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TECHNICAL REPORT

Developing and Testing Informed-Consent Methods in a Study of the Elderly in Mexico

Emma Aguila, Maria Dolores Cervera, Homero Martinez, Beverly A. Weidmer

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Preface

As part of a noncontributory pension program for people age 70 and older in the state of Yucatan, Mexico, the government of the state of Yucatan and the RAND Corporation collaborated on an evaluation component to assess the program's impact on the health and well-being of program beneficiaries. (For more information on the evaluation study, see Aguila, Kapteyn, et al., forthcoming; and Aguila, Borges, et al., forthcoming). The evaluation component included a survey of a sample of adults age 70 and older. The survey collected detailed information on a range of topics, such as social and economic characteristics, as well as biomarkers and anthropometric measurements.

Participation in the survey was completely voluntary and required documentation of informed consent from participants. Given the high levels of illiteracy among the elderly respondents, developing an informed-consent procedure that, above all, participants could understand and accept and that also met the other requirements that sponsoring institutions and governments need proved to be a considerable challenge.

This report documents our approach for obtaining informed consent among this unique respondent population. We review previous procedures for obtaining informed consent in similar populations and our approach to adapting procedures to this particular population and describe the adjustments we made to comply both with U.S. and Mexican norms related to protection of human subjects participating in research. The process also included educating and familiarizing the local data-collection team about human-subject protection issues, the importance of adhering to the informed-consent protocol, and the process for educating study respondents on the purpose of the informed-consent documents and procedures. This research should be of interest to researchers seeking to gain informed consent from respondents in similar projects, particularly among populations with low levels of literacy.

This research was conducted by the RAND Center for Latin American Social Policy (CLASP) and made possible with funds from the government of the state of Yucatan; the National Institute on Aging (NIA) (through grants R01AG035008, P01AG022481, and R21AG033312); the RAND Center for the Study of Aging (with grant P30AG012815 from NIA); RAND Labor and Population; and CLASP.

RAND Labor and Population has built an international reputation for conducting objective, high-quality, empirical research to support and improve policies and organizations around the world. Its work focuses on children and families, demographic behavior, education and training, labor markets, social-welfare policy, immigration, international development, financial decisionmaking, and issues related to aging and retirement, with a common aim of understanding how policy and social and economic forces affect individual decisionmaking and human well-being.

CLASP, part of RAND Labor and Population, unites a distinguished collective of international researchers invested in addressing the most-pressing challenges and finding unique solutions that can contribute to a path of sustainable development for Latin Americans at home, in the United States, and around the world.

For questions and comments regarding CLASP, please contact Lucrecia Santibanez, director, CLASP, at 310-393-0411 x6310, or by email at Lucrecia_Santibanez@rand.org.

For questions and comments regarding this report, please contact the project leader, Emma Aguila, at 310-393-0411 x6682; by email at Emma_Aguila@rand.org; or at the University of Southern California, Sol Price School of Public Policy, 213-821-0702, or eaguilav@usc.edu.

Materials related to this survey project, including the list of appendix materials and the list of technical reports and research papers, are available at http://www.rand.org/labor/centers/clasp/research/projects/social-security-program.html.

Contents

Preface iii
Figures and Table vii
Summary ix
Acknowledgments xiii
Abbreviations xv

CHAPTER ONE
Introduction 1

CHAPTER TWO
Norms and Regulations for Human-Subject Research in Mexico and the United States 5
Primary Human-Subject Concerns 5
Principles of Informed Consent 5
Review by the RAND Human Subjects Protection Committee 7
Informed-Consent Requirements in Mexico: Norms and Limitations 9
Informed-Consent Requirements and Procedures in Yucatan 12

CHAPTER THREE
Developing and Testing Informed-Consent Methods Among the Elderly in Yucatan 13
Development of Informed-Consent Forms 13
Language 14
Pilot Test 14
Training of Field Staff 14
Informed-Consent Field-Test Results 15
Revised Forms 16
Overview of Actual Informed-Consent Procedures 17

CHAPTER FOUR
Conclusion 19

Appendixes 21

References 23

Figures and Table

Figures

1.1. Mexico and the State of Yucatan..... 1
3.1. Overview of the Informed-Consent Process..... 18

Table

1.1. Data-Collection Components..... 2

Summary

In an effort to improve the quality of life for older adults, the government of the state of Yucatan, Mexico, and the RAND Corporation collaborated to design, implement, and evaluate a noncontributory pension program for people age 70 and older. This program included an evaluation component to test its impact. The impact-evaluation component included a survey of randomly selected people age 70 and older and members of their households. These surveys collected data on demographic characteristics and detailed information on individual and household income and assets, expenditures, employment history, self-reported health status and physical functioning, social networks, and physical activity, among other topics.

Ethical and legal considerations require that people providing such information be able to provide informed consent when doing so. Obtaining consent from older people and from people with low levels of literacy or limited language fluency can pose challenges. For field trials, we sought to develop an informed-consent procedure that was culturally sensitive and complied with Mexican norms and standards, as well as the ethical standards for conducting research with human subjects set by the U.S. government and followed by the RAND Human Subjects Protection Committee (HSPC).

This report documents the process we developed to obtain informed consent from those choosing to participate in our research. We provide background on the development of norms and regulations for conducting research involving human subjects in the United States and Mexico. We review how we developed and tested a culturally sensitive approach for collecting informed consent among the elderly in Yucatan, including our testing of methods and subsequent adaptations. Finally, we review the implications of our findings for similar future research efforts.

U.S. and Mexican Norms and Regulations for Human-Subject Research

The process of obtaining informed consent has three key features. These are (1) disclosure to potential participants of information needed to make an informed decision on whether to participate, (2) steps to ensure that potential participants understand this information, and (3) ensuring that the decision to participate is completely voluntary. In order to protect the rights of research subjects and ensure the confidentiality of the information obtained from individuals, the informed-consent process must be followed throughout the life of a research project, from the time a potential participant is first approached until the study is completed and thereafter. The informed-consent process should ensure that all critical information about a study is completely disclosed to prospective participants before they consent to participa-

tion and that prospective participants or their legally authorized representatives (e.g., parents of minors unable to provide informed consent) understand what participation in the study entails. Each prospective participant should be given an opportunity to ask questions and receive appropriate answers before deciding whether he or she wants to take part in the research study. Each should be able to freely decide whether to participate in the research study, to stop participating at any time and for any reason and without any effect on any benefits or services he or she may be receiving or entitled to receive. In addition, each research subject should be asked to provide informed consent anew before the start of any new data-collection activity conducted as part of the same study.

Any U.S. organization conducting federally funded research must have an institutional review board (IRB) to ensure compliance with federal regulations, including those for protecting human subjects. At RAND, the HSPC performs the duties of the IRB, reviewing research involving human research subjects. Within the organization, RAND's president and chief executive officer (CEO) acts as the institutional official as defined by the federal regulations governing human-subject research, and the HSPC reports to RAND's senior vice president for research and analysis. The membership of the HSPC is made up of scientists and nonscientists who complete human-subject protection training before participating as voting members. The HSPC Membership and Advisory Committee meets annually or more often as needed to ensure that the collective expertise on the HSPC is well aligned with RAND's current and anticipated human-subject research agenda, as well as with regulatory requirements.

