



Cal Poly Pomona - Human Research Protections Program Institutional Review Board (IRB)



Protocol Application (version: January 31, 2011)

IRB principles: respect for persons, beneficence, justice

Cal Poly Pomona (CPP) is committed both to research in advancement of teaching and science and to the protection of the individuals involved. As part of the assurance filed with regulatory agencies including the federal Dept. of Health and Human Services and policies from others like the State of California, the University has designated a human subjects' committee, called the Institutional Review Board or IRB, to review proposals for research involving living persons. This application, when submitted to the IRB, will be evaluated in terms of its compliance with ethical standards regarding the treatment of subjects (participants). The type of review – full, expedited, or exempt – will be determined by the IRB. While individual researchers are ultimately responsible for their practices, the IRB's review is designed to provide objective input as additional protection for the subjects. Further, it is of benefit to those who could be held accountable for the research practices, i.e., the researchers and the University. All research conducted by students, faculty, and sponsored individuals must have prior IRB approval.

Hints and help:

- Complete **all sections in yellow** about your research proposal. Incomplete protocols will be returned. There are **blue highlighted links** to additional information. Look at the helpful hints as indicated in *italics* with each question of the protocol. It is highly recommended to have someone not involved in the writing of the protocol look it over for clarity and typographical errors.
- More information about the IRB at Cal Poly Pomona is available at the **Research** web page, <http://www.csupomona.edu/~research/irb/>. There are sample protocols and consent forms, links to training materials, policies and procedures, etc.
- Submit your completed protocol application to the IRB office within the Office of Research (**Research**). E-mail it and any attachments such as surveys, informed consent forms, and recruiting flyers to bkennedy@csupomona.edu, the IRB administrator. To facilitate tracking, please include in the file name 1) your last name and 2) one or two key words describing its subject.
- Also, print off, sign, and bring or mail **this front page** as hard copy to the IRB office at **Research**, Building 1, room 229. You -- and all co-PIs -- must sign the "Declaration by all Investigators" before the review will begin.
- Training in the conduct of human subject research is critical and investigators must demonstrate their knowledge and awareness through the completion of appropriate coursework. In 2007, the IRB adopted the CITI "Course in The Protection of Human Research Subjects" (<https://www.citiprogram.org>) as the primary means of training and as a **requirement of protocol approval**. Please provide documentation of your training with this application; you may be asked to pursue additional training appropriate to your study.
- For other assistance, contact the Compliance Associate within **Research**, Bruce W. Kennedy MS RLATG CMAR CPIA, at 909-869-4215 and bkennedy@csupomona.edu. **(NOTICE: This protocol application is presented here for its content to help investigators in understanding the design of a Business Administration protocol. It was approved and used by the investigator, who has permitted its reproduction here as an example. Policies and procedures within the Cal Poly Pomona IRB may have changed since, so be sure to complete your protocol according to current information available elsewhere from this site or the Compliance Office. Dated: 28 June 12)**

| Investigator information | Primary investigator (faculty, student, etc.) | Others (your faculty advisor, co-PIs, facilitator, sponsor, collaborators, etc.) |
|--|---|---|
| Name: | Business Student | Business Professor |
| Affiliation (college/dept): | California State Polytechnic University-Pomona-MBA Program, College of Business Administration | California State Polytechnic University-Pomona-Graduate College of Business Administration Department |
| Phone contact (office or cell): | (xxx)-xxx-xxxx | (xxx)-xxx-xxxx |
| Email contact: | xxxxx@csupomona.edu | xxxxx@csupomona.edu |
| Title of this IRB protocol: Online strategic research for a pie shop | | |
| Date submitted: 3/30/2010 | <input type="checkbox"/> _X_new <input type="checkbox"/> _amendment <input type="checkbox"/> _renewal; previous number: | |
| Any vulnerable subjects (risks)?: <input type="checkbox"/> _minors <input type="checkbox"/> _pregnant women <input type="checkbox"/> _medically sensitive <input checked="" type="checkbox"/> _X_other: None | | |

DECLARATION BY ALL INVESTIGATORS: This proposal is guided by the ethical principles regarding research involving human subjects as set forth in the [Belmont Report](#). I/We agree to abide by the policies and procedures of the IRB at CPP, including obtaining appropriate training in human subject research for myself and those involved in its conduct. I/We will not initiate any research associated with this proposal on or off campus until authorized by the IRB. I/We will inform the IRB of any adverse events that occur or of a need to modify the study design. I/We understand that approval, when granted, is valid for up to one year and will submit a renewal for its continuation if needed.

| | | |
|--|---------------------------------|---|
| <i>(send this signed page to the IRB office)</i> | Signature, certifying the above | Date |
| primary investigator: | Business Student | 3/30/2010 (to be completed as fresh signature) |
| all others, including advisors: | Business Professor | 3/30/2010 (to be completed as fresh signature) |

| | | | | | |
|----------------|---------------------------------------|---|--------|------|----|
| IRB office use | review type: full IRB (risk involved) | expedited/designated review (minimum risk/harm) | exempt | PEIP | NA |
|----------------|---------------------------------------|---|--------|------|----|

| | | | |
|--|---|---------------------|----------------|
| date rc'd: revised | assigned to: | training: PI others | approval date: |
| protocol #: | | | renewal date: |
| copies: chair file | final: signed ICF approval-memo authorizations e-mailed | | |
| <i>This protocol has been reviewed and approved for conduct by the IRB, California State Polytechnic University, Pomona.</i> Jeffery S. Mio PhD, Chair, IRB | | | Date |

I. DESCRIPTION OF THE RESEARCH PROJECT

Research is defined as “a systematic investigation including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” (45 CFR 46.102(d))

- A. Purpose of this project – What hypothesis are you testing? Why are you conducting this study; explain the rationale? What are the objective(s) and goal(s)?** *Provide enough detail such that a) the IRB member(s) reviewing your protocol will understand your research plan and b) to support a judgment of the risks and benefits in order to approve the “use” of the research participants.*

The purpose of this research is to help establish an online store, in order to help Mrs. Smith’s pie shop increase its customer base through expanding its business through online sales. There are five main questions, which need to be answered in order for the pie shop to establish the online store successfully:

RQ1: What kind of products do customers prefer to see in the online store?

RQ2: How many of each product will the customer be allowed to order through the online store?

RQ3: What kind of packaging supplies and shipment channels do customers prefer for the online store?

RQ4: What kind of product prices and promotions do customers prefer from the online store?

RQ5: What kind of payment method and online service features do customers wish to have from the online store?

I am conducting this study because e-commerce has become increasingly popular in Hawaii. I would like to help the physical restaurant successfully establish an online store in order to increase their customer base. My goal is to successfully establish the online store so that it fulfills customers’ needs, and increases the revenue for the family owned business.

- B. Relevance – State specifically the relationship of your proposed research to other, previous scientific and/or scholarly investigations in the field. Provide full citations (APA or MLA reference styles are good).** *What literature is related to your research? What are you doing that builds on that information?*

There are no previous scientific and/or scholarly investigations related specifically to my research on Mrs. Smith’s pie shop. There is data available on how other businesses have utilized the types of data I aim to collect, in order to successfully launch an online store. As mentioned previously, e-commerce is growing in popularity, and because of this more research is being done in the business community to understand what makes some online businesses thrive, while others fail. Specifically, finding answers to questions such as: what services do customers want through an online vendor, and how do they want them delivered and paid for, are important to understand before taking the step to move forward in e-commerce. Because there is little research that has been done on small family owned bakeries seeking to go online, I hope that my research will help future small businesses be able to venture into the online market successfully.

- C. Methods – Summarize the design (independent variables, interventions, treatments, etc.) of your proposed study. What are your expected outcomes? Describe in detail all procedures to be done with human subjects. What types of test(s) will be performed on or with the subjects? How will you carry them out and with what data gathering instruments and apparatus? When do you plan for the research to occur? Where will the research be held (and is authorization or permission needed there)? Who will conduct the research besides yourself?** *Define terms, abbreviations, and procedures that may be specific to your discipline for the understanding of the IRB reviewer. By authorization, it is meant for example, a company’s permission to use worker’s time or a school principal’s acknowledgement – if so, provide documentation to the IRB. Don’t assume that the IRB reviewer will intuitively know the steps and logistics of your methods and process.*

I will create a survey that includes 20 questions about the online store, such as, shipment methods, customer service, preferred products, packaging materials, and order quantity. The survey will be administered to any potential customers who have access to the internet in Hawaii. It will not include questions such as gender, income, age, and living area. I will use SurveyMonkey to create the online survey. The online survey will include a website consent form and 20 questions. I will put the survey link on the restaurant’s website (<http://www.mrssmithspies.com>) for individuals to complete. I plan to start the survey research in May. I will be conducting the research, and the restaurant owner has agreed to support the research by putting the survey link on the company website.

II. AFFILIATIONS

These questions ask about how you are related to the institution and subjects where the research project is to be conducted. As examples: you are a teacher using your students in a classroom setting as your subjects, or you work for the company where a marketing survey is to be conducted, or you have a financial interest in a product being tested, or you are working with a colleague in another country.

