CLINICAL TRIAL
CONTRACTING/LEGAL ISSUES

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Contract Research Process	Legal/Procedural Issues	Compliance Tips
1. Identification of research project and preliminary review of scientific value/purpose of research project.	♦ *Clinical trials or other research with little scientific value implicate the federal Anti-kickback Statute and IRS requirements. In addition, clinical trial proposals that offer inducements to physicians to participate implicate the federal Anti-kickback Statute. See also, AMA definition of "Genuine Research Purpose."* ♦ Does research have scientific value? (may need review by IRB for complete assessment). ♦ Does protocol demonstrate appropriate "scientific purpose"?	♦ Develop specific research intake process. ♦ Ensure that all information is complete and accurate before being forwarded to legal/finance. Determine nature of study and nature of all financial arrangements. Make initial determination on scientific value of study before study is presented to IRB. ♦ Determine extent of resources (including space, personnel) to be used to conduct the study.
2. Address IRS Issues.	*Compliance with IRS requirements addresses health regulatory issues of scientific purpose.* ♦ Must further hospital mission statement.	♦ Legal should confirm that trial poses minimal risk to hospital in these areas.

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	♦ Must be research undertaken for new applications of products or drugs in order to improve the ability to treat various conditions or diseases. (IRS) ♦ Research cannot be "quality control programs," "ordinary testing for certification programs," or the sole function of the principal investigator. (IRS). ♦ Does study have scientific value and is it for new applications of drugs or products to improve the ability to treat certain conditions or diseases? ♦ Does the study require the exclusive use by the sponsor of bond-financed facility space?	
3. Develop research budget/review budget.	♦ *The development of the budget, the provision of money directly to the investigator and the ability to earn and keep profits generated from participation in the trial implicate the federal Anti-kickback Statute and compromise patient care, see federal Anti-kickback Statute, Prescription Drug Marketing Special Fraud Alert.* ♦ Are budgeted amounts based upon FMV? ♦ Do any funds flow directly to the investigator (physician)? ♦ Were there any inducements to the	♦ Develop process for conducting FMV analysis for rates paid pursuant to the research project. One such method might be to calculate physician's time involved and pay based upon an hourly rate or to calculate based upon usual and customary charges for the services provided. ♦ Include in FMV site resources allocated for study and overhead amounts. Develop standard overhead cost calculation for use on all studies. ♦ Develop procedures that address: who follows the release of the funds, where the

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	investigators to get subjects to participate in the study? ♦ Do any financial incentives exist for physicians to coerce patient participation? ♦ Are investigators or the hospital keeping profits derived from the research? ♦ Is there a process in place to ensure allocation/return of excess funds? ♦ Time records/documentation. ♦ Is the study limited to the appropriate number of investigators/sites? ♦ No direct payments. ♦ Are there any payment terms not included in the budget? ♦ Review impact of cumulative financial relationships. ♦ Develop qualification criteria for inestigators/sites (do not limit to high prescribers). ♦ No incentives for participation ♦ Is this a clinical trial for which the Medicare Program can be billed? If yes, does it make sense to bill the Medicare Program?	checks go, whether the study terms are being met. ♦ Ensure that excess funds are not diverted to back to the investigator—*e.g.*, return funds or allocate to a non-related charitable organization. Selection of charitable organization should be reviewed by legal; drug company should be notified of allocation; if allocation from all clinical trials exceeds a certain threshold in a 12-month period – all subsequent funds must be returned to sponsors. Funds may be distributed to hospital or exempt affiliate (such as a related foundation).
4. Obtain financial conflict of interest disclosures.	*Financial conflicts of interest implicates the federal Anti-kickback Statute and can compromise research integrity. <u>See</u> also Consensus Statement of Conflict of Interest Policies for Academic Institutions (Jan. 2001).*	♦ Develop financial conflict of interest disclosure form to be completed by everyone involved with the study. ♦ Develop patient freedom of choice forms. ♦ Develop process for completion of form

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	♦ Apply to <u>all</u> involved (*e.g.*, nurses, medical students. ♦ "Financial interest" includes fees, gifts, honoraria, options, directorships, special relationships with potential for personal material gain. ♦ Disclosure must be ongoing.	and for meaningful disclosure. ♦ Develop written policy.
5. Require written contract for term of 1-year	*Clinical research trial contracting can be structured to fall within the personal service and management safe harbor to the federal Anti-kickback Statute. Compliance with the safe harbor offers protection against liability under the kickback statute. Conduct outside a safe harbor must be analyzed based on the "facts and circumstances."* ♦ Signed written document. ♦ Specifies services. ♦ Part time vs. full time. ♦ 1-year term. ♦ Aggregate compensation set in advance, fair market value not based on referrals. ♦ Legal activity. ♦ Commercial reasonableness.	♦ Develop template contract. ♦ Require compliance with template. All deviations should receive legal review. ♦ Provide template to contracting parties.
6. Establish appropriate monitoring systems for billing federal health care programs.	♦ *Participation in clinical drug trials raises a number of obligations with respect to billing Medicare for services rendered. In*	♦ Appoint someone in the billing department to act as the clinical research trial liaison and the billing expert for clinical trials.

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	addition, the OIG is concerned that providers are billing the Medicare program for services for which the provider already has been reimbursed pursuant to a clinical trial agreement with a manufacturer. Improper billing implicates the Federal Anti-kickback Statute and the Federal False Claims Act. ♦ The billing rules for billing the Medicare program for clinical trials vary depending upon whether the clinical trial is for a drug, for a cancer drug, for an approved drug, non-approved use or for a non-approved use. The rules also differ for devices.	This person would be responsible for interfacing with the study coordinator, as needed, providing training to the billing department, monitoring the status of research trials and assessing the billing status of drugs/devices subject to a clinical trial. ♦ Develop a training process for the billing department so that they are informed of all study services and the scope of the study to enhance more accurate billing. ♦ Develop a process for identifying all study patients, *e.g.*, color code files or asterix on the computer. ♦ Develop a clinical trial cover sheet for all trial patients that includes: ♦ All services performed as part of the study [and those services for which the study sponsor reimburses]. ♦ The type of product that is the subject of the trial, *e.g.*, device, approved drug—non-approved use, non-approved drug or cancer drug. ♦ This sheet should be attached to the appropriate patient files. In addition, the cover sheet and names of the participating patients should be maintained. ♦ The coversheet should be forwarded to the billing department where [who] does the

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		following:
7. Research Meetings.	*Research meetings to exotic locations or with no scientific purpose implicate the federal Anti-kickback Statute. See also, AMA Guidelines on Gifts to Physicians.* ♦ Modest. ♦ Not promotional. ♦ Scientific purpose. ♦ Appropriate size. ♦ Appropriate participants. ♦ Appropriate locale.	
8. Completion of clinical trial.	*Appropriate completion of the study with appropriate follow-up demonstrates that the study had a valid scientific purpose and scientific pursuit.* ♦ Completion of clinical trial requirements. ♦ Are study results published? Utilized?	♦ Ensure that billing no longer bills patient as if study is in place. ♦ Excess funds will need to be allocated. ♦ Necessary preparation will need to be maintained. ♦ Institute procedures if patient remains on drug/device post-study completion.
9. Establish monitoring and checks and balances for contract compliance.	*The investigators/sites are under a legal obligation to put checks and balances in place to ensure that the clinical research trials are operating within legal requirements.* ♦ Audit clinical trial randomly during the course of the trial.	Examples of audit areas include, but are not limited to: ♦ Are services for enrolled patients billed correctly? ♦ Has patient recruitment met requirements? ♦ Is investigation following study protocol? ♦ Is study operating within parameters of

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		budget? ♦ Do any financial conflicts of interest exist? ♦ Does study continue to have legitimate scientific purpose? ♦ Are funds correctly allocated?