Federal regulations and the HSPC require that, for a participant to be capable of providing informed consent, he or she must receive, among other things

- a description of the research study, its purpose, possible risks and benefits, expected duration, and what participation entails
- name and contact information of those to whom questions may be directed
- assurance that participation is completely voluntary and that any decision to participate or not will not affect any benefits to which he or she is entitled.

Mexico has its own procedures for determining informed consent. Institutions that conduct research involving human subjects are mandated by law to establish a local research ethics committee (LREC), equivalent to the U.S. institutional review boards. LRECs are responsible for reviewing and applying research ethics when evaluating all types of research, with such reviews typically reserved for projects that include the direct participation of human subjects.

In practice, however, social science and biomedical research conducted in Mexico in recent years has had little regulation, and there are many institutions that carry out research that have no LREC. It is not uncommon for research projects to fail to follow an informed-consent protocol. When followed, informed-consent processes in Mexico focus more on the completion of the consent form as a legal requirement than on the process of acquiring meaningful informed consent. These situations can make binational research difficult, given U.S. requirements for IRB approval.

Obtaining informed consent among older people who may have impaired decisionmaking abilities and sometimes low levels of education and literacy involves particular challenges. Researchers must take care to ensure that the nature of the research project is explained in such a way that potential participants fully understand what they are being asked to do and have the option to consult with family members before providing informed consent or starting their

involvement in the research project. As has been shown by previous anthropological studies in Yucatan, obtaining consent for such studies is but one part of the process of introducing oneself to the community and building relationships and rapport, and gathering information is important to gain trust and be able to conduct the study.

Developing and Testing Informed-Consent Processes in Yucatan

Initial consent forms developed for the study included those for participation, those to allow access to respondents' administrative and health records, and those for the collection of anthropometric measures and biomarkers. To develop these forms, we reviewed consent forms that had been used and approved by the HSPC in similar projects. We also reviewed those for similar projects conducted in Mexico but found that these used oral informed-consent procedures. Our review of the informed-consent documents and procedures used in similar studies in the United States involved a written informed-consent process. We therefore assumed that a process with only an oral consent process was unlikely to be approved by the HSPC.

We developed informed-consent forms in English, had the HSPC review and approve them, and then translated them into Spanish and Mayan, the languages in which we were to conduct interviews. We also trained field staff in the process for obtaining informed consent prior to a subject's participation in the project.

We conducted two separate field tests using these forms in two different Yucatan locations. One test was among 200 Spanish-speaking respondents, and another was among 80 Mayan-speaking respondents. During the field tests, interviewers were to review exactly what a respondent was being asked to do, answer any questions or concerns the respondent had and, if the respondent agreed to participate, ask him or her to sign two different forms indicating consent to participate in the survey and granting access to administrative and health records.

We started using informed-consent methods that are standard in the United States, but many respondents were intimidated by the length and complexity of the consent forms. They were extremely nervous about signing the forms, even after having read the forms or having someone read the forms to them. Many respondents, particularly those with low levels of schooling, had difficulty understanding the consent forms, while many others were unable to read them because of illiteracy or poor vision. The lack of knowledge and understanding of consent forms caused many respondents or their family members to worry that they could be taken advantage of. In some cases, respondents refused to sign the consent forms even though they otherwise indicated they were willing to participate in the study. The main concern about signing a form that was uncommon for them was that it could compromise or release rights over property or possessions.

We subsequently revised the consent forms to shorten them and make them easier to understand while maintaining all elements of informed consent required by the HSPC. To revise the forms and procedures, we collaborated with local researchers experienced in conducting primary data collection in Yucatan. We also devised a procedure by which interviewers signed the consent forms themselves to indicate that they had witnessed the informed consent of the participating subject, rather than asking participants to sign consent forms.

Conclusions and Implications

The elderly represent a growing and important vulnerable population that presents special challenges for developing informed-consent processes. Such processes should not overburden respondents or discourage them from participating in research. The informed-consent procedures we developed for the evaluation of the Yucatan pension program provide a useful model for obtaining meaningful informed consent that promotes understanding of participation requirements, accounts for cultural norms and constraints, and addresses language and literacy challenges.

Acknowledgments

This report has benefited greatly from the feedback, stories, and participation of every one of the older adults who voluntarily agreed to partake in the evaluation study, which would not have been possible without their cooperation. Their contributions could help improve the future of the next generation of older adults.

We also wish to thank the RAND Center for Latin American Social Policy (CLASP) and the government of the state of Yucatan for their collaboration and efforts in completing this study. We especially thank Ivonne Ortega Pacheco, former governor of the state of Yucatan, for her ongoing support for the implementation of this project.

We renew our thanks to the field and administrative staff in Yucatan and the RAND research team for their dedication and support throughout each stage of the project. A complex project of this nature requires a team with diverse expertise and a commitment to high-quality scientific policy evaluation. The collaboration between RAND and the government of Yucatan contributed to the effective design, development, and implementation of the pension program and its evaluation, an effort that would not have been possible without this collaborative effort. Specially, we want to thank the RAND Human Subjects Protection Committee for its excellent work reviewing all consent forms and information materials for this project.

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Abbreviations

CAPI	computer-assisted personal interview
CEO	chief executive officer
CLASP	RAND Center for Latin American Social Policy
CONEVAL	Consejo Nacional de Evaluación de la Política de Desarrollo Social, or Mexican National Council for Evaluation of Social Development Policies
DSP	data-safeguarding plan
HHS	U.S. Department of Health and Human Services
HRS	Health and Retirement Study
HSPC	RAND Human Subjects Protection Committee
INEGI	Instituto Nacional de Estadística y Geografía, or National Institute for Statistics and Geography
IRB	institutional review board
LREC	local research ethics committee
PI	principal investigator

CHAPTER ONE

Introduction

In an effort to improve the quality of life for older adults, the government of the state of Yucatan, Mexico, and the RAND Corporation collaborated to design, implement, and evaluate a noncontributory pension program for people age 70 and older (Aguila, Kapteyn, et al., forthcoming; and Aguila, Borges, et al., forthcoming). Yucatan, in southeastern Mexico (Figure 1.1), is somewhat similar to the rest of Mexico in two ways of interest. First, statistics from the National Institute for Statistics and Geography (Instituto Nacional de Estadística y Geografía, or INEGI), indicate that, in 2010, Yucatan had an older population (at least 60 years of age) similar in proportion, 10.1 percent, to that nationwide, 9.1 percent. Second, statistics from the Mexican National Council for Evaluation of Social Development Policies (Consejo Nacional de Evaluación de la Política de Desarrollo Social, or CONEVAL) indicate that, in 2010, 47.9 percent of the population of Yucatan lived in poverty, compared with 46.2 percent for all Mexico.