- A. Are you collaborating with another group such as a school, community association, government agency, etc.? Is IRB approval necessary, or being obtained, elsewhere (domestically or internationally)? Is the project being sponsored or supported through a grant, contract, or other financial arrangement? Does the funding agency require IRB approval? Describe as appropriate.** *The IRB is required to collect such data for OHRP (Office for Human Research Protections) on studies funded by DHHS (NIH, FDA, etc.).*

I am not collaborating with any groups. An IRB approval elsewhere is not necessary for my study since my survey is about customers' opinions about the online store, services, and products. There is no sponsoring or support through a grant, contract, or other financial arrangement.

- B. Personal gain – Do you, as an investigator involved with the project, or any family member (spouse, child, etc.) have a financial or other “self” interest in this study? If yes, describe.** *For example: an MBA student may conduct a consumer survey about establishing a business (restaurant) she herself wants to open. In this case, there could be a need for disclosure of the fact in the informed consent form.*

Yes, I am doing a strategic plan for my own family's business and the results of the survey will help the restaurant to decide whether or not to establish the online store. The results will also help the business to improve in order to fulfill customers' needs.

- C. Are you a student? Is this project part of a classroom experience or a graduate program? Has your advisor/mentor reviewed your IRB application? Describe as appropriate.** *Student protocols cannot be reviewed by the IRB until there is evidence of the advisor's contribution and approval including his/her signature on the front page of this application.*

I am a MBA student. The project is part of my graduate program, and my advisor has reviewed my IRB application.

- D. Do you have any pre-existing relationships of any kind with the subjects (participants) or institutions involved in conducting this study? If so, please describe them.** *If you work for a company and need to keep its identity confidential, note that here.*

I do not know if I have any pre-existing relationship with the participants. The participants are anonymous and are anyone who has access to the internet and visits the company website. So while it is possible that I have met some of the participants, there is no way for me to know that. The institution involved is my family owned business in Hawaii.

- E. If you are not affiliated with Cal Poly Pomona, who is your co-PI or facilitator on campus?** *A co-PI applies when there is a collaborative research project being proposed in this protocol. A facilitator applies when there is need for logistical support to conduct your study at Cal Poly Pomona. Not all studies need a facilitator, but the IRB may, upon review of your protocol, make it a condition for approval. See section 14.14 of the [IRB policies and procedures](#). Obtaining a facilitator is the responsibility of the PI(s). Describe as appropriate. Specify the name, email address, and phone number of either your co-PI(s) or facilitator.*

N/A

- F. Though there may not be one, could there be the perception of a conflict of interest for either you, as the investigator, or for the subjects in this study? If so, how will you manage that?** See http://www.csupomona.edu/~policies/Administrative/conflict_of_interest_and_financial_disclosure.html.

There could be the perception of a conflict of interest for me in this study. I have a personal interest in the success of the online store. Having said this, there would be no way for me to influence the participants in the study. My study is focused on potential customers' opinions about the online store, and individuals will not be forced to do the survey. They can provide any answer that they feel is right.

III. DATA COLLECTION

Collection methodologies include, but are not limited to: surveys, interviews, focus groups, oral histories, participant observation, observations of public behavior, research in public schools, and the analysis of existing data. Data include: survey sheets and questionnaires, biological samples, audio and video tapes, transcripts of verbal communication, photographs, paper and electronic records, previously collected (existing) information, etc. Personal and private data deemed by the IRB to be a risk to subjects if revealed can include gender, income, number of children, age, religion, ethnicity, e-mail addresses, and more. Even when labeled as demographic data, it is still personal and private and could potentially identify an individual. This is not to say such data should not be collected, but mechanisms must be described in

this protocol to protect the interests of the subjects should they be (somehow) identified.

The HIPAA Privacy Rule regulations [45 CFR 164.514(b)] list specific elements that are considered to be personal identifiers. These include: name and initials; street address, city, county, precinct, zip code, or equivalent geocodes; elements of dates (except year) directly related to an individual (date of birth, admission date, discharge date, date of death); elements of date including year for persons 90 or older; telephone and/or fax number; e-mail address; social security number; medical record or health plan identification number; account number; certificate and license number; vehicle identifier and serial number including license plate number; device identifier and serial number; web address (URL), internet IP address; biometric identifier including finger and voice print, full face photographic image and comparable image; other unique identifying number, characteristic, or code.

