|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Instructions** | | | | | | | | |
| * IMPORTANT:This template should NOT be used for activities that may be regulated by U.S. Food & Drug Administration (FDA), such as those involving drugs, medical devices, human food additives, color additives, electronic products, or any other test articles regulated by the FDA. * Only certain activities require MSU IRB approval. These include activities that meet the federal definition of “research” involving “human subjects.” *Complete and upload this form when there are any questions of whether an activity meets the federal definition of “human subject research.”* If it is determined that the activity is not “human subject research” and is not otherwise subject to MSU IRB review, a determination letter will be provided. * CLICK™ IRB:   + Include the template with a New Study Submission.   + Upload the completed template to the Basic Information SmartForm page, Question 10. * See HRPP Manual Section 4-3, Determination of Human Subject Research, for more information | | | | | | | | |
| **Complete Questions 1-3.** | | | | | | | | |
| 1 | Study title. | | | | | | | |
| 2 | Briefly explain why you believe your study does not require MSU IRB review. | | | | | | | |
| 3 | MSU is or may be the Primary Awardee. | | | No  Yes | | | | |
| * *Please note that MSU would be considered engaged in an HHS-conducted or -supported non-exempt human subjects research project if MSU receives an award through a grant, contract, or cooperative agreement directly from HHS for the non-exempt human subjects research (i.e. awardee institutions), even where all activities involving human subjects are carried out by employees or agents of another institution.* | | | | | | | |
| 4 | Does the activity involve drugs, medical devices, human food additive, color additive, electronic product, or any other test article regulated by the FDA? | No  Yes | | | | | | |
| If you answered YES, complete 4A and 4B. | | | | | | | |
| 4A | Will data be submitted to or held for inspection by the FDA in support of a research application or marketing permit? | No  Yes | | | | | | |
| 4B | Will the safety or effectiveness of a device be tested on human samples? | No  Yes | | | | | | |
| **Complete Questions 5-6, unless the activity is conducted, supported, or otherwise required to comply with the U.S. Department of Justice requirements.** If the activity is conducted, supported, or otherwise required to comply with the U.S. Department of Justice requirements, complete questions 7-8 instead. | | | | | | | | |
| 5 | Is the activity research? | | | No  Yes | | | | |
| * *Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For purposes of this part, the following activities are deemed not to be research:*   + *(1) 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.*   + *(2) 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).*   + *(3) 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.*   + *(4) Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.* * *Note: Quality assurance (QA) or improvement (QI) or program evaluation (PE) are activities that often involve individuals but are undertaken to measure effectiveness of a practice, program, or service and may not be considered a systematic investigation designed to develop or contribute to generalizable knowledge and therefore may not meet the federal definition of “research.” Please see HRPP Manual 12-1, QA, QI, or PE for more information.* * *Although publication can be an indication that a study meets the definition of research, “publication” is not within the definition of research and it is not necessary or sufficient to meet the definition of research.* | | | | | | | |
| If you answered YES, please explain. | | | | | | | |
| If you answered NO, complete 5A and 5B. | | | | | | | |
| 5A | The activity is a systematic investigation. | | No  Yes | | | | | |
| * *Systematic means having or involving a system, method, or plan including plans for analyses (e.g., a protocol, grant proposal, work statement).* * *Investigation means a searching inquiry for facts; detailed or careful examination (this may be an hypothesis for example).*   *To be considered a “systematic investigation,” the concept of the activity must:*   * *Attempt to answer research questions (in some research, this would be a hypothesis)* * *Is methodologically driven, i.e., collects data or information in an organized & consistent way* * *Data or information is analyzed in some way, be it quantitative or qualitative data analysis* * *Conclusions are drawn from the results* | | | | | | | |
| If you answered NO, please explain. | | | | | | | |
| 5B | The activity is designed to develop or contribute to generalizable knowledge. | | | No  Yes | | | | |
| * *Contribute means to result in.* * *Generalizable means universally or widely accepted to apply to a population beyond the site or population studied.* * *Knowledge means conclusions expressed for example in theories, principles, and statements of relationships in a particular discipline or body of knowledge.* * *Evaluate if the study method is adequately DESIGNED to develop or contribute to generalizable knowledge (please note the specific language is DESIGNED - not INTENDED).*   *To be considered “generalizable knowledge,” the activity would include the following concepts:*   * *Knowledge contributes to a theoretical framework of an established body of knowledge* * *Results are expected to be generalized to a larger population beyond the site of data collection or population studied* * *Results are intended to be replicated in other settings*   *MSU masters’ theses and Ph.D. dissertations are considered to represent generalizable knowledge.* | | | | | | | |
| If you answered NO, please explain. | | | | | | | |
| 6 | Does the activity involve human subjects? | | | | No  Yes | | | |
| *Human subject means a living individual about whom an investigator (whether professional or student) conducting research:*   * *Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or* * *Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.* | | | | | | | |
| If you answered YES, please explain. | | | | | | | |
| If you answered NO, complete 6A, 6B, 6C, and 6D. | | | | | | | |
| 6A | Living individuals are involved. | | | | | No  Yes | | |
| *For example, obtaining information only about someone who is deceased would not meet the definition of a human subject.* | | | | | | | |
| If you answered NO, please explain. | | | | | | | |
| 6B | The activity is “*ABOUT*” the living individual. | | | | | | | No  Yes |
| *For example a survey that only collects information about an institution, organization, etc. would not obtain information ABOUT a living individual.  However if any information about the individual (e.g. the respondent’s title, age, opinions, etc.) is also obtained, the research involves human subjects because it is information about the respondent.* | | | | | | | |
| If you answered NO, please explain.  CLICK IRB UPLOAD: Upload a copy of the survey, interview questions, or data collection sheet (if applicable) to the Supporting Documents SmartForm page. | | | | | | | |
| 6C | Information or biospecimens will be obtained through an intervention or interaction. | | | | | | | No  Yes |
| * *Intervention includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes, e.g. physical procedures includes collection of blood pressure, blood draw, e.g. manipulation of subject or their environment includes watching a movie, listening to music, playing a video game.* * *Interaction includes communication or interpersonal contact between investigator and subject, e.g. online surveys, telephone interviews, focus groups.* | | | | | | | |
|  | If you answered NO, please explain. | | | | | | | |
| 6D | Identifiable private information will be obtained. | | | | | | | No  Yes |
| * *Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).* * *Identifiable private information is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.* * *For example, private identifiable information includes data or specimens obtained by the investigator that are labeled with, or accompanied by, information that could readily identify the subject. However, OHRP does not consider research involving* ***only*** *coded private information or specimens to involve human subjects if the following conditions are both met:*   + *the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and*   + *the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example, investigator and holder of the key enter into an agreement, IRB approved policies and procedures that prohibit release of key, other legal requirements.* | | | | | | | |
| If you answered NO, please explain.  CLICK IRB UPLOAD: Upload a complete list of variables to the Supporting Documents SmartForm page. | | | | | | | |
| 6E | Identifiable biospecimen(s) will be obtained.   * *An identifiable biospecimen is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen* | | | | | | No  Yes | |
| If you answered NO, please explain. | | | | | | | |
| **Complete Questions 7-8 ONLY IF the activity is conducted, supported, or otherwise required by the U.S. Department of Justice.** | | | | | | | | |
| 7 | Is the activity research? | | | | | | | No  Yes |
|  | * *Research* *means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.* * *Note: Quality assurance (QA) or improvement (QI) or program evaluation (PE) are activities that often involve individuals but are undertaken to measure effectiveness of a practice, program, or service and may not be considered a systematic investigation designed to develop or contribute to generalizable knowledge and therefore may not meet the federal definition of “research.” Please see HRPP Manual 12-1, QA, QI, or PE for more information.* * *Although publication can be an indication that a study meets the definition of research, “publication” is not within the definition of research and it is not necessary or sufficient to meet the definition of research.* | | | | | | | |
|  | If you answered YES, please explain. | | | | | | | |
| If you answered NO, complete 7A and 7B. | | | | | | | |
| 7A | The activity is a systematic investigation. | | No  Yes | | | | | |
| * *Systematic means having or involving a system, method, or plan including plans for analyses (e.g., a protocol, grant proposal, work statement).* * *Investigation means a searching inquiry for facts; detailed or careful examination (this may be a hypothesis for example).*   *To be considered a “systematic investigation,” the concept of the activity must:*   * *Attempt to answer research questions (in some research, this would be a hypothesis)* * *Is methodologically driven, i.e., collects data or information in an organized & consistent way* * *Data or information is analyzed in some way, be it quantitative or qualitative data analysis* * *Conclusions are drawn from the results* | | | | | | | |
|  | If you answered NO, please explain. | | | | | | | |
| 7B | The activity is designed to develop or contribute to generalizable knowledge. | | | No  Yes | | | | |
| * *Contribute means to result in.* * *Generalizable means universally or widely accepted to apply to a population beyond the site or population studied.* * *Knowledge means conclusions expressed for example in theories, principles, and statements of relationships in a particular discipline or body of knowledge.* * *Evaluate if the study method is adequately DESIGNED to develop or contribute to generalizable knowledge (please note the specific language is DESIGNED - not INTENDED).*   *To be considered “generalizable knowledge,” the activity would include the following concepts:*   * *Knowledge contributes to a theoretical framework of an established body of knowledge* * *Results are expected to be generalized to a larger population beyond the site of data collection or population studied* * *Results are intended to be replicated in other settings*   *MSU masters’ theses and Ph.D. dissertations are considered to represent generalizable knowledge.* | | | | | | | |
|  | If you answered NO, please explain. | | | | | | | |
| 8 | Does the activity involve human subjects? | | | | No  Yes | | | |
| *Human subject* *means a living individual about whom an investigator (whether professional or student) conducting research obtains: (1) Data through intervention or interaction with the individual, or (2) Identifiable private information.* | | | | | | | |
| If you answered YES, please explain. | | | | | | | |
| If you answered NO, complete 8A, 8B, 8C, and 8D. | | | | | | | |
| 8A | Living individuals are involved. | | | | | No  Yes | | |
| *For example, obtaining information only about someone who is deceased would not meet the definition of a human subject.* | | | | | | | |
|  | If you answered NO, please explain. | | | | | | | |
| 8B | The activity is “*ABOUT*” the living individual. | | | | | | | No  Yes |
| *For example a survey that only collects information about an institution, organization, etc. would not obtain information ABOUT a living individual.  However if any information about the individual (e.g. the respondent’s title, age, opinions, etc.) is also obtained, the research involves human subjects because it is information about the respondent.* | | | | | | | |
|  | If you answered NO, please explain.  CLICK IRB UPLOAD: Upload a copy of the survey, interview questions, or data collection sheet (if applicable) to the Supporting Documents SmartForm page. | | | | | | | |
| 8C | Data will be obtained through an intervention or interaction. | | | | | | | No  Yes |
|  | *Intervention means both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or subject's environment that are performed for research purposes, e.g. physical procedures includes collection of blood pressure, blood draw, e.g. manipulation of subject or their environment includes watching a movie, listening to music, playing a video game*  *Interaction includes communication or interpersonal contact between investigator and subject, e.g. online surveys, telephone interviews, focus groups.* | | | | | | | |
|  | If you answered NO, please explain. | | | | | | | |
| 8D | Identifiable private information will be obtained. | | | | | | | No  Yes |
| * *Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and 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).* * *Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. 45 CFR 46.102(f)* * *For example, private identifiable information includes data or specimens obtained by the investigator that are labeled with, or accompanied by, information that could readily identify the subject. However, OHRP does not consider research involving* ***only*** *coded private information or specimens to involve human subjects if the following conditions are both met:*   + *the private information or specimens were not collected specifically for the currently proposed research project through an interaction or intervention with living individuals; and*   + *the investigator(s) cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example, investigator and holder of the key enter into an agreement, IRB approved policies and procedures that prohibit release of key, other legal requirements* | | | | | | | |
|  | If you answered NO, please explain.  CLICK IRB UPLOAD: Upload a complete list of variables to the Supporting Documents SmartForm page. | | | | | | | |