The evaluation of this randomized control trial sought to determine the effects that a cash transfer–based pension had on the health and well-being of elderly recipients by collecting detailed individual and household information through an in-person, computer-assisted personal interview (CAPI). The CAPI survey was fielded several times: before the announcement and implementation of the social security program (December 2008), again six months after (June 2009) individuals assigned to the treatment group received their first social security payment, and then after that at approximately 12-month intervals (June 2010).

Specific information collected in the survey included demographic characteristics of the primary respondent, as well as other members of the household, and detailed information

Figure 1.1
Mexico and the State of Yucatan

RAND *TR1288/8-1.1*

on income and assets, employment history, expenditures on nondurable goods, family transfers, self-reported health status and physical functioning, health care access and use, medication use, social networks, social support and care-giving responsibilities, diet and food insecurity, and physical activity. The surveys were conducted in Spanish and Mayan, both used in Yucatan. In addition to the survey, interviewers also sought to collect various health measurements and biomarkers, as well as access to medical records and administrative records from government programs in which primary respondents might have participated. Table 1.1 outlines measures for the evaluation and the sources for them. Detailed information about the survey and the collection dates of self-reported and biomarker data in the field can be found in Aguila, Kapteyn, et al. (forthcoming) and Aguila, Borges, et al. (forthcoming).

As indicated above, interviewers had three sources of information. Ideally, interviewers gathered nearly all information from the primary respondent, a household adult age 70 or older. If the primary respondent could not or preferred not to complete the interview, then interviewers sought information on the eligible adult from a proxy respondent, who might also

Table 1.1
Data-Collection Components

Data-Collection Component	Primary Respondent (adult age 70 or older)	Secondary Informant (provides household-level information)	Proxy Respondent (interviewed in the event that the primary adult cannot or prefers not to complete interview)
In-person, individual-level interview	x		x
In-person, household-level interview	x	x	x
Blood pressure	x		
Pulmonary capacity	x		
Grip strength	x		
Balance test	x		
Timed walk	x		
Height	x		
Weight	x		
Waist circumference	x		
Height to the knee	x		
Arm length	x		
Hemoglobin test (to test for anemia)	x		
Collection of dry blood spots (to test for levels of blood glucose and other indicators of well-being)	x		
Consent to access school records for children age 5 or older		x	

provide the household-level information collected as part of the interview. Interviewers were also allowed to seek household-level information from a secondary informant if this person was deemed to be the most knowledgeable respondent for this type of information. Lastly, interviewers had to obtain consent to access school records from the parent or legal guardian of any children age 5 or older living in the household.

Ethical and legal considerations require that people participating in research studies provide informed consent before doing so (Cámara de Diputados del Congreso de la Unión, 1984; 45 CFR Part 46; World Medical Association, 1964). Obtaining informed consent from older people or from people with low levels of literacy or limited language fluency, can pose numerous challenges. For this study, we sought to develop an informed-consent process that, in addition to meeting the paramount goal of protecting participants' interests, was culturally sensitive, complied with Mexican norms and standards for conducting research with human subjects, and complied with ethical standards for conducting research with human subjects set by the U.S. government and followed by the RAND Human Subjects Protection Committee (HSPC).

This report documents our efforts to develop culturally appropriate informed-consent processes for our research study. In the next chapter, we review the development of norms and regulations for conducting research involving human subjects in the United States and Mexico. In the third chapter, we review how we developed and tested a culturally sensitive approach for collecting informed consent among the elderly in Yucatan, including our testing of methods and subsequent adaptations. In the fourth and concluding chapter, we review the implications of our findings for similar future research efforts.

CHAPTER TWO

Norms and Regulations for Human-Subject Research in Mexico and the United States

Our research, as noted, involved a collaboration between the government of Yucatan and the RAND Corporation. In addition to ensuring that those participating in the study had adequate protection and provided meaningful informed consent, we had to satisfy both U.S. and Mexican norms and regulations.

In this chapter, we review how we sought to ensure that participants' consent was informed, as well as how we sought to address relevant norms and regulations and the issues raised during the process of developing the informed-consent protocols for the evaluation research. We begin by providing an overview of the primary concerns for protecting human subjects involved in research, then discuss the principles of informed consent. We also review the relevant protocols both in RAND research on human subjects and in Mexico and Yucatan specifically.

Primary Human-Subject Concerns

There are three primary concerns regarding the screening, sampling, and interviewing of human respondents. First, such research must respect the respondent's needs during the interview process. This includes the respondent's need for information, privacy, and control over the interviewing process. Second, such research must safeguard the confidentiality of respondent information. Third, and similarly, such research must safeguard the confidentiality of information obtained from respondents about other household members.

Principles of Informed Consent

Protecting respondents requires that a researcher obtain a respondent's informed consent for participating in a research study, or, if a respondent is a minor or otherwise unable to provide consent, the consent of a legally authorized representative. The requirement for obtaining the informed consent of individuals before involving them in research is also prevalent in the Code of Federal Regulations (45 CFR 46.116 and 45 CFR 46.117), applicable to research conducted by organizations based in the United States.

The principles of informed consent require that potential participants be treated as autonomous individuals and that the rights and welfare of people with diminished autonomy be

appropriately protected.[1] Prospective research subjects must be given the opportunity to decide whether they want to participate in a research study (or not), as well as to learn what is expected of their participation and what will happen to them during the study. Prior to deciding on their participation, they should also be given a clear description of risks and benefits (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

The informed-consent process has three key features: (1) disclosure to potential participants of information needed to make an informed decision on whether to participate, (2) steps to ensure that potential participants understand this information, and (3) ensuring that the decision to participate is completely voluntary. Informed consent must be obtained before the research subject begins to participate in the research process and should be legally effective.

The informed-consent process must be followed throughout the life of a research project. It begins when the potential participant is first approached about the study and continues throughout the life of the study, to ensure the adequate protection of the rights of human research subjects and the confidentiality of information (thus protecting the rights of participating individuals who may be exposed to various risks in the event of a breach in confidentiality). Prospective participants should be given an opportunity to ask questions and receive appropriate answers before deciding whether they want to take part in the research study. Every participant should be able to freely decide whether to participate in the research study and to stop participating at any time and for any reason should he or she wish and without any effect on any benefits or services he or she may receive or be entitled to receive. The informed-consent process should also ensure that all critical information about a study is completely disclosed to prospective participants before they consent and that prospective participants or their legally authorized representatives (e.g., parents of minors unable to provide informed consent) understand what participation in the study entails. Individual research subjects should be asked to provide informed consent anew before the start of any new data-collection activity conducted as part of the same study.

The procedures and language used in obtaining informed consent should be appropriate for the target population, written at an appropriate reading level and using language and terms that most members of the target population can understand. For most research studies, potential participants are required to review (or have an interviewer review with them) the content of the informed-consent form that describes the research study and what participation entails. Potential participants also must have an opportunity to ask questions about the study, their participation, and risks and benefits, as well as any aspect that may not be clear to them, and to receive answers to their satisfaction. Only after this requirement has been met may participants provide their informed consent.