- A. What data about the subjects will be collected? In what format (see above)? How will it be coded or identified? Will social security numbers be used? What will become of the data at the end of the study (returned, destroyed, archived)?** *If data like audio and video tapes are kept, the subject must be told of the purpose (e.g., conference presentations) and for how long, as part of the informed consent process. The subject has the option, after the study is over, to contact the researcher to withdraw permission for continued use.*

I will collect data about potential customers' opinions about the online store. The survey will include several multiple-choice questions about the online store's services, products, order quantities, shipment methods, packaging...etc. The survey does not require a social security number or any other identifier. The results will be used for the restaurant to decide whether to establish the online store or not, and how to improve the restaurant business. The data online will be stored for one year time before being deleted.

- B. If applicable, have you submitted a copy of the survey or questionnaire to the IRB?** *(If using a published survey, do you need and have you provided permission to use it?) Provide the URL for electronic surveys. (It will be tested during IRB review; discard those data before 'going live.')*

yes in development (only finalized surveys can be approved) comment below:

Link: <https://www.surveymonkey.com/s/mrssmithspie>

- C. Who will have access to and use the data? How will the raw data be kept protected and secure? How will the data, results, and conclusions be utilized (e.g., presentations, publications, or other)?** *(per California law, CC 1798.24, the researcher must provide a plan sufficient to protect personal information from improper use and disclosures, including sufficient administrative, physical, and technical safeguards to protect personal information from reasonable anticipated threats to the security or confidentiality of the information.)*

I will be the only individual with access to the results. The results will show customers' opinions about the online store and they will not include any personal information like income, age, gender, address, social security number, or occupation. I will use a password code to secure the results in my personal computer.

- D. Does the research project have provisions or plans for the ongoing monitoring of data collection to ensure safety of subjects? If so, describe the plan.** *This generally applies to longitudinal studies, meaning long-term interaction with the subjects. For example: a dietary study of a novel food product looking at physiological responses, or a repeated measures study where information is provided by subjects for many weeks, or studies involving data collection for months and different research assistants would be contacting subjects, or a behavioral study that might have lasting (mental) impressions.*

This research is anonymous. I will collect data about potential customers' opinions about the online store. During the data collect period the survey company (SurveyMonkey) will protect the data. I have read the privacy policy on SurveyMonkey and am satisfied with the privacy protections that they provide. After the survey reaches the target number (200-300 surveys), I will close the survey and download the data from SurveyMonkey. The data will be kept in my personal computer with password code to secure the results.

- E. For studies involving medical records, explain compliance with the HIPAA privacy rule (Health Insurance Portability and Accountability Act) and disclosure of protected health information (PHI).** *(see http://www.csupomona.edu/~research/irb/Hints_help_examples.shtml for the "Experimental subject's bill of rights – Medical research" consent form if invasive procedures are to be performed)*

not applicable comment: .

IV. SUBJECTS

A human subject is a "living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information." (Dept. of Health and Human Services)

- A. How many subjects (or participants) will be involved in the research project? What is the statistical validation for that number?** *It is acceptable to have a range, but it must be a close approximation. For projects with surveys (e.g., electronic, phone, written, door-to-door canvassing), indicate the number to be recruited, the anticipated*

response rate, and thus the final number of actual participants.

The survey range will be 200 to 300. This sample size is decided by the research given the requirement of developing a strategic plan for existing business like this.

- B. Briefly describe the subject group(s), that is their characteristics -- for example age groups, gender, students, faculty members.** *What are you looking for in your subjects?. See as well the section on recruitment of subjects.*

The subject group will be any potential customers who visit the pie shop's website in Hawaii. It is not necessary to know participants' name, age, gender, occupation, income, and address.

- C. What are the benefits, if any, to the subjects from their participation in the study?** *Will they personally gain something through the research by being a subject? This information – summarized – must be included in the consent (and/or assent) form as well. If there is no direct benefit, then state that.*

Subjects' participation of the survey will help to improve the service and products of the restaurant. The restaurant will improve the service and products according to the survey, in order to benefit the customers.

- D. Will the subjects be compensated? Will they be given something? If yes, in what way (token of appreciation, money, gift, cash card, course credit, etc.)?** *This information – summarized – must be included in the consent (and/or assent) form as well. If there is no compensation, then state that.*

The participants are all volunteering to participate in the survey and they will not be compensated or given anything.

- E. Describe the control and/or comparison group(s), as applicable.**

There will not be any control or comparison groups.

V. VULNERABLE SUBJECTS

When a subject has limitations, is coerced or manipulated, there is a loss of capability to volunteer, and the subject may be vulnerable. The IRB considers the possibility that, for example, bosses can coerce at the workplace and teachers can manipulate in the classroom. Research conducted with vulnerable subjects requires demonstration of training with that specific population.

