Rules to Play the Game and Win

🎉 🎉 Who’s the Biggest Loser?
One of the biggest causes of information breach is lost devices. If an unencrypted laptop has PHI on it and is lost or stolen, notices of unintentional disclosure must be sent out to patients, and depending on circumstances, Federal authorities may be notified—possibly with huge consequences.

 вал d on a Rookie: You need to be trained to ship safely
If a lab ships a hazardous material, including dry ice, without proper packing and labeling, harm or destruction may result. Even without a bad outcome, the University is likely to be seriously fined, and your department may bear the cost. OSEH training is online and efficient. Just Do it!

_dice-close new Outside Interests within 30 days
If you’re late in your disclosures, the non-compliance must be reported to the funding agency and the University may be required to do an “investigation” to be sure that no bias occurred.

Know the Rules of the Game: Read Conflict Management Plans
“It takes a village!” The conflicted party and anyone involved in conducting a study from the PI, to the person filling out the delegation log, to the one conducting the consent process—should be familiar with the conflict management plan in order to assure compliance, particularly with the informed consent requirements.

Risky Business? Keep your lab safe!
Make sure everyone is properly trained, that items are labeled, and wear appropriate protective gear. When people forget such precautions, injuries and even death can result! A professor at UCLA narrowly escaped imprisonment based on such an incident.

Does it or Doesn’t it? Know whether or not you should register your clinical trial in www.ClinicalTrials.gov
Failure to do so can result in fines, loss of funding, or inability to publish!

Preserve the sanctity of your lab and clinical trial records
White out, torn pages, and similar missteps can result in research integrity problems or the inability to prove that you really did do the right thing!

Make sure you follow your protocol, your contract, your grant proposal, your gift agreement, your publication agreement, your conflict management plan, etc.
Make sure you know what you agreed to, and stay within those bounds.
Make sure co-investigators on NIH grant submissions have made their annual M-Inform disclosures
A federal grant cannot be submitted until everyone named on the grant has submitted their outside interest disclosures—nag them early! Applies to all PHS funded research.

Know who is asking you to work with them
The internet is full of “sharks” and “wolves”. Predatory journals may look like they’re legitimate businesses, but they are only seeking to take your money, not to enhance scholarship. Hedge funds may try to get you to advise them (and possibly disclose confidential information in the process). Internet “second opinion” sources may seek your participation and then exploit your name and UM affiliation.

Get IRB approval before doing anything that might be human research
If you engage in regulated human research without realizing it, and don’t get IRB approval first, there will be additional IRB and University consequences, your research subjects/patients may need to be notified, as might federal authorities such as the FDA and/or DHHS OHRP. Your reputation and future ability to be funded for or conduct human subject research may be at risk.

Contact us early when forming a start-up company
If you are conducting research involving your company or expecting your company to do business with UM, we can help avoid research/procurement delays by starting the conflict management process early.

Don’t accept gifts from biomedical companies or vendors
Personal gifts, as well as most gifts to departments, etc., are prohibited. This includes meals provided for meetings at UMHS, being taken out to dinner, dinners offered at local restaurant CME presentations, chocolate, or travel expenses to see a company’s product.

Contact us whenever a federal agent/inspector contacts you, makes an appointment with you, or shows up at your door
Examples of federal agencies you may encounter include: FDA, CDC, OBA, USDA, FAA, ICE, NRC, OHRP, OLAW, EPA, DEA, etc.

Contact Public Relations whenever you receive an inquiry from the media, particularly regarding a sensitive or potentially negative issue
PR can be reached at 764-2220, or during off-hours at 936-4000.

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