Participants should receive a copy of the informed-consent form so that they can refer to it if they have any questions or concerns regarding the study and their rights, as well as whom to contact for clarification or further information. Researchers must understand that a signed consent form does not always indicate adequately informed consent. They also must under-

[1] The Belmont Report, Ethical Principles and Guidelines for the Protection of Human Subjects of Research, defines an autonomous individual as "an individual capable of deliberation about personal goals and of acting under the direction of such deliberation" (National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979).

stand, as noted, that the informed-consent process starts when recruiting participants and extends throughout the duration of the project.

Review by the RAND Human Subjects Protection Committee

U.S. organizations conducting federally funded research must have an institutional review board (IRB) to ensure compliance with federal regulations regarding the protection of human subjects. An IRB must obtain an assurance of compliance for federal-wide use that has been approved by the U.S. Department of Health and Human Services (HHS) under 45 CFR 46.103(a). Each IRB reviews research involving human subjects conducted or supported by HHS and must be registered with HHS. At RAND, the HSPC follows the guidelines established by HHS. In order to obtain from HHS the "Federalwide Assurance for the Protection of Human Subjects," which must be renewed after a three-year period, the HSPC assures compliance with the regulations of 16 federal departments and agencies. The HSPC reviews all RAND research projects, regardless of the source of funding or where research will take place. The HSPC must review and approve all RAND research projects involving human subjects before data collection or acquisition can begin. Principal investigators (PIs) are responsible for submitting their research for HSPC review, for complying with HSPC requirements before recruiting or enrolling human subjects or acquiring data, for reporting on the progress of a research project at least annually, and for immediately reporting any harm to human research subjects or unanticipated events involving risks to participants or others. Likewise, any changes to previously approved documents must be reviewed and approved again by the HSPC.

As required by the HSPC's policies and procedures, prior to the start of data collection for the evaluation of the Yucatan pension program, we submitted the research protocol and all data-collection protocols, procedures, forms, and materials to the HSPC. Both the National Institutes of Health and the government of Yucatan provided funding for our project—and hence necessitated that our work, in addition to protecting the interests of participants, comply with multiple regulations. The data-collection team in Mexico was employed by the state government. However, the RAND team was actively involved in recruiting, training, and overseeing all data-collection and support staff. The RAND team also developed all project materials (including informed-consent documents, data-collection protocols and procedures, and all surveys used as part of the evaluation study). Survey data were transferred to the RAND team throughout the collection period, and the RAND team is responsible for storing, processing, and analyzing all survey data.

All data-collection staff in Mexico were considered to be "agents" of RAND in implementing this research project. The RAND team therefore had to ensure that project-team members and local data-collection staff adhered to required policies and procedures for protecting human research subjects. This include ensuring that participants be fully informed and understand what participation in the study entailed, what they would get for participating in the study, any risks involved, and their rights as research subjects. The RAND team and local data-collection staff also had to undertake appropriate measures for protecting respondents from unnecessary risks or injury during the course of the study and for adequately safeguarding all respondent-provided information at all times.

To facilitate and expedite review, the HSPC appointed a subcommittee composed of members with particular expertise on the research topic to help develop materials and proce-

dures that reflected guidance of the full HSPC in its initial and continuing reviews of the project. The HSPC typically requests full committee review of projects that, like this one, involve difficult human-subject issues or elaborate data-collection procedures. Such review identifies issues that may require special attention by the PI. For these issues, a subcommittee will provide guidance in developing written consent materials that are understandable to participants and meet all the requirements for informed consent. For this study, the HSPC assigned a bilingual (English/Spanish) researcher experienced in conducting field research in Mexico to review the project's submission to the HSPC.

As part of the review process, the HSPC required that we submit for review the research protocol, informed-consent and data-collection forms, and a detailed data-safeguarding plan (DSP). The DSP describes the data that will be collected during the course of the study, how these data are collected and stored, protocols and procedures for storing and safeguarding the data at all times, who will have access to the data, how long the data are kept, and when and how data will be ultimately destroyed. In addition, the DSP must describe who is responsible for safeguarding data, how the project will educate team members on data safeguarding, and how the project ensures that all team members follow data-safeguarding protocols and procedures. The DSP is submitted at the start of the project and updated prior to the start of any new data collection. The HSPC reviews the project's DSP annually to ensure compliance with approved procedures, or more frequently if any issues regarding data safety arise during the course of the study. If needed, the PI is required to modify or adjust the DSP.

Throughout the study, the PI is required to report on any issue that may affect project development or implementation, require any modification to study forms, or account for any contingency encountered by the study (for example, the loss or theft of a computer or a participant's complaint about procedures). The PI is required to submit annual reports as part of the continuing review process until the project is closed and no individual identifiers remain either in electronic or hard-copy form that could be used to link identifiers back to the data.

Overall, the basic elements of informed consent, as determined by U.S. federal regulations and the HSPC, require that the each participant receive the following:

- a description of the research study, including a statement that the study involves research, an explanation of its purpose, expected duration of participation, and a description of what participation entails
- a description of foreseeable risks or discomfort to the subject
- a description of known or foreseeable benefits to the subject or to others from participation in the research (including a description of payments or other types of incentives, if any)
- a disclosure of any alternative procedures for which the subject might be eligible
- a statement describing the confidentiality of information identifying the participant, including the limits of confidentiality and how it will be maintained
- for research involving more than minimal risk, an explanation as to whether any compensation is offered or any medical treatments for injuries the participant incurs and, if so, what they consist of, or where further information may be obtained
- the name and contact information of the person whom participants should contact if they have questions or concerns about the research study or their rights, as well as the name and contact information of whom to contact in the event of a research-related injury

- a statement that participation is voluntary, that deciding or declining to participate will not affect any benefits the subject is entitled to receive or is already receiving, and that the subject may discontinue participation at any time for any reason without penalty.

When appropriate, the IRB may also require one or more of the following to be included in informed-consent documents:

- an explanation of how or why the subject was identified
- a statement regarding potential risks to the subject from participation
- a statement indicating that the subject's participation may be terminated by the investigator without regard to the subject's consent
- a statement on any additional costs to the subject that may result from participation in the research
- a statement on the consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation
- a statement that significant new findings developed during research that may relate to the subject's willingness to participate will be provided
- the approximate number of research subjects involved in the study.

Informed-Consent Requirements in Mexico: Norms and Limitations

Mexico has its own and different procedures for determining informed consent, established by the National Commission of Bioethics. The commission was established in 1992 and became a permanent body by presidential agreement in 2000. It operates under the Ministry of Health as an independent body—that is, it has technical and operational autonomy. The commission promotes the establishment of bioethics commissions in every state; at the time this study took place, 20 of the 32 federal states had such commissions (Yucatan was not among these). The commission establishes and disseminates norms and guidelines for research ethics committees, including the process of obtaining informed consent in the conduct of social and biomedical research (Comisión Nacional de Bioética, 2005). Informed consent is a legal requirement under the General Health Law of 1984 (Cámara de Diputados del Congreso de la Unión, 1984). The General Health Law regulates all research related to the generation of knowledge of human health and psychological processes; knowledge of the relationship between causes of disease, medical practice, and social structures; prevention and control of health problems; knowledge and assessment of the environment's harmful effects on health; techniques and methods that are recommended or employed in health services; and the production of materials for health. This law ensures that individuals who are invited to participate in biomedical studies, clinical trials, or other research projects are provided with all the information needed to make an informed decision about whether to participate in a research project or clinical trial (Vargas-Parada et al., 2006).