- A. Minors – Will [children](#), minors, or wards be recruited for this research? If so, explain in what way. How will their assent to participate be obtained?** *Children in most circumstances are those less than 18 years of age. Research with children involving no greater than minimal risk requires the permission of one parent and the assent of the child (45 CFR 46.404).*

Not applicable.

- B. Others – Explain research involving other vulnerable subjects such as [prisoners](#), [pregnant women](#), or culturally or medically vulnerable groups?** *Consider the circumstances. For example, a pregnant woman answering a survey about being a teacher may not be vulnerable, but she could be if it's a study about baby furniture.*

Not applicable.

VI. POTENTIAL RISKS AND THEIR ASSESSMENT

Definition of risk: A potential harm, discomfort, or inconvenience associated with your research that a reasonable volunteer would be likely to consider significant in deciding whether or not to participate. Risks include legal, social, emotional, or psychological issues, physical or biological hazards, revealing an identity, damage to reputation, exposure of behavior or medical character, illness, injury, side effects of applied or consumed products, revealing or loss of private information, etc. Risk comes at various orders of magnitude, ranging from mere inconvenience to perceptible bodily pain.

- A. What are the risks? Describe any potential harm, discomfort, or inconvenience, however minimal, as you would explain them to the subjects.** *This information – summarized – must be included in the consent form as well.*

Completion of the survey poses no more risk than any other regular activity in daily life. The survey will not include any questions like age, gender, race, income, occupation, address, or other specific personal information. The survey will include questions about the potential online store. These questions involve: customer service, preferred products, shipment methods, packaging materials, and order quantity. All of the participants will be volunteering to do the survey and they will not be forced to complete it, or answer any question they are not comfortable answering.

- B. Describe your procedures for protecting against or minimizing the potential risks.** *Is a debriefing statement needed? A brochure from the Counseling and Psychological Services might be necessary. Do your procedures and contacts with medical emergency services for treadmill exercises or phlebotomy? Could someone else obtain personal and private data? Should an adverse event occur – something you don't anticipate or didn't plan on –*

There are only minimal risks for the research. All of the participants are volunteering to do the survey and they will not be forced to answer any questions. They are able to provide any information and answers they wish. The research is anonymous and any potential customers in Hawaii who have access to the Internet can obtain the survey. The survey is all about customers' opinions about the online store. It will not include any personal information and private data.

- C. Explain why these risks should be determined as reasonable in relation to the anticipated benefits, if any, while conducting research with the subjects. Include in your response the importance of the expected gain in generalizable knowledge, when evaluated against the risks.**

Because the research is limited to an anonymous survey and no personal information is collected, there are only minimal risks.

- D. Is the study anonymous or confidential? Describe in detail your procedures meant to assure the protection of subjects' information, sensitive data, and privacy.** *(See the CPP IRB [web page](#) for a discussion of what is confidential and what is anonymous. There are processes to de-identify data as well.)*

The study is anonymous. Any potential customers in Hawaii who have access to internet can obtain the survey.

VII. RECRUITMENT

As applicable, attach copies of flyers, e-mail or blog text, advertisements, etc., to be used for the recruitment of subjects. Review by the IRB is necessary for approval of your protocol. Include the statement as follows: The Cal Poly Pomona Institutional Review Board has reviewed and approved for conduct this research involving human subjects under protocol YY - ### (meaning year and sequence number).

- A. How will you approach your subjects to potentially participate in the study? Where will you recruit them? Will translation of materials be necessary to other languages or to a different reading and comprehension level for recruiting purposes?** *Consider that children often need simplified language. And studies show that the average adult reads at a 5th to 8th grade level.*

The subjects will be approached through the shops website. I will place an advertisement to participate in the study on the website, with a consent form for potential participants to read. If they agree to the consent form, they will click on a link that will take them to the survey. The survey and consent form will be available in English, Hawaiian, and Japanese. In effect, the subjects could be anyone in Hawaii with access to the internet, who visits the shops website. The advertisement/announcement on the company's website will state the following:

"Attention!! Do you love Mrs. Smith's pies? Would you like to be able to order pies from the comfort of your home, and have them delivered to your doorstep?

If you answered yes to any of these questions, then we here at Mrs. Smith's pie shop invites you to be part of the exciting process of helping us develop our brand new online store. After you read the consent form below, click on the link to take a quick survey. You will be asked questions such as your preferences for pies and other yummy items we currently sell, or hope to. We would also like to know which delivery and payment methods are most convenient for you, our valued customers.

There is no risk in taking our survey, as we do not require any other personal information from you, besides your valued opinions!

We appreciate your time and feedback, and hope that you will join us, and make your opinions heard.

