SECOND ANNUAL

MEDICAL RESEARCH SUMMIT

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How can ethical issues become fraud issues?

Good faith and fair dealing, as understood in the community, now involves deception, breach of trust or lying to the government.

- Misrepresentations to Government
- Misrepresentations to Internal Oversight Committees that Government Relies On

- reckless endangerment
- medical necessity
- worthless services
- misleading patient about efficacy, risks
- patient experimentation without disclosure
- false representations (e.g., by pharmacy) about drug regimen reviews

Primary focus on patient as victim

Responsibility of providers to use best judgment on behalf of patient

Corruption of provider judgment by payments

What about biotech?

- clinical research fraud
- misleading patients

- exposing patients to harm
- kickbacks to physicians and institutions
- FDA false statements/failure to report

CLINICAL RESEARCH:

WHAT DO WE EXPECT?

Harvard Medical School, other leading NIH institutions proposed to National Medical College Association, February 8, 2001

1. Meaningful and full disclosure to patients.

This is research, not treatment. Our primary responsibility is to manage the study to obtain accurate information about the study medication. You should consult your personal physician for advice if you have any concerns about participation in this study.

There is a risk of harm to you from participation

- drug or device itself
- failure to use alternative treatment methods

I/We will benefit financially from this research, and from your participation.

- payments to researcher
- headhunter fees
- grants

I/We have an interest in the success of the drug under study - stock, options

- consulting arrangements

I/We have a responsibility to conduct this as a blind trial. This means that we do not know, and cannot tell you, whether you will receive the study medication, an alternative medication, or a placebo.

I/We have a responsibility to report to appropriate government agencies whenever an adverse event occurs during a research protocol. Therefore, you should report any side effect that occurs after you begin taking the drug to us, even if you are not sure whether it is related to the drug.

You have the right to decide voluntarily whether you will participate in this study. You have the right to drop out of the study at any time.

Different people have different reactions to medications, based upon factors such as age, weight, metabolism, use of other substances - prescription, etc., supplements, alcohol, and other diseases. It is important to provide us with accurate information about these issues - both for your safety and to provide full information from the study.

2. Studies should be designed by researchers, not by marketing departments.

- selection of study subjects - do they correspond to the population likely to take this drug?

- selection of dosage levels - do they correspond to the levels likely to be used in current practice? Or are the dosage levels manipulated to give the study drug an advantage over competitor drugs in the same category?

- selection of study end points - are they selected at the outset of the study, or chosen at the end to give a misleadingly favorable impression of a study drug?
- selection of measures of effectiveness - are they selected at the outset, or chosen at the end of the study from a variety of measures to favor the company drug?

3. Researchers should be expected and permitted to write and to publish what is, in their best judgment, the most accurate and fair conclusions from studies they undertake.

- the author of the published study should be the person given credit as the author. No ghost writing should be allowed. "Whose Article is it anyway?" Drummond Rennie in 354 Lancet 136 (July 10, 1999) Flanagin, et al. "Prevalence of Articles with Honorary Authors and ghost authors in peer-reviewed medical journals JAMA July 15, 1998 280(3) 222-4

- the researcher, and the editors of the referred journal, should have the final say in how the results of their research are presented. Gag clauses and prior approval clauses should have no place in medical research. See Bodenheimer, T. "Uneasy Alliance-Clinical Investigators and the Pharmaceutical Industry" 342 New England Journal of Medicine (2000) 1539-44

- the preparation of biased or slanted research for publication is scientific misconduct, and unethical.
- researchers should disclose, in any publication, any personal financial interests which a reasonable person would believe had the likelihood of influencing the results of their research.

- departmental and institutional review of proposed publication should focus on the quality, reproducibility, and record support for the study and reported results. The effect of publication of the study on the ability of the institution to attract additional funding should not be an explicit or implicit part of the review.

4. Those who do research should tell the truth about the results, including side effects, and should undertake reasonable efforts to find out what those results are.

RESTORING TRUST

- Criminal Prosecutions
- Civil Settlements
- Corrective Action Plans