By law, every public or private institution belonging to the national health system that conducts research on human subjects must have a research ethics committee. Institutions that conduct research involving human subjects are mandated by law to submit their research protocol to a local research ethics committee (LREC). LRECs, the equivalent of IRBs in the United States, are responsible for reviewing and applying research ethics in evaluating all types

of research; typically, such reviews are primarily reserved for projects that include the direct participation of human beings (Valdez-Martínez et al., 2006).

In practice, social science and biomedical research conducted in Mexico in recent years has had little regulation, with many research projects routinely failing to use an informed-consent protocol (Garcia, 2009; Lamas et al., 2010; Outomuro, 2008). Although the commission promotes the establishment of LRECs as part of its capacity-building mandate, in practice, the establishment of LRECs is left to the individual capacity of universities, research centers, or other research entities (Comisión de Salud Fronteriza México–Estados Unidos, 2010). Many Mexican universities and research centers have no LRECs. Health institutions that do not regularly carry out research, such as state-level ministries of health, are not required to (and often do not) have LRECs. Researchers collaborating with these institutions may find it necessary to find another institution, such as a local university that has an LREC, to review the study. There are no guidelines for such review, and there is often a disconnection between the reviewing institution's LREC and the goals and needs of the proposed research. As a result, the process may be long and tedious, often discouraging researchers to go through it (Comisión de Salud Fronteriza México–Estados Unidos, 2010). This can make binational research difficult, given U.S. requirements for IRB approval.

According to the commission, informed consent involves a social process that should provide information about the research in a way that is understandable to the respondent, allows the researcher to verify that the respondent understands what participation involves, and provides the opportunity for the respondent to ask questions and have them answered (Comisión Nacional de Bioética, 2005). The process must also allow the respondent to refuse to participate in the study without being the subject of intimidation or coercion or being unduly influenced by incentives that could be viewed as coercive (Aguilera-Guzmán et al., 2008).

In practice, however, informed-consent processes in Mexico focus more on the completion of the consent form as a legal requirement than on the process of actually acquiring effective "informed" consent, including respondents' full understanding of what participation entails. A shortage in adequate training, guidance, and supervision of LRECs results in reviews that focus on rules, regulations, and improving research methods and analyses rather than on protecting the rights and well-being of participants (Ángeles-Llerenas, Wirtz, and Lara-Álvarez, 2009; Valdez-Martínez et al., 2006).

Numerous studies highlight questionable practices in the informed-consent processes for research projects conducted in Mexico. For example, Vargas-Parada et al. (2006) found that, in a clinical research project at a general hospital in Mexico, "most investigators gave only minutes to the patient to make a decision and 20% of the time, informed consent was obtained while the patient was hospitalized." In such a situation, patients may have felt pressured to participate in order to obtain treatment. They also may have been under distress or pain or medicated and not fully able to provide informed consent. In addition, only 16 percent of researchers provided the patient a copy of the informed-consent form; some researchers threw away the signed consent forms soon after the research study was completed. Verástegui (2006) notes that, in research involving advanced cancer patients in Mexico, 49 percent of patients had difficulty understanding informed-consent forms and "almost half of the patients believed that signing the document was mandatory before they could receive treatment." Thirty percent of patients were also illiterate and hence unable to read the informed-consent document. Vega et al. (2011), in a review of studies on the commercial sexual exploitation of children, found

that 75 percent of participants reported not having been asked beforehand to provide informed consent.

Aguilera-Guzmán et al. (2008) found that oral consent sometimes replaced written consent in Mexican social science research. The authors found that some studies conducted with indigenous communities point to trust issues that made indigenous study participants feel uncomfortable about signing any piece of paper. In these cases, the legal framework was sidestepped because participants were recruited through oral agreement.

Valdez-Martínez et al. (2006) found that LRECs value informed consent, but many studies have found difficulty in getting participants to truly understand the research and thereby provide informed consent. Other studies note that, although researchers in Mexico understand and accept the concept of informed consent, many participants cannot fully understand its required elements because of the complexity of the language used and illiteracy or low levels of literacy (Vargas-Parada et al., 2006).

Some authors further argue that it is important to recognize the limitations of informed-consent documents, particularly for clinical trials, that must include a description of research elements, such as randomization and risks and benefits (Vargas-Parada et al., 2006). Lack of attention to the characteristics of certain vulnerable populations, including limited or no education and the complexity of the information provided to subjects, may bring into question the validity of the informed-consent process. Research respondents may feel compelled to participate because of the influence of the researcher (as in the case of a physician asking for patient's participation) or their lack of other access to the treatment offered. This can undermine the autonomy of the decision to take part in the trial.

Barron et al. (2004) note in particular the challenges in obtaining adequate informed consent among older people, including physical frailty, reduced autonomy and privacy (often, the elderly in Mexico live with their children or other family members), impaired decision-making, and neuropsychiatric illnesses. Nevertheless, some studies emphasize the need for informed consent throughout the course of research, including a dialogue between respondents and researchers that will help improve understanding of what participation entails (Santillan-Doherty, Cabral-Castañeda, and Soto-Ramírez, 2003).

Conducting research in Mexico presents many other broader challenges to ensuring consent that is truly informed. Santillan-Doherty, Cabral-Castañeda, and Soto-Ramírez (2003) note the difficulty of free choice for human subjects in research because of the greater power, stemming from their authority, that researchers have over their subjects. In recent years, a leading main topic of bioethics in Mexico has been the medical research sponsored by Western drug companies. Increasingly, drug companies turn to Mexico to conduct clinical trials because it provides a large population, modern medical facilities, and a population that is more likely to participate because of lower levels of income and access to health care than populations in other countries. Because many Mexicans have limited or no medical insurance, participants may have little or no means of treatment other than that offered through clinical trials. They may also be so poor that the offer of a financial incentive may persuade them to participate against their better judgment. The authors found that only one-third of Mexican doctors respect their patients' wishes and that only half recognize the patient's capacity to make decisions. Doctors often lack knowledge or awareness of ethical issues in research, and this permeates all aspects of research, including the informed-consent process. In the context just described, establishing and implementing informed-consent procedures that fully and mean-

ingfully provide information on what participation entails and that adequately protect human subjects is even more crucial (Verástegui, 2006).

Informed-Consent Requirements and Procedures in Yucatan

Other institutions that conduct research in Yucatan have LRECs. One of these is a public, university-based research institution that frequently conducts biomedical research in the state. Investigators from this university are required to obtain informed consent from human subjects participating in research. Another LREC that reviews research conducted in Yucatan is the local campus of a national research center whose headquarters are in Mexico City. Locally, most work conducted through this research center need not be approved by the LREC. Nevertheless, researchers that conduct bio-anthropological research among urban populations in the capital city obtain written informed consent. Those working with Mayan and non-Mayan populations in rural areas obtain oral consent because their research uses anthropological methods, such as observation or interviews. Even those who collect anthropometric measurements in these populations obtain only oral consent.

