# How to do Expedited Review Ethically

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Workshop for IRB Accreditation in Taiwan
November 4-6, 2004

Taipei, Taiwan

# Learning Objectives

- Understand categories of expedited review
- Establish methods for determining what may qualify for expedited review

# Is it a new research request?

- Utilize the expedited category list to confirm the research may qualify as expedited review (See attachment 1)

- Confirm the activity involves minimal risk as defined by regulation

- Fair Process: The Chair may not disapprove an activity initially submitted by an investigator who requests expedited review. The Chair may defer the project for review by the full committee.

# Expedited Review at the time of Continuation Review

- Okay for any activity that initially was reviewed by expedited process

- Okay for activity that was previously approved by the convened IRB, however at the time of continuation review (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects

# Expedited Review at Time of Continuation Review

Also okay for process that was previously approved by the convened IRB, however at the time of continuation review:

- no subjects have been enrolled and no additional risks have been identified; or
- the remaining research activities are limited to data analysis.

# Expedited Review at the Time of Continuation Review

Also okay for continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight (See Expedited Categories Chart) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

# Expedited Review of Modifications Submitted to Existing IRB Approved Studies

- Utilize checklist in IRB to confirm examples of what might qualify for expedited review or full review (See Attachment 2)

- Need to reassess study modification in context of risk/benefit assessment and relevance to informed consent process/document

# Informed Consent for Minimal Risk/Expedited Review Activities

- May be waived or required.
- IRB can determine that consent need not be documented.
- Determinations need to be documented in review materials.

# Resources

- Attachment 1 - Expedited Categories (1998) found on OHRP website

http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

- Attachment 2 – FHCRC Criteria for Deciding if Modification Requires Full or Expedited Review

- New OHRP Decision Making Charts 8 and 9 (2004)

http://www.hhs.gov/ohrp/humansubjects/guidance/decisioncharts.htm