- B. Describe the criteria you will apply when selecting and enrolling subjects into the study.** *Inclusion criteria are those characteristics on which you will be recruiting and accepting subjects. Exclusion criteria are characteristics on which subjects will be screened and potentially excluded from participating.*

The criteria for selecting and enrolling individuals to be subjects is that they must live in Hawaii, have access to the internet, and are willing to take the survey featured on the store website.

- C. Describe your procedures for the recruitment of a representative sample of the population based upon race, ethnicity, gender, health status, or other characteristic. If this is not the case, discuss the**

reasons for not having such a balanced sample (such as, the research is focused on a certain subject group).

The purpose of the research is to find out the potential customers' opinions about the pie shop introducing a new online store. It is not necessary to know participants' race, ethnicity, gender, health status...etc.

VIII. TRAINING

Formal training and practical experience in research with human subjects are critical for the protection of the participants and minimization of risk that might be associated with the conduct of the study. Federal regulations require that investigators possess training. The Cal Poly IRB adopted in 2006 the on-line [CITI program](#) as required training in human subjects research. All investigators submitting applications to the IRB after January 1, 2007, must complete appropriate modules of CITI as a condition of approval of a protocol. Other formal training will be considered by the IRB on an individual basis.

- A. Describe the training possessed by you. Include when it was obtained and the CITI completion report number. Will you obtain any additional training related to this proposal?** If you are a student, your advisor (faculty mentor) must possess training as well, which you are to describe in the next section (VIII.B.).

Business Student

CITI training under California State Polytechnic University, Pomona, completed 05/25/2010, completion report number: xxxxxxxx.

- B. Describe the training possessed by others including your co-investigators, collaborators, students, staff, faculty members, a student's mentor or advisor, etc., from Cal Poly or elsewhere, working on this study. Include when it was obtained and the CITI completion report number.**

Business Professor

CITI training under California State Polytechnic University, Pomona. It was completed 03/01/2010, completion report number: xxxxxxxx.

IX. INFORMED CONSENT

The informed consent form (ICF) is the means by which you as the PI convey the principles of human subjects protections to your subjects: respect, beneficence, and justice. There are examples on the IRB website. Complete the accompanying consent form(s) below. Include it as part of the URL in electronic surveys. Include it when submitting this protocol application for review. Include the assigned IRB protocol number in your ICFs.

- A. How will you obtain and document informed consent (for adults) or assent (for children)? Which study personnel will be involved in obtaining consent and/or assent?** For certain types of research methods, like on-line surveys, it is possible to obtain a waiver of consent (implied or passive) from the subjects. Contact the IRB for a determination and the requirements. A justification must be provided to obtain the waiver.

The survey will be posted on the company's website (<http://www.mrssmithspies.com>), and an informed consent form will be provided before the online survey. If someone agrees to participate in the survey after reading the consent form, he or she will be asked to proceed to the survey. If someone does not agree, he or she will be asked not to proceed to take the survey. The study is anonymous. Any potential customers in Hawaii who have access to Internet can obtain the survey.

- B. Will there be recruitment of subjects who cannot themselves provide informed consent? If so, how will informed consent be documented for this population?**

Not applicable.

- C. Describe how you will maintain the consent forms received from the subjects? Where (location) will they be kept? For how long/until when? Will they be kept separate from subject data and specimens?**

Not applicable.

X. CONSENT FORM

The IRB requests the following header be included in the ICF(s) of all Cal Poly Pomona approved protocols. It is reproduced on the next page followed by a write-in block for your Informed Consent Form to be completed. Alternatively, you can send it

as an attachment, but it must have the informational header below.

California State Polytechnic University, Pomona Informed Consent Form for Research Involving Human Subjects

You are being invited to participate in a research study, which the Cal Poly Pomona Institutional Review Board (IRB) has reviewed and approved for conduct by the investigators named here. This form is designed to provide you - as a human subject - with information about this study. The Investigator or his/her representative will describe this study to you and answer any of your questions. You are entitled to an Experimental Research Subject's Bill of Rights and a copy of this form. If you have any questions about your rights as a subject, complaints about the informed consent process of this research study, or experience an adverse event (something goes wrong), please contact the Compliance Office within Cal Poly Pomona's Office of Research at (909) 869-4215. More information is available at the IRB website, www.csupomona.edu/research/irb.