Anthropological research is the most common type of research in Yucatan. Mexican anthropological scholars recognize the need to put in writing the ethical principles that are taught in undergraduate and graduate training programs in anthropology, building a more formal process (Escamilla and Valladares, 2005). One basic principle is obtaining what is referred to as oral informed consent. Because anthropological research usually requires that the investigator stay in the community over a period of time or make daily visits to the community, obtaining consent is but one part of the process of introducing oneself to the community, building relationships and rapport, and gathering information (Simonelli and Earle, 2003).

The challenge of obtaining written informed consent when working in Yucatan and more widely in Mexico is not just a matter of limited education levels and the complexity of the information presented in the informed-consent process. Rather, a cultural-historical perspective is necessary to understand two significant challenges. First, requiring signatures as part of the informed-consent process generates a great deal of mistrust (even after reading the contents of the informed-consent form) because of fear that the informant will be "tricked" into signing away or releasing his or her assets (including his or her land and home). Second, asking respondents to provide a signature before providing information about the family's socioeconomic and demographic characteristics and the participant's health and daily activities is also viewed with suspicion because this type of information is routinely provided without written consent in other contexts (e.g., census surveys, visits to the doctor).

In short, our efforts to obtain informed consent among elderly participants in Yucatan had to address multiple challenges. These included challenges pertaining to working with the elderly, many of whom have very low levels of literacy, as well as challenges related to the need to situate ethical codes in the context of the country in which one is working while preserving their principles contained in those codes (Escamilla and Valladares, 2005; Ramos, 2004). In the next chapter, we review our efforts to address these challenges.

CHAPTER THREE

Developing and Testing Informed-Consent Methods Among the Elderly in Yucatan

As noted, we faced four challenges in developing informed-consent procedures and forms for this project. First, and above all, of course, we had to protect the interests and confidentiality of those participating in our research. Second, we had to consider the specific context and setting for this project and, in particular, the characteristics of our target population, elderly persons in a Spanish-speaking country, many of whom spoke only Mayan or spoke Spanish only as a second language, or, even if speaking Spanish, had low levels of education or even literacy. Third, given low levels of education and literacy among many in our population of interest, we had to consider how limited independence (autonomy) could affect respondents' ability to make informed decisions. Fourth, we had to address the norms and standards set by U.S. federal regulations and followed by the HSPC, as well as the local context in Yucatan, Mexico, regarding research that involves human subjects.

In this chapter, we discuss the informed-consent procedures that we first developed based on informed-consent practices typically used in research studies conducted in the United States. We then describe the process and findings from a field test and the subsequent revisions to the informed-consent documents and procedures made in response to the findings from the field test.

Development of Informed-Consent Forms

The initial consent forms developed for the study included forms for the following purposes:

- for participation in the survey
- to allow access to the respondent's administrative and health records
- for the collection of anthropometric measures and biomarkers.

To develop informed-consent documents for this project, we reviewed consent forms that had been used and approved by the HSPC for similar projects. We also reviewed those for similar projects conducted in Mexico, including the Mexican Health and Aging Study and the Mexican Family Life Study.[1] We found, however, that some of these projects use an oral informed-consent procedure that was not typically used on similar projects conducted in the United States or on other RAND studies. We considered it unlikely that the HSPC would approve a similar approach on this study. We therefore opted to develop informed-consent

[1] For more information, please see Mexican Family Life Survey (undated); Vargas-Parada et al. (2006); Fernández Varela Mejía and Sotelo Monroy (2000); Santos, Llaguno, and Vernon (1999); and López-de la Peña (1996).

procedures and documents similar to those used in other studies that the HSPC had reviewed and approved.

In developing informed-consent procedures and forms for collecting anthropometric measures and biomarkers, as well as for the collection of dry blood spots and testing of hemoglobin (components that were introduced later in the study), we adapted the informed-consent documents used by the Health and Retirement Study (HRS) (HRS, undated), a large panel survey conducted by the University of Michigan since 1992 among U.S. residents at least 50 years of age. We adapted HRS procedures because they are targeted and have been adapted for older populations around the world.

Language

Studies that are similar in scope and complexity to this project typically require written informed consent, whereby subjects are asked to review and then sign a consent form. The consent forms for this study were first developed in English, submitted to the HSPC for review and approval, and then translated into Spanish. The Spanish version of the informed-consent documents was subsequently translated into Mayan by a professional translator and reviewed by bilingual reviewers. Appendix A provides the original English version of our informed-consent documents.

Pilot Test

In the spring of 2008, we conducted our first field test in the city of Progreso, Yucatan, with a sample of approximately 200 Spanish-speaking individuals. This involved testing the draft version of the survey in Spanish, as well as our full battery of proposed data-collection procedures, including the process for locating eligible households, identifying eligible respondents within a household, and introducing the study. The field test involved conducting the individual-level and household-level interviews (using CAPI) but did not involve the collection of anthropometric measures or biomarkers. To evaluate the adequacy of the informed-consent documents and ensure that participants understood what they were being asked to do, we tested them among participants in the individual and household interviews, as well as among those for whom we sought administrative and health records. To assess the Mayan-language version of the survey and informed-consent documents, we conducted a second field test in the town of Teabo, Yucatan, with a sample of approximately 80 individuals.

Training of Field Staff

The data-collection team that participated in the field test was hired locally and trained by bilingual RAND staff. Most of the interviewers (55 percent) had bachelor's degrees, while 41 percent had high school diplomas and 4 percent had middle school diplomas. The interviewers were typically young and male: Ninety-three percent of the interviewers were in their late twenties and early thirties, and 77 percent were men. Although about one-third of the interviewers had prior data-collection experience, most were unfamiliar with the rights of

human subjects participating in research studies and with the process for obtaining informed consent prior to a subject's participation in a research project. Before we launched the pilot field test, RAND staff and local researchers provided all data-collection staff with extensive training in all aspects of the survey. This included how to introduce themselves to respondents, how to describe the study, the informed-consent process, special issues in working with the elderly, data-safeguarding requirements and procedures, and handling adverse events. Training took place over a two-week period and involved lectures and presentations, group training sessions, and hands-on training working in pairs.

During the field test, interviewers were to introduce themselves and provide a brief overview of the study and then describe the informed-consent process to the respondent. In describing the informed-consent process, interviewers were to review exactly what the respondent was going to be asked to do, answer any questions or concerns the respondent had, and, if the respondent agreed to participate, ask him or her to sign two different consent forms. One of these forms indicated consent to participate in the survey, and the other granted access to the respondent's administrative or health records from any program in which he or she was participating. Only when the respondent had received all the information required for an adequate informed consent and signed appropriate forms were interviewers allowed to proceed with the interview. Each respondent was asked to sign two copies of each form, one for the project and a second copy to be left with the respondent. If a respondent declined to participate in the interview or was unable, unwilling, or prevented by a friend or family member from signing the consent form, interviewers were instructed to thank the respondent and the family for their time and proceed to the next house. Because we had limited time for the field test, we were unable to go back to households that initially declined to participate.

