Complying with the New Department of Health and Human Services (HHS) Regulations on Financial Conflict of Interest

December, 2011
What HHS Will Require After August 2012

- **ALL** financial interests of all key investigators on HHS-funded projects must be disclosed and re-evaluated annually or within 30 days of a change.

- Significant financial interests must be reviewed in relation to **ALL** institutional responsibilities (not just research).

- **U-M, not the PI**, will be responsible for determining relatedness to proposed research and managing significant financial interests before spending on HHS awards can start.

- Public disclosure of financial conflicts of interest (FCOI) and management plans

**DEADLINE FOR COMPLIANT SYSTEM: AUGUST 24, 2012**
What’s at risk

- If we do not comply, unable to submit proposals and accept awards
- Research expenditures on HHS-supported projects (FY11)
  - Over $594,000,000
- People paid from HHS funds
  - Total employees: 10,080
    - 1,727 key personnel
    - 851 GSRAs
    - 7,502 research and admin personnel
Impact is Campus-wide

Percentage of Unit Research Sponsored by HHS

<table>
<thead>
<tr>
<th>Department</th>
<th>Percentage</th>
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<tbody>
<tr>
<td>Life Sciences Inst.</td>
<td>88%</td>
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<tr>
<td>Nursing</td>
<td>87%</td>
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<tr>
<td>Ctr Human Growth &amp; Dev</td>
<td>85%</td>
</tr>
<tr>
<td>Pharmacy</td>
<td>82%</td>
</tr>
<tr>
<td>Inst. Social Research</td>
<td>77%</td>
</tr>
<tr>
<td>Medical School</td>
<td>69%</td>
</tr>
<tr>
<td>Public Health</td>
<td>67%</td>
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<tr>
<td>Dentistry</td>
<td>64%</td>
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<tr>
<td>Flint</td>
<td>49%</td>
</tr>
<tr>
<td>Ford School</td>
<td>37%</td>
</tr>
<tr>
<td>LS&amp;A</td>
<td>30%</td>
</tr>
<tr>
<td>Law School</td>
<td>23%</td>
</tr>
<tr>
<td>Social Work</td>
<td>16%</td>
</tr>
<tr>
<td>UM Transportation Res Inst.</td>
<td>10%</td>
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<tr>
<td>Engineering</td>
<td>3%</td>
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</tbody>
</table>
How COI is Handled Today

Disclosure

Identification, Review, & Management

Monitoring & Compliance
How COI is Handled Today

Disclosure

- M-Inform
  - Managed and used by Medical School
  - Also used by Engineering, Pharmacy, Dentistry, Art & Design, LSI, A&UP

- All Other Schools/Colleges/Units, including LSA and SPH, use a variety of local solutions (e.g., spreadsheets, email, paper files).

- PIs currently identify relationship of outside interests to existing projects.

Identification, Review, & Management

Monitoring & Compliance
How COI is Handled Today

Disclosure

Identification, Review, & Management

- Two COI Committees
- Decentralized Tools:
  - Proposal Management (eRPM)
  - Regulatory Management (eRRM)
  - Email
  - Phone
  - FileMaker Pro Database
  - Other

Monitoring & Compliance
How COI is Handled Today

Disclosure

Identification, Review, & Management

Monitoring & Compliance

- Completed Manually
- Not all Schools/Colleges/Units disclose in one place

- New regulations require additional disclosures

- More rigorous timeline for disclosure of outside interests

- Institutions can no longer rely on Investigator disclosure to identify conflicts. Institution is responsible to identify.

- M-Inform currently contains disclosures for:
  - 95-98% of Med School faculty
  - 54% of all parties listed on UM PAFs
  - 18% of all UM personnel paid by HHS funds
Gaps/Risks/Needs

Disclosure

- Existing systems are not comprehensive, do not connect to disclosures and do not “talk” to one another.
  - PIs currently answer COI question on behalf of all collaborators

- All collaborators listed on proposals must have disclosed to submit and award new projects.

- eRPM does not currently collect all parties on NIH proposals and related progress reports

- Increased workload of COI Committee Staff due to required review of all projects with personnel with disclosed outside interests

Identification, Review, & Management

Monitoring & Compliance
Gaps/Risks/Needs

- Establish a public website for UM to publish managed Financial Conflicts of Interest.

- Regulatory reporting requirements necessitate data that is easy to access, organize, and report out with common storage and back-up.

- Data must be fully auditable for all “points of regulation.”

- There is no uniform mechanism to generate reports or audit compliance across the University.
What we need to do

Develop a new business process that includes:

- A comprehensive disclosure system
- Management tools for COI committees: input, review, tracking, and archiving.
- Tracking for research personnel after award
- A means for public reporting
- Training
Note: Med School Information Systems’ current strategic plan does not allow for M-Inform to become the enterprise solution for Disclosures.

Option 1) Expand M-Inform process to temporarily cover all Schools/Colleges with HHS Funding and Human Subjects research

Option 2) Leverage M-Inform model and existing disclosure forms on new ITS platform

Option 3) M-Inform becomes campus-wide solution for Disclosures.

Additionally, explore option to enhance HRMS to capture initial disclosure screening
IT Options & Recommendations

Identification, Review, & Management

Disclosure

Monitoring & Compliance

All Options Must Include:

- Enhance eResearch Proposal Management
  - Capture additional personnel through project life-cycle
  - Interface with disclosure and training systems

- Enhance eResearch Animal Management
  - Capture potential COIs on animal research studies

- Create a central information management system for COI Committees and Staff and Institutional Officials to collect, store, manage, and report on data
IT Options & Recommendations

Disclosure

Identification, Review, & Management

Monitoring & Compliance

All Options Must Include:

- Provide a UM website to publish SFI/FCOI information in alignment with new regulations

- Provide mechanism for federally required reports and institutional reporting needs

- Provide tools for monitoring and non-compliance investigation and remediation
Proposed Implementation Plan

- **Timeline**
  - **November 2011 – August 2012**
    - MSIS supports M-Inform for interim period
    - ITS builds enhancements to existing eResearch systems & develops new COI Management application & new Public Reporting website
  - **August 2012 – February 2013**
    - Transition M-Inform functionality from MSIS to ITS
    - ITS responsible for maintenance, support, and enhancements
  - **After February 2013**
    - ITS provides on-going maintenance, support, and enhancements

- **Risks & Benefits**
  - Benefit: MSIS mitigates risk of change related to new disclosure for initial implementation.
  - Risk: MSIS may not be staffed appropriately for Help Desk calls from all of campus
Project Development Team

- OVPR: Judy Nowack, Chair; Lois Brako, Co-Chair
- COI committees:
  - OVPR COI: James Ashton-Miller, Lynn Cook
  - MEDCOI: Ray Hutchinson, Pat Ward, June Insco
- DRDA: Marvin Parnes, Elaine Brock, Amanda Coulter
- ITS/MSIS: C. Handyside, D. Mulder, M. Hill, J. Roane
- PROVOST: Jeff Frumkin, Stephanie Riegle
- OGC: Maya Kobersy, Fiona Linn
- OTT: Robin Rasor
- PROCUREMENT: Colin Anderson, Elizabeth Spranger