INSTITUTIONAL RESEARCH AND INSTITUTIONAL REVIEW BOARDS:
A PARTNERSHIP IN RESPONSIBLE RESEARCH

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OK, TODAY'S PRESENTATION…

- A discussion of the duties/responsibilities of Offices of Institutional Research (OIR) and Institutional Review Board Committees (IRB)
- Desired learning outcomes:
  - Understanding some accepted purposes of OIRs and IRBs
  - Understanding data OIR might have oversight of
  - Understanding if OIR data requests are subject to IRB review
  - Understanding the different levels of IRB review when dealing with human subjects
  - Components of an informed consent and when it can be waived
  - Resources available to help researchers determine the IRB level of review of their projects

WHAT ARE THE PURPOSES OF INSTITUTIONAL RESEARCH?

- *"…provides information to support university decision-making through a variety of analytic activities, data-gathering tasks, and research projects. OIR serves as the clearinghouse for most statistical information…"* Yale University, 2015
- *"…contributing to the development of policies and practices that comport with Pomona's commitment to the effective and ethical stewardship of data assets."* Pomona College, 2015
- *"…decision support: a set of activities that provide support for institutional planning, policy formation, and decision making…"* Saupe (1990) as cited in *The Handbook of Institutional Research*
- OK, as IR professionals, we have a certain amount of managerial responsibility related to institutional data

WHAT ARE PURPOSES OF THE INSTITUTIONAL REVIEW BOARD?

- *"…an IRB is a committee that performs ethical review of proposed research."* U.S. Department of Health and Human Services, 2015
- *"…an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects."* U.S. Food and Drug Administration, 2015
- *"…the primary mission of the American University IRB is to facilitate those objectives by reviewing, approving, modifying, or disapproving research protocols submitted by AU researchers."* American University, 2015
- OK, IRBs possess a responsibility to protect/safeguard human subjects and institutional research protocols related to scholarly/research activities

TYPES OF DATA OIRs PROVIDE…

- Student information systems (Banner, PeopleSoft, etc.…)
- Student level surveys (NSSE, CIRP, Noel Levitz, etc.…)
- IPEDS
- Faculty/Staff surveys (FSSE, UT's Survey of Organizational Excellence, etc…)
- THECB
- College Choice Surveys (Petersons, US News & World Report, etc…)

- *Which data do we have oversight over? Most likely will fall under exempt review*
- The other sources are public access databases/sources; still might require IRB approval

HOW DID TARLETON IMPLEMENT CONTROLS TO INSURE REQUESTS FOR DATA ARE FOLLOWING PROPER PROTOCOLS?

- Online data request forms utilize Qualtrics online survey tool
- Asks requestor if data will be used for scholarly purposes….if yes, please provide IRB approval number (data cannot be collected until IRB approval/waiver received!)
- Office of Institutional Research/Effectiveness has made a good faith effort to determine if data is being used for scholarly/research activities and appropriate review has taken place
- Our online data request also assists in tracking requests (performance metrics) and ensuring requestors know what they are asking (we include a link to an online glossary of data terms)

INSTITUTIONAL REVIEW BOARDS RELATED ACTIVITIES

- Review research protocols (design, sampling, data collection/analysis, presentation of findings, etc.)
- Data to be used in conference presentations
- Ensure that if human subjects are involved, they are not put in harms way
- Proper notifications to research participants of their rights
- Governed by CFRs...Code of Federal Regulations…specifically Title 45, Public Welfare Department of Health and Human Services, Part 46 Protection of Human Subjects

LEVEL OF IRB REVIEW INVOLVING HUMAN SUBJECTS PROTECTIONS

- First, is the activity *research* that involves human subjects?
- Let's check our handy-dandy U.S. Department of Health & Human Services Decision Charts
- Let's look at Chart 1 as a starting point for further review
- Will the activity contribute to generalizable knowledge? No? Not research.
- Yes, will the activity involve obtaining data from living persons? Yes? It is research!
- Does it involve intervention and interaction with the persons? Yes? It is research involving human subjects!

LEVELS OF IRB REVIEW INVOLVING HUMAN SUBJECTS PROTECTIONS

- Exempt: Charts 2-7
  - Title 45, Part 46.101(b)
  - Research conducted in established educational settings, 45 CRF 46.101 (b)(1)
  - Research involving the use of educational tests, survey procedures, interviews, 45 CRF 46.101(b)(2) or (b)(3)
  - Research involving the use of existing data, documents, records, 45 CRF 46.101 (b)(4)
  - Does not require IRB approval, but decision tree should be referenced in making this determination

LEVELS OF IRB REVIEW INVOLVING HUMAN SUBJECTS PROTECTIONS

- Exempt: Charts 2-7
- Expedited: Charts 8 & 9
  - Has the research been previously approved by IRB? 45 CFR 46.109(d)
  - Does the research present no more than minimal risk to human subjects? 45 CRF 46.110(b)(1)
  - Is the research classified, or not eligible for expedited review? No!
  - Could identification of subjects put them at risk of criminal/civil liability? No!
  - Then can be approved without full IRB committee review

LEVELS OF IRB REVIEW INVOLVING HUMAN SUBJECTS PROTECTIONS

- Exempt: Charts 2-7
- Expedited: Charts 8 & 9
- Full committee review
  - All research involving prisoners, some research involving children, 45 CFR 46.101(i)
  - Research not conducted in commonly accepted educational settings, research not previously reviewed, research that is not a continuing review, research that presents more than a minimal risk to subjects, and classified research

U.S Department of Health and Human Services, 2015

COMPONENTS OF AN INFORMED CONSENT

- Participation is voluntary; and if they choose to participate, they may cease at any time
- Will they be compensated for participating?
- How will the findings be used?
- Will the responses be kept confidential?
- How will the data be secured? who, where, how!!!
- Who to contact in case of questions…including name, phone number.
- Informed consent not required for activities not deemed research by HHS Decision Trees!!.....and in some instances, when review is expedited…Charts 10 & 11

OK, LET'S CONNECT THE DOTS

- When a faculty, staff, or student requests data, for what are they using it?
- If for administrative purposes, go ahead, no IRB involvement required
- If for scholarly purposes…publications, conference presentations, have they received IRB approval?
- And, depending on what data they are requesting, when does it matter to OIR?
- Is it institutional data? Then yes!
- Is it public access? Then no concerns!
- But remember, IRB should be consulted even when the researcher is using public access data!

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