The PI, the survey director, the local project director, and the coordinator participated in the field tests and were able to directly observe the informed-consent process. Immediately following each field test, we held extensive debriefing sessions with field interviewers and supervisors, focusing specifically on issues and challenges related to the informed-consent process and forms.

Informed-Consent Field-Test Results

Following the field test, we held a debriefing meeting, as we mention above, with the interviewers to discuss the field-test experience and to identify processes or procedures with which interviewers experienced difficulty and that needed to be modified. The meeting discussed how respondents reacted to the study in general and to the process for obtaining informed consent in particular. Feedback from the interviewers reinforced what the survey director and PIs had observed: Most respondents had never participated in a research project before or had any reference about research projects and were completely unfamiliar with the informed-consent process.

Many respondents were intimidated by the length and complexity of the consent form. They were extremely nervous about signing the forms, even after having read the forms or having someone read the forms to them. Many respondents, particularly those with low levels of schooling, had difficulty understanding the consent forms, while many others were unable to read the forms because they either were illiterate or had poor vision. Many respondents feared they would be taken advantage of and therefore refused to sign the consent form even

though they were willing to participate in the study (that is, they agreed to participate in the study but refused to sign the consent form). In some instances, other family members (an adult son or daughter) actively discouraged or prevented the adult from signing the consent form even though they were willing to allow the adult to take part in the survey. These family members, too, feared that signing the consent forms would compromise or release their rights over their property.

The interviewers reported that the introduction and informed-consent process required as much as 30 minutes, which was tiresome and often led to a loss of attention or interest in the study. In our field-test observations, we also found that interviewers struggled with how to present the study to respondents, how to succinctly answer questions posed by respondents or their friends and family, and how to persuade respondents (or gatekeepers) to sign the consent forms and participate in the study.

Revised Forms

We used the feedback we received from interviewers and the findings from our field observations to substantially revise the consent forms. Our primary aim was to shorten the consent forms and make them easier to understand while maintaining all elements of informed consent required by the HSPC. For example, we shortened the description of the study and used simpler, lay language to describe what participation entailed.

In revising the forms and procedures, we collaborated with local researchers experienced in conducting primary data collection in Yucatan. We provided them a copy of the informed-consent documents and an overview of the informed-consent procedures used in the field test. We shared the findings from the field test and met with them to discuss how we might modify our procedures to address the issues we encountered. We also asked them to edit the informed-consent documents to simplify their language.

We drafted a proposal for revising the informed-consent procedures that addressed some of the major issues encountered in the field test, including the illiteracy of some respondents. We also proposed eliminating the signature requirement for the informed-consent form, instead having the interviewer sign the consent form as a "witness to informed consent." That is, by signing the consent form, interviewers would attest that they had reviewed the consent form with the respondent, addressed respondent questions or concerns, and obtained oral consent from the respondent to proceed with the survey.

For the form allowing us access to administrative or health records, we anticipated being required to obtain written evidence of consent. (In our experience, government programs and health providers are unwilling to provide copies of records unless the study provides a consent form from the individual in writing.) We therefore revised this form to allow respondents to sign, provide a fingerprint if unable to provide a signature, or have a legally authorized representative sign for them.

We submitted the revised documents and procedures to the HSPC for its review. Although the revised informed-consent procedures we proposed are not typically used in U.S. research projects, the HSPC recognized that this particular project presented unique challenges that required unique solutions and that informed-consent procedures and documents had to be adapted to reflect the reality of conducting research in Mexico among an elderly population with low literacy levels and particular cultural concerns.

Over time, we have added new research components to the research project, including hemoglobin testing, the collection of dry blood spots, and the collection of school records for children in the household age 5 or older. Each of these components has been submitted to the HSPC for review and approval, and each new component has required a new consent form. Appendix B includes our revisions of the original informed-consent forms, as well as informed-consent forms subsequently developed for additional components of the study.

Overview of Actual Informed-Consent Procedures

Our revised informed-consent procedures began with interviewer training. Before interviewing respondents, interviewers had to complete all phases of training on the participation of human subjects in research. They also had to provide all potential participants in every phase of the study a description of the study. Invited participants who agreed to take part in the study were asked to provide oral informed consent for the survey and written consent for all other study components (including the collection of administrative or health records, school records for school-age children, anthropometric measurements and biomarkers, and dry blood spots and anemia testing). The consent forms for the collection of anthropometric measurements and biomarkers were also collected at the end of the individual and household surveys. Because these procedures were somewhat invasive, we were required to obtain consent in writing at the end of the individual-level interview for them. Allowing interviewers to go through the informed-consent process for these activities at the end of the 60- to 90-minute interview, after they had established rapport with the subject, facilitated the process and improved the consent rate.

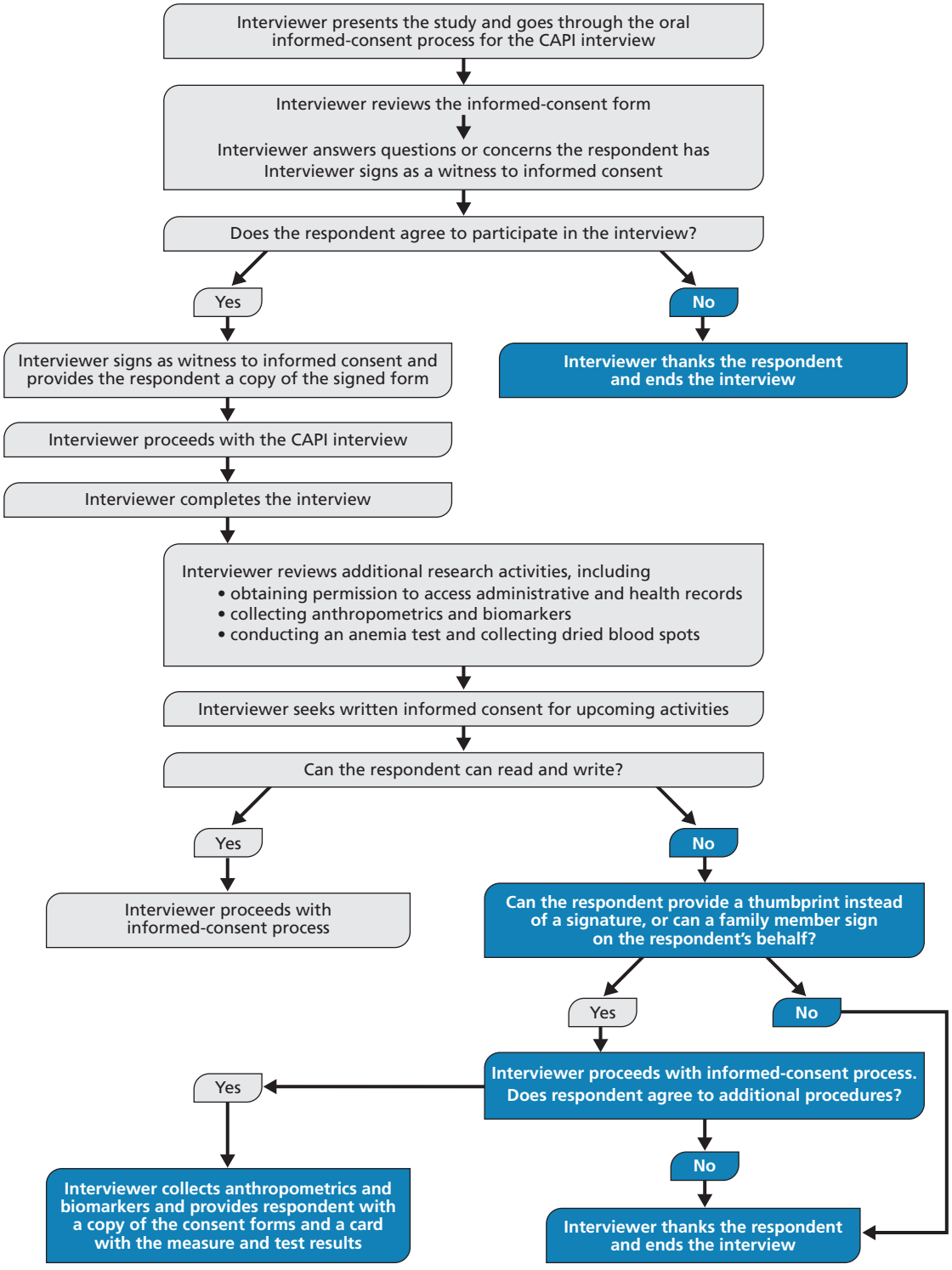
If it became apparent to the interviewer (or if the interviewer was informed by another household member) that the selected participant did not have the capacity to take part in the survey (for example, if the participant was too ill or frail or hard of hearing), then the interviewer could attempt to interview a proxy respondent (preferably a spouse, adult child, or other household member who lived with the selected respondent and knew about the respondent's daily life and activities).

