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. For the purpose 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

Human subject means a living individual about whom an investigator (whether professional or student) conducting research:
(i) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens or
(ii) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Intervention includes both physical procedures by which information or biospecimens are gathered (example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes. Interaction includes communication or interpersonal contact between investigator and subject.

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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).

Table 1: Examples of What Does and Does Not Require Loyola IRB Review and Approval Prior to Initiation of Research.

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Clinical Research	Involves research to increase scientific understanding about normal or abnormal physiology, disease states or development and to evaluate the safety, effectiveness or usefulness of a medical product, procedure, or intervention.	YES
Pre-Review of Clinical Data Sets	Preliminary activities typically designed to help the Investigator refine data collection procedures. This data is to be included in the analysis or publication.	YES
	Activities (e.g., review of medical data, queries, etc.) intended only to assess the feasibility of future research.	NO
Research Involving Only Decedents	Research involving only data (or tissue) obtained from individuals who are deceased prior to the conduct of the research. There must not be any interaction or intervention with living individuals, or collection of private data or specimens associated with living individuals. Under HIPAA regulations, researchers must obtain a HIPAA waiver of authorization for review of identifiable protected health information (PHI).	NO *(contact Privacy Officer for HIPAA requirements)*
Standard Diagnostic or Therapeutic Procedures	The collection of data about a series of established and accepted diagnostic or therapeutic procedures, or instructional methods for dissemination or contribution to generalizable knowledge.	YES
	An alteration in patient care or assignment for research purposes.	YES
	A diagnostic procedure added to a standard treatment for the purpose of research.	YES
	An established and accepted diagnostic, therapeutic procedure or instructional method, performed only for the benefit of a patient or student but not for the purposes of research.	NO
Case Report - Clinical	Report about three or less clinical experiences or observations identified in the course of clinical care, provided that it does not involve biospecimens or FDA regulated products (e.g., drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE. Case reports are generally done by retrospective review of medical records and highlights a unique treatment, case or outcome. Please note: HIPAA polices apply to this project.	NO
Case Report - Other	Report about experiences or observations associated with three or less individuals.	NO

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Quality Assurance and Quality Improvement (QA/QI) Activities - Clinical or Procedures (Federal guidance on QA/QI activities is available)	A QA/QI activity that involves introducing an untested or innovative practice or intervention, for not only the purpose of improving quality, but also for establishing scientific evidence to determine how well the practice/intervention achieves its intended results.	YES
	Systematic, data-guided activities designed to improve clinical care, patient safety and health care operations. The activity is designed to bring about immediate positive changes in the delivery of health care, programs, or business practices at Loyola University Maryland. If there is intent to disseminate results beyond Loyola, please contact ORSP for further guidance.	NO
Quality Assurance and Quality Improvement (QA/QI) Activities -Non-Clinical (Federal guidance on QA/QI activities is available at)	A QA/QI activity that involves introducing an untested or innovative practice or intervention, for not only the purpose of improving quality, but also for establishing scientific evidence to determine how well the practice/intervention achieves its intended results.	YES
	Data collected with the limited intent of evaluating and improving existing services and programs or for developing new services or programs at Loyola University Maryland. Examples include teaching evaluations or customer service surveys. Contact ORSP with questions or additional guidance.	NO
Innovative Procedures, Treatment, or Instructional Methods	Systematic investigation of innovations in diagnostic, therapeutic procedure or instructional method in multiple participants [more than three (3)]. The investigation is designed to test a hypothesis, permit conclusions to be drawn, and thereby develop or contribute to generalizable knowledge.	YES
	The use of innovative interventions that are designed solely to enhance the well-being of an individual patient or client and have a reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the particular individual.	NO *(unless FDA regulations requiring IRB approval apply such as use of: articles (e.g., drugs, devices, biologics) that have not been approved for use in humans; articles requiring exemption from FDA oversight; articles under an IND/IDE)*
Establishing Subject Pools	Activities with the purpose of recruiting subjects for future research studies.	YES
Pilot Studies	Pilot studies involving human subjects are considered human subjects research.	YES