Below is this header in Spanish:

Forma de Consentimiento Informada para Investigación que Implica Sujetos Humanos

Usted está invitado a participar en un estudio de investigación que el Comité Examinador Institucional (CEI) de Cal Poly Pomona ha revisado y aprobado para ser conducido por los investigadores nombrados aquí. Esta forma está diseñada para proporcionarle información acerca de este estudio en su calidad de sujeto humano. El investigador o su representante le describirán este estudio y le contestarán cualquier pregunta que tenga. Usted tiene derecho a la Declaración de Derechos del Sujeto que participe en una Investigación Experimental y a recibir una copia de este documento. Si tiene alguna pregunta o quejas acerca del proceso descrito en dicho documento, por favor llame a la Oficina de la Conformidad que forma parte de la Oficina de Investigación de la Universidad de Cal Poly Pomona al (909) 869-4215. Más información esa disponible en sitio web de el CEI en el www.csupomona.edu/research/irb.

A properly written Informed Consent Form (ICF) will include the following elements. You, as the Principal Investigator, are responsible for addressing each when writing your consent and/or assent form. Both federal and California regulations require the inclusion of these elements to adequately inform subjects when participating in research. You may wish to use this page as a checklist. Incomplete forms will be returned to you for revision. See the IRB website for examples.

- o A telephone number and/or e-mail address of all primary investigator(s) of this proposal, including faculty members and graduate students, who would be the point(s) of contact for the subjects
- o Affiliations (professional and institution) of the contacts and investigators; use full names, thus don't write Cal Poly Pomona - use California State Polytechnic University, Pomona
- o Clarification of the contacts in research projects which involve multiple sites (there can be multiple offices of research for example)
- o Title of the protocol (same as on the front page of this application)
- o Protocol number as assigned by the IRB (it will be provided after the protocol is submitted to the IRB administrator); it must appear distinctly (e.g., bolded, its own line)
- o A statement that the study you are conducting involves research
- o An explanation of the purpose(s) of the research, why it's being conducted by you
- o A description of what the subject must do as part of the research, what data will be collected, what will happen to the data after the "active" phase of interaction with the subject is completed. (It has been found useful to include blocks in the ICF for subjects to initial when audio or video taping, so as to further document that these methods will be conducted.)
- o The expected duration of the subject's participation on the study (e.g., 50 mins in one day, four visits between May 1 and June 30)
- o The information about the procedures must be presented in layman's terms (at the 5th grade reading level); it must fully explain to the subjects what they are expected to do
- o The entire consent and/or assent form may need to be translated into the subject's language of fluency
- o Identification of any procedures or methods which are experimental
- o A description of any reasonable and foreseeable risks or discomforts to the subject
- o Changes of pronoun as appropriate to the subjects (e.g., you will be asked ...; your child will do ...)
- o A description of any benefits to the subject or others which may reasonably be expected (or not) from the research
- o A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
- o For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments would be available if injury occurs and, if so, what that would consist of and where further information may be obtained
- o California law, under Health & Safety Code Section 24172, requires that any person asked to take part as a subject

in research involving a medical experiment, or any person asked to consent to such participation on behalf of another, is entitled to receive the [Experimental Research Subject's Bill of Rights](#) written in the language in which the person is fluent.

- o An explanation of whom to contact for answers to pertinent questions about the research and research subject's rights, and whom to contact in the case of a research-related injury to the subject
- o A statement that participation is voluntary, that declining to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits, to which the subject is otherwise entitled
- o Printed name and signature lines for the subject and the date signed
- o Printed name and signature lines for the principal investigators (e.g., faculty member or the graduate student conducting the research) and perhaps research associates; and the date signed
- o A statement that the subject is entitled to receive a copy of the completed informed consent form

California State Polytechnic University, Pomona Informed Consent Form for Research Involving Human Subjects

You are being invited to participate in a research study, which the Cal Poly Pomona Institutional Review Board (IRB) has reviewed and approved for conduct by the investigators named here. This form is designed to provide you - as a human subject - with information about this study. The Investigator or his/her representative will describe this study to you and answer any of your questions. You are entitled to an Experimental Research Subject's Bill of Rights and a copy of this form. If you have any questions about your rights as a subject, complaints about the informed consent process of this research study, or experience an adverse event (something goes wrong), please contact the Compliance Office within Cal Poly Pomona's Office of Research at (909) 869-4215. More information is available at the IRB website, www.csupomona.edu/research/irb.

Title of Study: Online strategic research for Mrs. Smith's pie shop

Primary Investigator: Business Student

Phone and Email: (xxx)-xxx-xxxx xxxxx@csupomona.edu

Academic advisor: Business Professor

Phone and Email: (xxx)-xxx-xxxx xxxxx@csupomona.edu

Background of Research

The purpose of this research is to understand customers' opinions and preferences regarding establishing an online store, to help Mrs. Smith's pie shop increase its customer base and expand their business via Internet technology. You are invited to participate in this research in hopes that you can play an important part in helping Mrs. Smith's pie shop learn about their online marketing potential. There are questions about customers' preferred products, the reasonable quantity of products allowed to be ordered, customers' preferred packaging supplies and shipment methods, customers' preferred product price and promotions, payment methods, and online service features.

