Working with IRB's

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SSHS 2008 Grantees

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Purpose of this session:

- To provide evaluators for the SSHS grants with an introduction to IRBs
- To provide some strategies that will help make the process easier
- To network with other evaluators for SSHS
- We will not be able to answer your individual questions specific to your grant implementation. Your project officer is the contact for site-related questions.

Network of Support

Introductions of evaluators:

- Name
- Which site(s) you are working with
- Is this your first SSHS grant?

What is an IRB?

- Institutional Review Board (IRB)
- Responsible for protecting the rights and welfare of people involved in research
- Review plans for research involving human subjects
- Regulations set by the Food and Drug Administration and the Office for Human Research Protection (OHRP/NIH)
  - http://www.hhs.gov/ohrp


HOW THE IRB MEMBERS SEE THEMSELVES:
THE BELMONT REPORT
45 CFR 46
APPROVED
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Is It Research?

- Your Federal Project Officer has the final say about whether your evaluation is research.
- Common Rule 45 CFR 46.102(d) defines what research is and is not.
- The webinar provided by the FPOs defined research
- If it is NOT research, you do not need to do an IRB, but will still need to adhere to the consent rules under the Pupil Rights Amendment and FERPA.

Where do I start?

- Start with your district
  - Does your district have its own IRB?
  - Does anyone in the district have experience working with an IRB?
- Check out nearby colleges or universities
- Check out community hospitals
- Go online to find independent IRB

Safe Schools Healthy Students

Federal Wide Assurance

- Both LEA and evaluator need FWA #
- Online training and forms at website below
- IRB will ask for the FWA numbers
- Check to see if you have an FWA# at:

http://www.hhs.gov/ohrp/assurances/assurances_index.html

Criteria for IRB Approval

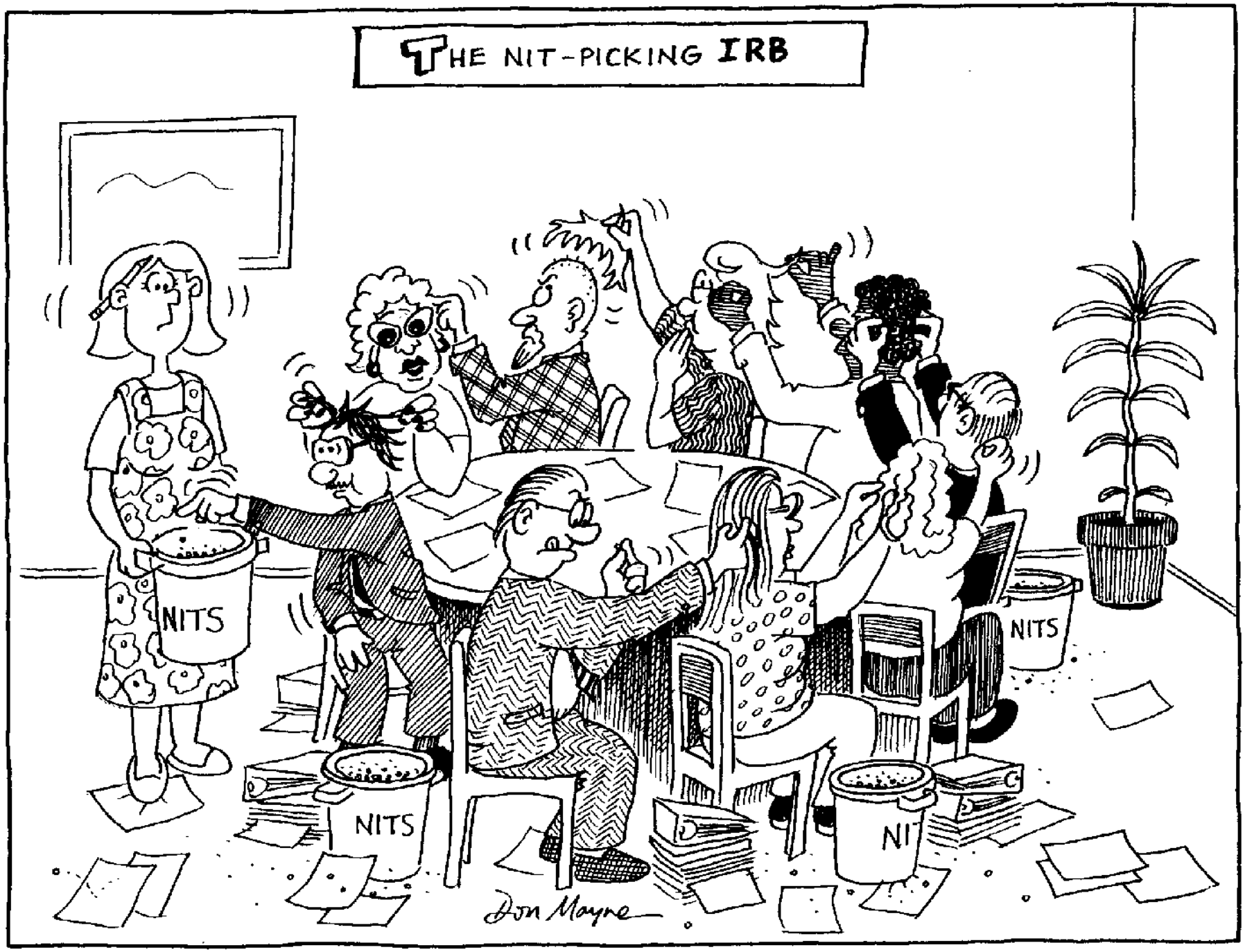
- Risks to subjects minimized
- Risks to subjects reasonable in relation to benefits
- Equitable selection of subjects
- Informed consent
- Provision for monitoring data collection to ensure safety of subjects
- Protection of children

How to Work with IRB

- Ask questions
- Develop relationships
- Read what they have on their website
- Keep it simple

What to Expect

- Protocol should describe proposed research and data collection activities
- Copy of informed consents/assents
- Annual renewals describing work completed and any problems
- IRB approval letters are attached to progress reports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Questions?

Discussion……