

Department of Veterans Affairs

Perspectives & Expectations

Social, Behavioral & Educational Research

Long Beach, California – February 11, 2005

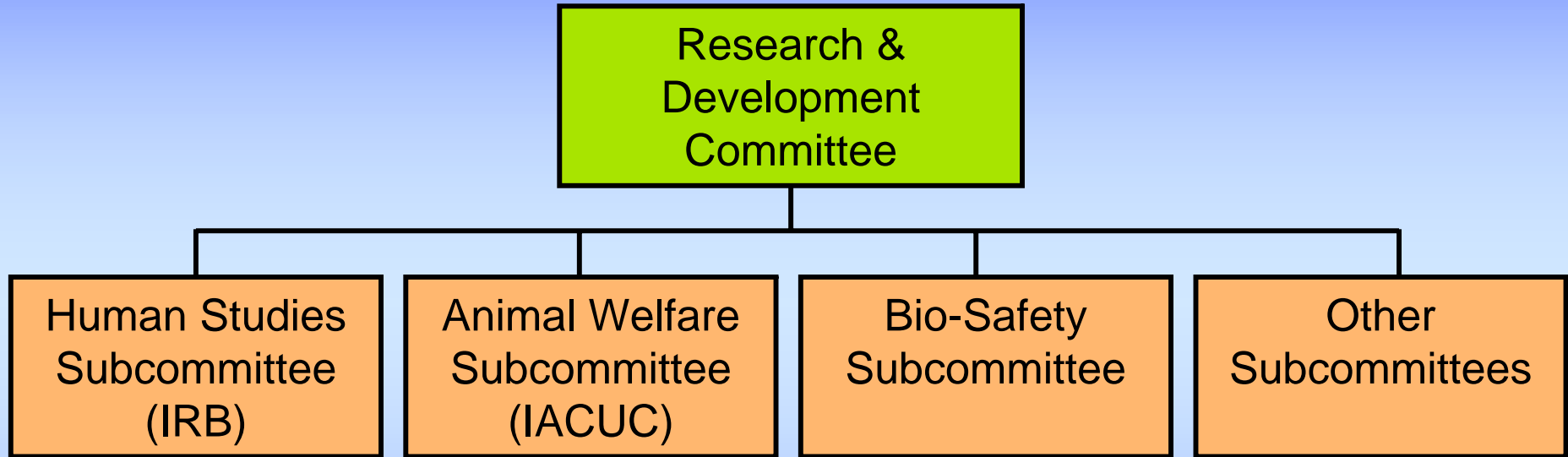
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VA Facility Research Organization



Subcommittees may be:

Independent

or

Affiliated

or

Inter-Institutional

Protections Implemented by the VHA

Change in culture institution/individuals

Senior Executive Seminars

Assurance program in concert with OHRP (FWA)

HRPP Accreditation (NCQA)

Office of Research Oversight

Research Compliance Officers

Non-VHA employees have WOC appointments

Credentialing of all research employees + WOC

Annual education/training for those engaged in research

Matter of Confidentiality

HIPPA can apply to:

Social, behavioral and educational research

Those who are deceased

International research

VHA Electronic Records

Demographic Data

Military History

Financial Status

Medical Records [Coded; Medical/Nursing Notes]

Pharmacy Records [Coded, Drug quantity refills, Prescriber]

Laboratory Data [Hematology/Biochemical/Serology/Microscopic]

Diagnostic Data [Radiology, Nuclear, Cardiac/Pulmonary function]

Medial Utilization Records [Diagnostic codes/Appointment schedules/Inpatient days/Outpatient visits]

Research Involving Large, Existing Data Sets

Social science investigators often use large, existing data sets in their research

Research is exempt from IRB review when:

The information in the data sets is neither identifiable nor sensitive

Data sets are publicly available (i.e., available to the general public, with or without charge) even if they contain sensitive, identifiable information

Research Involving Large, Existing Data Sets Continued

IRB review is required when data sets contain sensitive, identifiable private information about living individuals

IRB must determine whether the information can be used without additional informed consent from the subjects

IRB should examine the conditions of informed consent under which the data were originally obtained to determine:

whether the proposed research is permissible under the original terms of consent, and if not

whether it is permissible to waive the usual informed consent requirements [45 CFR 46.116(d)]

Research Involving Large, Existing Data Sets Continued

IRB may determine that the research can proceed only if the investigator obtains and uses "anonymized" data:

Codes and other identifiers are permanently removed from the data set before data released to the investigator

Removal is such that neither the investigator nor the source maintaining the data set can re-establish subjects' identities.

Maintaining/Using Data Depositories

Anonymizing a data set may greatly diminish the usefulness of the data

An alternative: maintain the data set as a data depository under OHRP guidelines

IRB oversees all elements of depository activity:
setting the conditions for collection, storage,
secure maintenance
sharing of the data with external investigators

Maintaining/Using Data Depositories

IRB determines the parameters for sharing data (which are identifiable within the depository) in a manner such that additional informed consent of subjects is not required.

Ref: OHRP's guidance dated November 1997 & August 1996

Maintaining/Using Data Depositories

These parameters involve formal, written agreements stipulating that the:

Depository will not release any identifiers to the investigator;

Investigator will not attempt to recreate identifiers, identify subjects, or contact subjects;

Investigator will use the data only for the purposes and research specified; and

Investigator will comply with any conditions determined by the depository IRB to be appropriate for the protection of subjects.

Risks to Subjects in Social, Behavioral and Educational Research

Minimal risk to subjects [45 CFR 46.1 02(i)]:

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those encountered in daily life or during the performance of routine physical or psychological examinations or tests

Risks in Social, Behavioral and Educational Research

More often psychological and social than physical

Embarrassment

Loss of Social Status

Emotional Distress

Psychological Trauma

Invasion of Privacy

Loss of Employment

These risks are very subjective and just as real as physical trauma to the subjects who experience them

Risks in Social, Behavioral and Educational Research

Psychological reaction to situations/questions

Powerful emotions such as stress, anxiety, and guilt may be drawn out through participation resulting in:

- Short-term suffering

- and/or

- Long-term suffering

Risks in Social, Behavioral and Educational Research

Breaches of confidentiality

Stigmatizing

Risk of criminal or civil liability

Result in serious/ permanent damage to a subject's:

Financial standing

Employability

Insurability

Reputation

Need to protect both subject's participation and data

Risks in Social, Behavioral and Educational Research

IRBs should review risks seriously

Identify risks – not investigators responsibility

Establish that risks are minimized

Establish that "risks to subjects are reasonable in relation to anticipated benefits"

Establish that subjects will be adequately informed about "any reasonably foreseeable risks or discomforts"

Risks in Social, Behavioral and Educational Research

Minimizing Risk of Harm

Careful thought and planning can reduce risks

Use other procedures that are less risky

Use procedures to decrease the likelihood of harm

Have in place procedures to deal with harm if they occur

Protocol and informed consent document should contain appropriate interventions to:

Contend with release of strong emotions

Prevent breaches of confidentiality

Implement protections before first subject enrolled

Risks in Social, Behavioral and Educational Research

Consent Process

Should explain risk in terms that the subject can relate to - everyday life experiences

Should empower subjects to make their own determination about risk

Should not cause more harm than the research itself