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PROTECTION OF THE RIGHTS AND INTERESTS OF HUMAN SUBJECTS IN THE AREAS OF PROGRAM EVALUATION, SOCIAL EXPERIMENTATION, SOCIAL INDICATORS, SURVEY RESEARCH, SECONDARY ANALYSIS OF RESEARCH DATA, AND STATISTICAL ANALYSIS OF DATA FROM ADMINISTRATIVE RECORDS

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Protection of the Rights and Interests of Human Subjects in the Areas of Program Evaluation, Social Experimentation, Social Indicators, Survey Research, Secondary Analysis of Research Data, and Statistical Analysis of Data From Administrative Records

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An important task facing the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research is the establishment of standards for the burgeoning new areas of program evaluation, social indicators, and related activities (to be collectively designated "program evaluation" in this manuscript unless greater specificity is needed). All of these activities are "research" (usually behavioral research) in the sense of Public Law 93-348; thus they fall within the scope of the commission's assignments. As Institutional Review Boards become increasingly involved in approving such research, they could benefit from guidelines prepared by the NCPHSBBR for this novel set of problems.

While the participants in such research clearly have rights and interests which may be violated, the nature of these threats is somewhat unique. Rarely will risk to physical health be involved. Indeed, the experimental group participants often receive an apparent boon which the control group participants may well feel they equally deserve, so that control group rights may often be the greater problem. The more frequent danger in program evaluation is the risk that the research data will be misused since sensitive information is often collected. Such data may be subpoenaed by prosecutors searching for evidence of crimes, or become a source of malicious gossip or blackmail. Federally funded program evaluations frequently require auditing, verification, and reanalysis. These activities may preclude a promise of complete confidentiality to the respondents and increase the risk that the information they provide will be used improperly. However, if respondents are fully informed of these risks, the quality of the research data may be diminished. From these few examples it is apparent that these areas of social research present a different set of problems from those encountered in medical and laboratory research.

This problem area has already received attention from several national organizations. For instance, the Social Science Research Council's Committee on Social Experimentation considered these issues at length over a four-year period, producing a short chapter on "Human Values and Social Experimentation" (Riecken, Boruch, et al., 1974, pp. 245—269). The contemporaneous National Academy of Science - National Research Council "Committee on Federal Agency Evaluation Research" addressed these issues in its report entitled Protecting Individual Privacy in Evaluation Research (Rivlin, et al., 1975). (One of the present authors participated in both of these committees.) The Privacy Protection Study Commission, established by the Privacy Act of 1974, has extensively considered the problem of maintaining confidentiality of research information (Notice of Hearing and Draft Recommendations: Research and Statistics, January 6, 1977). The Social Science Research Council has a longstanding committee

and special staff devoted to Social Indicators, and is establishing a new committee on program evaluation. The Brookings Panel on Social Experimentation recently published a series of papers on this topic (Rivlin and Timpane, 1975). Special committees with this concern exist in many professional organizations. This recent activity provides the National Commission with a unique opportunity to integrate these diverse findings into a general code protecting the rights of subjects participating in these new areas of research.

Background Comments:

Lake the others who have agreed to write background papers for the Commission, the present writers have volunteered to do so because of strong concerns on this matter. In these areas of research, two widely cherished valued are in potential conflict. The subject's right of privacy may conflict with the researcher's need to gather sensitive information necessary for meaningful program evaluation. We wish to make explicit our manner of resolving this conflict. In agreement with the dominant mood in Washington, we recognize the right to privacy of individuals participating in these areas of research. This paper includes several suggestions which would result in increased protection for the privacy of research participants. However, our greater fear is that Congress and the administration will needlessly preclude important program evaluation and access to research information through ill-considered efforts to protect individual privacy. For example, special procedures of file linkage permit inexpensive and highly relevant program evaluation. Although these procedures require the retrieval of administrative records, they may be employed without jeopardizing the privacy of program participants. (The case for such procedures will be presented in the context of specific recommendations.) We urge that special caution be exercised to avoid creating rules that unnecessarily restrict these procedures.

Before providing our recommendations we wish to set the scope of this report by defining some of the major terms that will be employed:

Program Evaluation: Assembly of evidence bearing on the effectiveness and side effects of ameliorative programs, social innovations, etc. These programs have usually been initiated by governments.

Social Indicators: Statistical summaries, often in time-series form, bearing on the well-being of the nation or smaller social units. Social indicators may be viewed in contrast to more common economic indicators. Many social indicators are generated from statistical summaries of administrative records. Others, such as indicators based on the Census, are produced by institutionalized survey procedures. Increasing attention is being given to "subjective" social indicators, in which representative samples of the public report on their "happiness" or satisfaction with various aspects of their lives in public opinion surveys.

Social Experimentation: This will be narrowly defined, as it was in the SSRC volume (Riecken, et al., 1974), to refer to an experimental form of policy research and/or program evaluation, experiments carried out in social (as opposed to laboratory) settings evaluating governmental or other social interventions. (This definition excludes experiments in public settings to test social science theories, an important form of social experimentation that the National Commission is attending to through other background papers.)

Respondents: Participants, interviewees, anthropological "informants," the persons whose responses are recorded, the "subjects" of research, etc. Many social scientists prefer the terms "respondent" or "participant" to the term "subject," since the term "subject" has been associated with an exploitative attitude neglecting the rights and interests of the research cooperator.

Statistical Data: The Privacy Act of 1974 uses this term to refer to information collected originally for research rather than administrative purposes. This usage will be avoided here in favor of research data-

Statistical Analysis, Statistical Product, and Statistic: These terms refer to summary indices no longer containing individually identifiable data that may be based on either research data or administrative records. Means, standard deviations, correlation coefficients, t ratios, F ratios, probability levels, etc., exemplify statistical products. Frequency counts and percentages usually qualify as statistical products precluding individual identification, but not if the identities of individuals can be deduced through association of research data with public records.

Administrative Records: Refer to data collected originally for bureaucratic purposes rather than research purposes. School grades, achievement test scores, earnings subject to withholding tax, unemployment insurance payments, days hospitalized, incidence of serum hepatitis, auto insurance claims, all represent administrative records that can be of great value in program evaluation if they are used in ways safeguarding individual privacy.

Record, File, Data Bank: These are terms used for collections of data on individuals, either administrative or research data.

Reanalysis and Data Analysis by Outsiders: Refer to the use of research data or administrative records for purposes other than were originally understood by the respondents, and by persons other than the regular custodians of the data.

File Merging: Refers to combining individual data from two files containing data about the same respondents, so that one or both of the files, or a third file, ends up containing individually identified data originating in another file. Unified data banks involve file merging.

File Linkage: Refers to linking data from two or more files so that statistical products are generated involving data from both files. File merging is the most complete form of file linkage, and where permissible, the most statistically efficient. It is important to note, however, that there are restricted forms of file linkage that do not involve file merger, and where no individually identified data are transferred from any file to any other (e.g., the "mutually insulated" file linkage to be discussed below).

Recommendations:

1. Review and Review Boards

Let us start with a concrete recommendation: