**INSTRUCTIONS**

Determining what research meets the federal regulatory definition of human subjects research can often be a difficult and confusing task. Currently, neither federal regulation nor Baylor policy requires a researcher to submit to the IRB for a determination of whether research constitutes human subject research. **This form is both:**

1. **A worksheet to help you determine if your research involves human subjects (sections I-III); and**
2. **A submission form to request formal review (optional).**

When to use this form:

* Prior to initiating any research activities.
* If you are unsure whether or not you need to submit your research for either an exemption determination or IRB review.
* If you are unsure if your activity is research under the federal definition.
* If you are unsure if your research involves human subjects.
* If you need a **formal documented determination that IRB review is not required**. Increasingly sponsors (e.g., funding agencies, device and drug manufacturers, etc.), faculty advisors, collaborators, vendors, or journal editors want verification from an impartial source that activities do not require IRB approval.

**The Office of the Vice Provost for Research (OVPR) has final authority in determining if an activity is human subjects research requiring IRB review or eligible for exemption. A determination that IRB review is not required does not absolve individuals conducting the activity of any other ethical or legal responsibilities and obligations that may apply.**

How to use this form:

* Consider and answer each question in the order presented.
* Use lay language and spell out acronyms. Do not cut and paste from or refer to a grant or abstract.
* The term “data” for the purpose of this form refers to information of any type (e.g., records, data sets, recordings, photos, scans, etc.) including any biological specimens.
* To obtain a formal determination that IRB review is not required from OVPR, please submit a completed form via IRBNet.

You may reference the OHRP Decision Charts to help you determine whether your research qualifies as research involving human subjects: <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html>

**If you have any questions, please contact the Office of Research Compliance at:** [IRB@baylor.edu](mailto:IRB@baylor.edu) **or T: 254-710-3708**

**This form cannot be used to request an exemption or IRB approval.**

**SECTION I: IS THE ACTIVITY RESEARCH?**

|  |  |  |
| --- | --- | --- |
| Federal regulations define ***research*** as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.  [45 CFR 46.102(l)] | | |
| **A.** | Does your research fall within any of the following categories?  If **YES**, federal regulation deems your activity as **NOT RESEARCH**. *Do not fill out the rest of the form.* | Yes  No |
| * Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected. * Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). * Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes. * Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions. | |
| **B.** | Is the activity a systematic investigation? | Yes  No |
| * A systematic investigation is an activity that involves a prospective plan that incorporates data collection (quantitative or qualitative) and data analysis to answer a question. * Activities are not research if they do not involve a systematic approach involving a predetermined method for studying a specific topic, answering a specific question, testing a specific hypothesis, or developing theory. * Examples of activities that typically ***are*** systematic investigations:   + Interviews and focus groups   + Surveys and questionnaires   + Analysis of data and/or specimens   + Observational studies and Epidemiological studies   + Cognitive and perceptual experiments   + Medical chart reviews * Examples of activities that typically ***are not*** systematic investigations:   + Training and classroom activities where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods provided the activities are not designed to develop or contribute to generalizable knowledge   + Single case reports | |
| **C.** | Is the activity designed to develop or contribute to generalizable knowledge? | Yes  No |
| * Activities designed to develop or contribute to generalizable knowledge are those designed to draw general conclusions, inform policy, or generalize findings beyond a single individual or an internal program. * Results do not have to be published or presented to develop or contribute to generalizable knowledge. * Examples of activities that typically ***are*** designed to develop or contribute to generalizable knowledge:   + Student independent studies, directed projects, theses, or dissertations   + Anonymous surveys   + Oral histories designed to compare/contrast, draw conclusions, inform policy, or generalize findings * Examples of activities that typically ***are not*** designed to develop or contribute to generalizable knowledge:   + Biographies   + Oral histories that are designed to create a historical record of specific personal events and experiences and provide a venue for people to tell their stories.   + Program or course evaluations, unless they can be generalized to other individuals   + Classroom exercises that are solely to teach research methodologies or simulate research activities   + Activities required for quality assessment (QA) or quality improvement (QI) | |
| **NEXT STEP**   * If **both B & C** above are checked **YES**, the activity is research. **Proceed to the next section.** * If **either or both B & C** above are checked **NO**, **proceed to** **SECTION III**. | | |

**SECTION II: DOES THE RESEARCH INVOLVE HUMAN SUBJECTS?**

|  |  |  |  |
| --- | --- | --- | --- |
| Federal regulations define human subjects as a living individual about whom an investigator (whether professional or student) conducting research (1) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens, or (2) Obtains, uses, studies, analyzes, or generates identifiable private information or  identifiable biospecimens. [45 CFR 46.102(e)] | | | |
| Is data or biospecimens being **obtained** **about** a **living** individual? | | Yes  No | |
| Obtain: The receipt or access of information or specimens for research purposes. This includes information or specimens already in the possession of the researcher. Additionally, this includes “**third party**” or “**secondary subject**” situations in which researchers obtain information about one individual through interaction with another individual.  About: The data relates to the person. Asking individuals what they think about something (e.g., asking for an opinion) is almost always about the person. Asking for factual information, or other questions where the answers are expected to be independent of the person being asked, are generally not about the individual.  Living: Individuals who are alive according to applicable local and national regulations. With respect to specimens, data, and other information gathered without direct interaction with the individual, it is assumed that the individuals are living unless there is a reason to think otherwise. | | | |
| **NEXT STEP**   * If checked **YES**, proceed to **the next question**. * If checked **NO**, human subjects are not involved. **Proceed to SECTION III.** | | | |
|  | | | |
| **A.** | Will the data or biospecimens be obtained through **intervention**? | Yes  No | |
| Intervention: Physical procedures or manipulations of the individual or the individual’s environment, that are performed for research purposes. Manipulations may be physical, social, psychological, or emotional. “Environment” includes an individual’s social and virtual environments as well as physical environment. | | |
| **B.** | Will the data or biospecimens be obtained through **interaction**? | Yes  No | |
| Interaction: Communication or interpersonal contact between a member of the research team and the individual. Surveys – whether in-person, web-based, mail, email, phone, etc. – are an interaction between researchers and individuals. | | |
| **NEXT STEP**   * If **ONE** or **BOTH of A & B** are checked **YES**, human subjects are involved. **DO NOT submit this form to the IRB.** * If **both** boxes are checked **NO**, **proceed to the next question**. | | | |
|  | | | |
| **A.** | Will the data or biospecimens be **identifiable**? | Yes  No | |
| Identifiable: The identity of the individual is or may readily be ascertained or associated with the information/biospecimen either directly or indirectly (e.g., a code & key, analysis of a collection of the data variables, etc.).  Note about coded data: Information or biospecimens are not considered to be individually identifiable when they cannot be linked to specific individuals by the researcher either directly or indirectly through coding systems. ***Coded*** means that:   1. Identifying information (such as name or social security number) that would enable the researcher to readily ascertain the identity of the individual to whom the information or specimens pertain has been replaced with a number, letter, symbol, or combination thereof (i.e., the code); **and** 2. A key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.   Therefore, research involving ONLY coded information or specimens is not considered identifiable and not considered to involve human subjects if the following conditions are BOTH met:   1. the information or specimens were not collected specifically for the currently proposed research through an interaction or intervention with living individuals; **and** 2. the researcher(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:    1. the key to decipher the code is destroyed before the research begins;    2. the researcher and the holder of the key enter into an agreement prohibiting the release of the key to the researcher(s) under any circumstances, until the individuals are deceased (note: the holder of the key cannot be a collaborator on the research for this to apply);    3. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to researchers under any circumstances, until the individuals are deceased; or    4. there are other legal requirements prohibiting the release of the key to the researchers, until the individuals are deceased. | | |
| **B.** | Will the data contain **private information**? | | Yes  No |
| Private information is defined as one or both of the following:   * Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place. * Information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record, an education record, or a residual medical specimen that is “leftover” from a health care procedure).   Please note the following:   * Any information about individuals that is collected specifically for the proposed research study through and interaction or intervention with the individual by the investigator or other research team member is considered to be private. * If permission is required to obtain/access information, then the information is usually considered private. * Biospecimens are assumed to be private unless meet publicly available definition. * Publicly available data are not considered private. Publicly available means that the general public could obtain the data or specimens. If access is limited to researchers, data/biospecimens are not considered publicly available.   There are numerous “gray” areas in distinguishing “private” from “non-private.” For example, there are some situations that are best considered “semi-private.” This may include some behaviors, communications, and interactions that occur in electronic or social media. Also, a specific type of information may be considered private for one group of individuals but not for another. | | |
| **NEXT STEP**   * If **BOTH A & B** are checked **YES**, human subjects are involved. **DO NOT submit this form to the IRB.** * If **ONE** or **BOTH of A & B** is checked **NO**, human subjects are not involved. **Proceed to SECTION III**. | | | |

**SECTION III: OTHER ACTIVITIES THAT REQUIRE IRB REVIEW**

|  |  |
| --- | --- |
| Does the activity involve the use of any of the following: | |
|  | **DRUG** An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or an article (other than food) intended to affect the structure or any function of the body of man or other animals. (Note, however, that (1) a dietary supplement intended only to affect the structure or function of the body and not intended for a therapeutic purpose is not a drug and (2) a food used as such (i.e., primarily for its taste, aroma, or nutritive value) and not for a therapeutic purpose or to affect the structure or function of the body, other than by providing nutrition, is not a drug.) |
|  | **BIOLOGIC** A virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. (Biological products include, among other products, bacterial vaccines, allergenic extracts, gene therapy products, growth factors, cytokines, and monoclonal antibodies.) |
|  | **DIETARY SUPPLEMENT** A product taken by mouth that is intended to supplement the diet and that contains one or more dietary ingredients. The dietary ingredients in these products can include vitamins, minerals, herbs and other botanicals, amino acids, other dietary substances intended to supplement the diet, and concentrates, metabolites, constituents, extracts, or combinations of the preceding types of ingredients. Dietary supplements can be found in many forms such as tablets, capsules, softgels, liquids, or powders. |
|  | **DEVICE** An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article which is intended for (1) use in the diagnosis of disease or other conditions, or (2) use in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or (3) intended to affect the structure or any function of the body of man or other animals. |
|  | **IN VITRO DEVICE** A product used to collect, prepare, and examine specimens (e.g., blood, serum, urine, spinal fluid, tissue samples) after they are removed from the human body. **Note:** FDA regulations consider anonymous specimens to be human subjects and requires IRB review. |
| **NEXT STEP**  If **ANY OF THE ABOVE BOXES** are checked, the activity is human subjects research as defined by the FDA.  **DO NOT submit this form to the IRB.** | |

**You have finished the worksheet portion of the form. Complete the following pages *ONLY* if you wish to submit this form to OVPR for a formal determination that IRB review is not required.**

**In order for OVPR to review, the entire form with answers to the worksheet questions is required to be submitted.**

**PRINCIPAL INVESTIGATOR (must be Baylor University faculty, staff, or student)**

|  |  |  |  |
| --- | --- | --- | --- |
| Name: | | | Degree(s): |
| Department: | | | Phone: |
| Campus Address: | | | Email: |
| Faculty  Staff  Student | | | |
|  | | | |
| **If student:** | | | |
| Undergraduate student | Graduate or Professional Student  (degree program): | | |
| Faculty Advisor: | | | |
| Email: | | Phone: | |

**ACTIVITY/PROJECT INFORMATION**

(in lieu of filling out this section, you can submit a separate research plan/protocol document)

|  |
| --- |
| Title of Activity/Project: |
| Purpose of Activity/Project: |
| Intended Use of Results: |
| Number of Participants: |
| Description of Activity/Project: |

**FUNDING**

|  |  |
| --- | --- |
| Indicate the type of funding for this research: | |
|  | No external or internal funding. |
|  | Internal funding.  Approved  Pending  List source(s): |
|  | External funding.  Approved  Pending  List source(s) (no initials or acronyms):  Is Baylor the primary awardee?  Yes  No. If no, identify primary awardee:  Has this proposal been submitted to the BU Office of Sponsored Programs?  Yes  No  \*For Department of Defense research, submit **SUPPLEMENT: DEPARTMENT OF DEFENSE (F-06)\*** |
|  | Intend to submit for funding. List source(s)?  Date of submission: |

**INCENTIVES**

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| --- |
| An incentive is anything of value that will be offered to motivate or encourage an individual to participate in the research or to “compensate” the individual for time/effort. This could be money, gift cards, t-shirts, tickets, course or extra credit, etc. |
|  |
| Will individuals be offered any of the following? *[Check all that apply.]*  Cash. Amount:  Gift Card. Amount:  Tangible items (e.g., t-shirt, mug, tote bag)  Extra credit or course credit  Other. Identify: |

**OPTIONAL**

**The following question is optional and will only be used for internal purposes within OVPR.**

|  |  |
| --- | --- |
| Why are you requesting an official determination? *[Check all that apply.]* | |
|  | Not sure if the activity is human subjects research or not. |
|  | I would like official documentation for my files. |
|  | I hope to publish in a peer reviewed journal and I would like to know that IRB review is not required prior to beginning the study. |
|  | Review of incentive/compensation plan for Accounts Payable documentation. |
|  | Request from Baylor’s Office of Sponsored Programs to release award funds. |
|  | Review is a requirement by one or more of the following:  Department/Faculty Advisor  Thesis/Dissertation  Other Baylor review committee (e.g., IACUC, IBC, etc.)  Sponsor/Funding Agency  Collaborator or Collaborating Institution  Performance Site  Journal  Other: |