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Secondary Analysis of Existing Data (already collected at the time the current research is proposed)	Secondary analysis of existing data or documents (**public or otherwise**), such as medical records, student records, data collected from previous studies, audio/video recordings, etc. that were initially collected for another purpose require review when the investigator initially has access to identifiable private information (**direct or indirect identifiers**). Even if the investigator abstracts the data in such a way that the information can no longer be connected to the identity of the subjects, this is human subjects research.	YES
Research Using Publicly Available Data Sets	Public use data sets (such as portions of U.S. Census data, data from the National Center for Educational Statistics, National Center for Health Statistics, etc.) are data sets prepared with the intent of making them available for the public. The data available to the public are not individually identifiable and therefore their analysis would not involve human subjects.	NO
De-Identified Existing Data	Data from agencies, organizations, or other research studies can represent information on individuals, however, if the dataset can in no way be linked back to the subjects (through a key to a coding system or by other means) by **the agency or the investigato**r, its subsequent use by investigators would not constitute human subjects research.	NO
Research on Organizations	Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources. Does not include identifiable private information about individual members, employees, or staff of the organization.	NO
Community Service Projects	Donated service or activity that is performed by someone or a group of people solely for the benefit of the public or its institutions.	NO *(but if human subjects data are collected during the activity to be used for research protocols, submission is required to the IRB)*
Secondary use of research data	Analysis of data gathered for a previous research protocol not related to current proposal and the data are de-identified or identified. De-identified means removal of the 18 identifiers recognized by the HIPAA regulations (HIPAA regulations).	YES

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Behavioral and Social Sciences Research	Focuses on individual and group behavior, mental processes, or social constructs and usually generates data by means of surveys, interviews, observations, studies of existing records, and experimental designs involving exposure to some type of stimulus or environmental intervention.	YES
Oral History	Interviews concerning the past that collect and interpret the voices and memories of people as a method of historical documentation and that are preserved by placement in some form of repository or archive for access by other researchers. Research activities conform to the Principles of Best Practices of the Oral History Association	NO *(but exercise of professional ethics is expected)*
Journalism	Activities focused on the collection, verification, reporting, and analysis of information or facts on current events, trends, issues or individuals involved in such events or issues. There is no intent to test hypotheses, and activities cannot reasonably be characterized as comprising systematic investigation. Research activities should be consistent with the Code of Ethics of the Society of Professional Journalists	NO *(but exercise of professional ethics is expected)*
Master's thesis/ Doctoral Dissertation/ Capstone	Graduate studies which involve human subjects or a clinical investigation which results in a thesis, a dissertation research or a capstone.	YES
Student Practicum and Internship (Departments within Loyola which actively seek opportunities for their students to become involved in "real world" activities or work assignments that will introduce them to and, in some cases, provide practical experiences in their chosen profession)	A practicum/internship that falls within the work scope of a local, state, or federal agency (*e.g.* Public Health Agency) or employment by private industry involving data collection for non-research purposes. No *a priori* research design or intent.	NO *(but professional standards apply)*
	Use of or access to human subjects data previously collected for non-research purposes (perhaps through a circumstance like the one above) in a systematic investigation designed to contribute to generalizable knowledge, one indicator of which is publication.	YES
	Independent research project not falling within the scope of a previously approved project.	YES
	Participation with or providing services to a PI conducting IRB-approved research. No work outside the scope of the IRB approval.	YES *(Modification to protocol to add student if providing research assistance at level of study personnel)*

ACTIVITIES	DESCRIPTION	SUBMISSION REQUIRED TO IRB
Classroom Assignments/ Research Methods Classes	Activities designed for educational purposes that teach research methods or demonstrate course concepts. The activities are not intended to create new knowledge or contribute to generalizable knowledge (e.g. published or disseminated at a capstone or conference).	NO *(but instructors have an obligation to ensure students meet professional and ethical standards)*
Internet Research	Research involving online interactions with human subjects where identifiers are known or can be ascertained such as email addresses, certain websites and bulletin boards. Also includes data collected where an individual cannot be directly identified and data are collected through intervention or interaction with research subjects.	YES
	Research involving online interactions with or data collection from internet community members that may expect a level of privacy and confidentiality such as vulnerable populations (HIV patients, alcoholics anonymous, sexual abuse survivors, etc.). Also includes data collected where an individual cannot be directly identified and data are collected through intervention or interaction with research subjects.	YES

Adapted from the University of Kentucky (http://www.research.uky.edu/ori/ORIForms/1-When_IRB_review_needed_guidance.pdf)