results will be second-guessed.

4. The Accused's Graduate Students – They will want to know whether their work will be interrupted, and whether their careers will be derailed due to the loss of prestige of their mentor.

5. Witnesses – They will be afraid of retribution, and want to avoid the responsibility of taking sides. But some will take sides, and view their roles as advocates rather than witnesses. They will also expect to be privy to the results of the investigation. Prepare written advice that is given to each witness explaining his or her role.

6. The Media – They will be looking to highlight the allegations, and will be less interested in the process you are using to assess their validity. Work closely with your public relations office.

D. Negotiating a Sponsored Research Contract with Industry

1. Industry representatives – They are paying for the research. They want to own it, including all inventions. Their industry is competitive and all research results must absolutely be kept secret – particularly if the results displease the marketing department.

2. Principal Investigator – She is conducting and managing the research. She may want to own the results. She may be willing to give away the results. She definitely wants to be in control of the negotiations. She already hired the post-doc who will be doing the work and she needs this money today to pay his salary.

3. University Counsel – You are concerned, among other things, with restrictions on publication, and with giving away the resulting inventions, as a matter of institutional policy. You are also concerned about publication rights because yielding on that point could threaten the institution's exemption from export control laws restricting access to the research by foreign nationals, not to mention the fact that the IRS might not consider this to be "research" at all under those circumstances. This means that your institution would be subject to taxes on monies paid on this contract. You also know that setting royalty rates for future inventions can threaten the tax-exempt status of the institution's bonds.

4. Your Office of Research Administrator – She probably has twenty other contracts on her desk and is focused on being service-oriented. She wants to prove that her office can handle private contracts as effectively as it handles agreements with the federal government.

E. The Faculty Member with Consulting Contracts and Board Memberships in Companies working in areas closely related to her Federal Sponsored Research

1. The Conflicts of Interest Committee – It is concerned about the increasing influence of financial interests on the researcher, and generally on the research and teaching mission of the university.

2. The Faculty Member – She believes that her connections with industry bring in more research to the university, and that she has the right to supplement her paltry academic salary.

3. Students and Post-docs – They are expecting research positions on the faculty member's contracts, and jobs from her outside companies, either now or after they leave the university. They are also trying to finish their degree or thesis, and worried about being tasked to work on matters that will delay them, but that are of financial benefit to their advisor.

4. The Technology Licensing Office – It is hoping to license the faculty member's inventions, but does not want the constraints of having to deal with her company. It will likely be worried that the faculty member's companies may claim ownership of inventions she creates at the university.

5. The Federal Agency – It expects the research results to be widely publicized and commercialized. It also expects the grantee institution to have properly disclosed the potential conflicts of interest.

F. Unexpected Events or Serious or Continuing Noncompliance in Human or Animal Subject Research

1. The IACUC or IRB ─ Needs support in investigating the situation, and wants primacy in deciding whether there is a problem and, if so, implementing a solution. It is responsible for deciding whether to take follow-up action, and will need advice as to whether any mandatory solutions impact the rights of the people involved.

2. Your Chief Research Officer ─ Will want to make sure that the incident does not result in institutional loss of reputation with the sponsoring agency, and may have preconceived views about the researchers involved. Will need guidance on whether to report to the oversight agency, and what to say in that report. May need guidance to make sure that the legal authority vested in the IACUC or IRB is protected.

3. The Principal Investigator ─ Is concerned both about keeping the research moving forward and about preserving her reputation. She may invoke the assistance of faculty committees if she is dissatisfied with administrative or committee action.

4. Research Staff ─ May have strong views about whether appropriate care was provided and protocols properly followed. If it is their actions at issue, they will be concerned about their jobs and reputations, and may invoke the assistance of staff advocates or dispute resolution mechanisms if they are dissatisfied with administrative or committee action.

5. The Oversight Agency (OHRP, FDA, APHIS or OLAW) ─ Will want a full report as soon as possible, and will want assurances that any underlying problems have been identified and a correction plan implemented. If they are dissatisfied, they may want to conduct their own inquiry.

6. Your Public Relations Office ─ Will want to be fully briefed, and will want to make sure that it controls communications with the media.

VI. WHAT FURTHER SOURCES OF INFORMATION ARE AVAILABLE TO HELP THE NEOPHYTE LAWYER WORKING IN THIS AREA?

A. NACUA Outlines and Materials. *See* generally NACUA's Outline Guide available on the web page. Four excellent overviews with a focus on compliance are:

1. Kathleen Irwin, *University Research Activities*, November 2-3, 2000.

2. Susan Carney, *The Research Institution: A Primer*, June 25, 2000.

3. Beth Cate, *A Compliance Program for Research Activities,* April 1, 2005.

4. Ann Adams, *Basics of Research Compliance: Research Intellectual Property, Federal Grants Administration, and Research Misconduct,* June 23-27, 2009

Good resources on drafting and negotiating certain types of research agreements are:

1. Mont Brownlee and Karen Mullin, *Clinical Trial Agreements: Negotiating Key Terms (Power Point Slides) June 28, 2011*

2. Heidi Henning, *Negotiating the Materials Transfer Agreement*, Nov. 10-12, 2004

3. Mark Bohnhorst, Theresa Colecchia, and BethLynn Maxwell, *Negotiating Difficult Clauses in Industry Sponsored Research Agreements,* June 22– June 24, 2008

B. Really Useful Web Sites from the Federal Government

1. On human subject research, the site for the Office for Human Research Protections is extremely informative: http://www.hhs.gov/ohrp/.

2. On HIPAA issues, the DHHS Office of Civil Rights: http://www.hhs.gov/ocr/privacy/

3. On research integrity, the site for HHS' Office of Research Integrity may be found at: http://ori.dhhs.gov/

4. On clinical trials, start with the FDA's IRB information sheets at: http://www.fda.gov/oc/ohrt/irbs/default.htm.

5. On animal welfare and research, search the USDA APHIS site at:

http://www.aphis.usda.gov/animal_welfare/index.shtml and the OLAW site at: http://grants.nih.gov/grants/olaw/olaw.htm.

6. On conflicts of interest, see the DHHS COI site: http://grants1.nih.gov/grants/policy/coi/index.htm.

7. OMB Circulars: The two most important are OMB A-110 (administrative requirements) and OMB A-21 (cost principles): http://www.whitehouse.gov/omb/circulars/index.html.

8. On reporting and managing federally funded inventions, the iEdison site is the central reporting portal for most federal agencies: https://s-edison.info.nih.gov/iEdison/

9. The NIH Grants Policy Statement, http://grants1.nih.gov/grants/policy/nihgps_2012/index.htm and the NSF Grant Policy Manual, http://www.nsf.gov/pubs/manuals/gpm05_131/index.jsp.

10. NIH's Office of Biotechnology Activities' website, http://oba.od.nih.gov/, provides resources on requirements for recombinant DNA research.

C. Other Organizations with Useful Web Sites

1. Association of University Technology Managers: www.autm.org. This site includes the Uniform Biological Materials Transfer Act ("UBMTA").

2. Council on Governmental Relations: www.cogr.edu.

3. The Association of American Medical Colleges research webpage: https://www.aamc.org/initiatives/research/. .

4. The National Association for Biomedical Research, for updates on legislation related to animal research: http://www.nabr.org/. .