InterPARES 2

Compliance with Requirements for the Protection of Human Research Subjects and Data

9/17/02

Introduction

According to the InterPARES Organizational Policy document, individual InterPARES researchers are responsible for ensuring that they comply with all procedures and requirements in their jurisdiction and institution for the protection of human research subjects and data. In most cases, they will do this by submitting required documentation about their research and data gathering protocols through the appropriate Institutional Review Board (IRB) or research ethics committee. No case study or other data collection activity may commence until each participating researcher involved has complied with applicable legal or institutional requirements.

This document outlines the documentation that must be prepared for each research undertaking (e.g., task force case studies) in order to assist participating researchers in complying with their specific requirements for the protection of human research subjects and data. Please note that the different legal jurisdictions and academic institutions to which InterPARES’ researchers belong may have differing procedures and requirements for reviewing issues relating to research ethics and the protection of human research subjects and sensitive records and data used or collected during the research process. Individual institutions and disciplines may also be more or less strict and detailed about their requirements. The preparation of research documentation according to the following guidelines by the group responsible for the research activity, however, will greatly assist individual researchers in obtaining the necessary institutional clearances.

What kinds of research and data collection activities might require review?

Legal requirements, institutional ethics committees and review boards may be concerned only with research that involves experimenting on humans, or they may be concerned with any research that involves interviewing or otherwise interacting with human subjects. Similarly, some may be concerned about existing records, record-keeping systems, and data that are consulted, while others may only be concerned with the collection, privacy, and eventual disposition of new data that are collected.

For example, in the United States, virtually all federally funded research with human subjects is governed by federal regulations patterned on those of the Department of Health and Human Services, found at Title 45 Code of Federal Regulations Part 46 (45 CFR 46), although other government agencies’ may also have pertinent regulations. Research is defined in 45 CFR 46 as, "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable
Human subjects are defined by the regulations as "living individual(s) about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." Institutional Review Boards are required by federal regulations to review all University affiliated human subject research, regardless of funding, to ensure the rights, welfare, and protection of all subjects. Federal regulations also stipulate that "research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects" may qualify as exempt from review. However, researchers will usually still need to apply for review in order to receive a certification that their research is exempt.1

Pilot studies and feasibility studies, even if they include only one subject, may require the same IRB consideration as a project that requests the participation of 100 or more subjects.

What documentation should be prepared for each activity?

At a minimum, for each research activity undertaken in InterPARES 2 that involves interaction with human subjects and/or data collection, four primary documents should be created:

1) A lay language summary (i.e., a brief description that can be readily understood by someone who is not an expert in the area being addressed by the research) of the research activity. This document should be no longer than one page;
2) An informed consent/assent form.2
3) A complete research protocol detailing each step of data collection and steps that will be taken to protect the privacy of human subjects or individuals mentioned in the data, as well as to protect the data itself; and a discussion of the final disposition of the data after the end of the research project. The information you provide must include sufficient detail to facilitate an effective review by all members of an IRB. This should, at a minimum, cover the following details:
   a. Background
   b. Objectives of the research
   c. Significance
   d. Thorough description of how human subjects will participate in the research
   e. Eligibility requirements for subjects, including how they were selected
   f. Design/methodology
   g. Analysis of the collected data
   h. References

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1 For further information, see the UCLA Investigator’s Manual, available at: http://www.oprs.ucla.edu/human/TOC.htm
2 Sample forms for different categories of human subjects are available in Chapter 4 of the UCLA Investigator’s Manual, ibid.
4) Final copies of any research instruments (such as surveys and questionnaires) to be used, together with copies of any advertisements, flyers, internet postings (with the internet address), etc., for subject recruitment. If any of these documents are submitted in draft to an institutional IRB, the IRB will likely require that a final copy be submitted before the research can proceed.

5) If the research is to be conducted at sites other than those reviewing the research protocol, it may also be necessary to obtain any necessary letters of compliance or IRB approvals from the other facilities or agencies proposed as a research site or source of potential subjects.

Within individual institutions, researchers may be asked to provide at least two other documents:

1) A copy of the relevant grant proposal under which the research is funded (the financial sections are not generally required);
2) A completed application to involve human subjects in research