You have been selected for this study because you are the potential customers for Mrs. Smith's pie shop, and it will be beneficial to have your valuable opinions in order to help the shop improve their products and service to their customers.

Investigational Procedures

If you choose to participate in this study, you will indicate your willingness by clicking below on the link to the online survey. The survey will take around 10 minutes.

Risks and Benefits

This investigational procedure does not pose any more risk than you experience in normal daily living. If you participate in this study, you may gain some basic knowledge about the pie making industry, but there is no compensation for participating. There is no significant benefits or risks involved in the study.

Privacy of Records

This study is anonymous. All the information you provide will be protected. The data will be reported in groups and no identifying information will be collected or reported.

Voluntary Participation

Your decision to participate in this study is voluntary. Even if you decide to participate now, you may stop at any time and close your browser. You may skip any questions you do not wish to answer. If you click on the link below and submit a completed survey, you are indicating your agreement to participate, and acknowledge that you have read and understand this form. If you have any questions, please contact an investigator identified at the top of this form prior to completing the survey.

If you agree to participate, please click the continued button to take the survey.

If you do not agree to participate, you can leave the survey link now.

Survey Link: <https://www.surveymonkey.com/s/mrssmith>

Survey questions:

1. Do you have access to the Internet at home, workplace, or school?

- Yes
- No

2. Have you ever thought about purchasing food online?

- Yes
- No

3. If you do purchase food online, how often do you order food online?

- Everyday
- Often
- Sometimes
- Seldom
- Never

4. Do you ever purchase products from Mrs. Smith's pie shop?

- Yes
- No

5. If so, how often do you purchase products from Mrs. Smith's pie shop?

- Everyday
- Often
- Sometimes
- Seldom
- Never

6. If Mrs. Smith's pie shop has an online store will you consider purchasing from the shop's online store?

- Yes
- No

7. What kind of products are you willing to purchase from Mrs. Smith's online store?

- Pies with fillings
- Pies without fillings
- Danishes
- Others (Please specify)

8. What kind of flavors for pies with fillings are you willing to purchase from Mrs. Smith's online store? (Choose more than one)

- Apple
- Cherry
- Blueberry
- Rhubarb
- Lemon Merengue
- Pot Pie
- Strawberry
- Red bean

9. What kind of flavors for pies without fillings are you willing to purchase from Mrs. Smith's online store? (Choose more than one)

- Cheese Cake

- Chocolate mousse
- Taro Root
- Grasshopper Pie

10. What kind of flavors for danishes are you willing to purchase from Mrs. Smith's online store? (Choose more than one)

- Chocolate
- Cream Cheese
- Apple
- Ham and Cheese
- Spinach and Goat Cheese

11. What is the quantity of pies with fillings are you willing to order?

- _____

12. What is the quantity of pies without fillings are you willing to order?

- _____

13. What is the quantity of danishes you are willing to order?

- _____

14. What kind of packaging do you prefer?

- Carton
- Plastic bag
- Plastic box
- Styrofoam box
- Others (Please specify)

15. What kind of shipment method do you prefer?

- Ship by US Postal Service
- Ship by UPS
- Ship to nearest 7-11
- Ship to the nearest Vons, Albertsons, or other grocery store
- Pick up at Mrs. Smith's pie shop (Hilo branch)

16. What kind of products prices do you think are reasonable?

- Same price as Physical store and added packaging fee and shipping fee depending on the order quantity
- Same price as physical store and added fixed packaging fee and shipping fee
- NT\$1 higher than physical store for each pie with free packaging fee but fixed shipping fee
- NT\$2 higher than physical store for each pie with free packaging fee and shipping fee

17. What kind of promotion do you wish to see on the online store?

- Buy ten get one for free
- Free shipping with NT\$1000 purchase
- 10% off for new online register customers
- 10% off for next order when you introduce new customers to Mrs. Smith's online store

18. What kind of payment method do you prefer?

- Credit card
- ATM transfer
- Payment through 7-11
- Payment through CVS

19. What kind of services are you looking for from Mrs. Smith's online store? (Choose more than one)

- Order products
- Payment & Refund
- Contact information
- Store policy and promotion
- Comments and feedback
- Products introduction
- Heating methods

20. What kind of suggestions do you have for Mrs. Smith's pie shops?

(Please specify)

Thank you for your time!