Interviewers were asked to document their witnessing of the granting of informed consent. All study materials were provided in both Spanish and Mayan and written at an appropriate reading level using simple language. Interviewing procedures were designed to respect respondent needs for information, privacy, and control over the interviewing process.

The initial contact with respondents was made in person. The interviewer fully disclosed the nature and purpose of the study by reviewing the informed-consent documents with the respondent, including what was expected of each respondent in terms of the number of interviews, the length of each interview, and the types of questions that were to be asked. To ensure that interviews afford comfort and privacy, respondents could choose to be interviewed in their own homes or at some neutral location, such as a school, church, or government office.

The informed-consent process was repeated before each interview, and a new consent form was required for each follow-up interview. Respondents could refuse to answer any question, participate in one study component but not another, or withdraw from the study altogether. Their decision in no way affected the benefits to which they were entitled from the state pension program. Figure 3.1 summarizes the informed-consent process.

Figure 3.1
Overview of the Informed-Consent Process



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CHAPTER FOUR

Conclusion

In Mexico, as elsewhere, informed-consent documents often use language that exceeds the reading and comprehension skills of participants, thus making it difficult for them to understand. Gaining informed consent from elderly adults presents additional challenges stemming from their physical frailty, reduced autonomy and privacy (it is not unusual for the elderly in Mexico to live with their children or other family members who act as guardians or gatekeepers), impaired decisionmaking abilities, cognitive impairment, or neuropsychiatric illnesses. Obtaining meaningful informed consent may also be difficult when the potential research participant is functionally illiterate or cannot read the language in which the consent form is presented.

In developing the consent forms required for the impact evaluation of the Yucatan pension program, we had to comply with the requirements and standards for conducting ethical research set by U.S. federal regulations and followed by the HSPC, as well as with Mexican norms and regulations. In addition, we had to navigate an environment in which a research study as extensive and complex as ours had not previously been undertaken.

We based our initial consent forms on those previously developed for similar target groups and field conditions and conducted extensive pilot testing to refine them. We conducted two different, successive field tests, in two different localities in the state of Yucatan, Mexico. The first field test included a Spanish version of the consent forms, and the second tested a translation of those forms to Mayan. Immediately following each field test, we held extensive debriefing sessions with field interviewers and supervisors, focusing specifically on issues and challenges related to the informed-consent process and forms.

Our field-test findings indicated that many respondents had low levels of education, poor vision, and hearing loss, which made the informed-consent documents difficult for them to read and understand. Some respondents were unable to read or write and therefore unable to sign the consent form. Many respondents had never before participated in a research study or had no reference about research studies and were unfamiliar with informed consent and research procedures. Many expressed distrust and were unwilling to sign a document they could not understand. In some cases, friends or family members would not allow them to sign the consent forms. Often, respondents said that they were willing to participate in the survey but did not want to sign consent forms.

We used the findings from the field test to revise the consent forms significantly. In revising the forms, we collaborated with local researchers experienced in conducting primary data collection in Yucatan and with Spanish-speaking RAND researchers with experience in Mexico. We shortened and simplified the consent forms for participation in the survey while maintaining the basic elements of informed consent required by the HSPC. We also modified

the informed-consent process to promote an exchange of information between the interviewer and respondent. Interviewers provided a copy of the consent forms to the respondent, read and reviewed the forms with the respondent, and then answered any questions or concerns the respondent may have had about the forms or about his or her participation in the study. Given that some respondents were unable or unwilling to provide a signature, we eliminated the signature requirement for the consent form and instead required the interviewer to indicate in writing their "witness to informed consent." We submitted the revised informed-consent procedures to the HSPC and obtained its approval before proceeding to implement these procedures in the field.

We also made revisions to the consent form that requests the respondent's permission for the project to obtain a copy of his or her administrative and health records. A respondent who was unwilling or unable to sign the form could provide a fingerprint indicating consent. In addition, we inserted a line for the signature, of a legally authorized representative to sign in lieu of the respondent, in the event that the respondent was unable to sign the form or to provide a fingerprint. Each respondent was again given the opportunity to review the form and ask questions of the interviewer and was provided with a copy of the form for his or her records.

The collection of anthropometric measurements and biomarkers took place at the end of the individual- and household-level in-person interviews. Because these procedures are somewhat invasive, we were required to obtain consent in writing prior to any measures or tests. Allowing interviewers to go through the informed-consent process for these activities at the end of the interview, after they had established rapport with the subject, facilitated the process and improved the consent rate.

The elderly represent a growing and important vulnerable population that presents special challenges for developing informed-consent processes. Such processes should not overburden respondents or discourage them from participating in research. The informed-consent procedures developed as part of this project provide a useful model for other projects conducted with older populations in Mexico or other countries with similar characteristics for obtaining meaningful informed consent that promotes understanding of participation requirements, accounts for cultural norms and constraints, and addresses language and literacy challenges.

Appendixes

Appendixes for this technical report are available online: http://www.rand.org/labor/centers/clasp/research/projects/social-security-program.html

- Appendix A: Original Informed-Consent Documents (English Version)
- Appendix B: Revised Informed-Consent Documents (English Version).

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