If your project includes ONLY those activities listed in this table, you do not need to submit a research application for IRB review. If, however, you need documentation of an NHSR determination by the IRB (for instance, if requested by the sponsor, a collaborator, or journal), submit a NHSR application in Kuali Research for HRPP administrative review. Through the electronic system, HRPP staff will inform you if the project meets the regulatory criteria for NHSR or if it qualifies as research, requiring submission of a research application and review and approval by the IRB.

* 1. [**Case report**](#Case)
	2. [**Decedent research**](#Decedent)
	3. [**Preparatory to research activities**](#Preparatory)
	4. [**Course-related activities**](#Course)
	5. [**Project was or will be conducted as a health care delivery improvement project (QA/QI)**](#QI)
	6. [**Standard medical practice, diagnostic or therapeutic procedures**](#Standard)
	7. [**Innovative procedures, treatments, or instructional methods for individual patient**](#Innovative)
	8. [**Use of publically available data sets**](#Public)
	9. [**Establishing a database/registry strictly for clinical care or improvement projects**](#Registry)
	10. [**Receipt and/or analysis of coded private information/biospecimens**](#Coded)
	11. [**Receipt and/or analysis of limited data sets**](#LDS)
	12. [**Receipt and/or analysis of fully de-identified data or specimens**](#Deidentified)
	13. [**Providing data/biospecimens outside of LSUHSC-NO for research**](#Outside)
	14. [**Public health surveillance activities**](#PHSA)
	15. [**Community service projects**](#Community)
	16. [**Research on organizations**](#Organizations)
	17. [**Oral history**](#Oral)
	18. [**Scholarly and journalistic activities**](#Scholarly)
	19. [**Criminal justice activities**](#Criminal)
	20. [**Authorized operational activities in support of national security missions**](#Security)

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| 1. **Case Report:** The project consists of a case report or retrospective analysis of medical or other experiences/observations associated with *five or less individuals*. If more than five cases are involved in the analytical activity, the activity will constitute “research” and will require IRB review. *A critical component is that nothing was done to the participant(s) with prior “research” intent.*

**NOTE:** Case reports are generally done by retrospective review of medical charts and highlights a unique treatment, case, and outcome. Although there is no requirement for IRB approval for a case report, the HIPAA Privacy Rule restricts how protected health information (individually identifiable health information) may be used and disclosed.For de-identified case reports (devoid of any of the 18 HIPAA identifiers), there is generally no need to obtain the patient’s signed authorization. However, if an author wants to publish a case report, some medical journals require that some type of patient authorization be obtained for de-identified case reports. This [Case Report Consent Form Template](https://www.lsuhsc.edu/administration/academic/ors/docs/Case%20Report_CF%20Template_LSUHSC_v8.05.19Unp.docx) in these instances. The authorization may be obtained by having the patient sign this document, or verbally, depending on the requirements of the publisher. It is the responsibility of the author to ensure that (i) no identifying photos or illustrations are included the case report (e.g. facial pictures have eyes/identifiable features blacked out, tattoos should not be visible) and (ii) the case(s) described in the report are not so unique or unusual that it might be possible for others to identify the patients in the case reports.For any case reports that includes an individual’s protected health information (PHI), the use of that information must be authorized by that individual per HIPAA regulations. Contact the IRB Office if an individual’s PHI will be included in a case report to ensure the HIPAA regulations are adequately addressed in the proposed project. |
| 1. **Decedent Research:** Research that uses ***only*** human cadavers, cadaveric tissue, decedent medical record information or discarded decedent specimens from clinical use is not subject to prior review and approval by the LSUHSC-NO IRB. According to Federal policy, research involving deceased individuals is NHSR and hence does not require IRB oversight **unless the research study includes both living and deceased individuals.**

All of the following statements must be true for the research on decedent PHI to be allowable:* The use is solely for research on the identifiable health information of decedents.
* The PHI sought is necessary for the purposes of the research.
* Upon request, be able to provide documentation of the death of the individual(s) about whom information is being sought.

*Protected health information (PHI):* Health information, including demographic information collected from an individual, that is created or received by a health care provider, health plan, employer, or health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, or to the provision of health care to an individual.**NOTE:** If the research project involves the use and/or collection of PHI of deceased individuals, review and approval by the LSUHSC-NO IRB is not required but HIPAA regulations still apply. The researcher must obtain approval of a Request to Access Decedent Protected Health Information (PHI) by completing the “*Certification of Research on Decedent Information*” form found on our [website](https://www.lsuhsc.edu/administration/academic/ors/docs/decedent.pdf). **Contact the Office of Compliance Programs for inquiries about HIPAA requirements.**  |
| 1. **Preparatory to Research Activities:** Activities (e.g., review of medical data, queries etc.) intended to: develop a research question or hypothesis; prepare a research protocol; write a grant application; or assess the feasibility of conducting a study.

**NOTE:**  If no HIPAA identifiers will be viewed, no certification is needed. However, if the researcher will access and use PHI, the investigator must complete the [Request for Review of Protected Health Information Preparatory to Research](https://www.lsuhsc.edu/administration/academic/ors/docs/Prep%20to%20Research%20Form_Final_9.20.18.docx) form and follow the instructions as listed on the form, obtaining the certifications and submitting it for HIPAA compliance purposes. Details can be found on our [website](https://www.lsuhsc.edu/administration/academic/ors/prep_to_research_guidance.aspx). Uses or disclosures of PHI for reviews that are preparatory to research are subject to the minimum necessary rules. |
| 1. **Course-Related Activities:** The project is limited to course-related activities designed specifically for educational or teaching purposes where data are collected from and about students as part of a routine class exercise or assignment and is not intended for use outside of the classroom (e.g., published as “research” or disseminated at a capstone or conference).

**NOTE:** IRB approval **may be** required if an instructor or department has an academic interest in pedagogy, and the classroom is used to test innovations with the goal of contributing to generalizable knowledge about pedagogy.  |
| 1. **Project was or will be conducted as a health care delivery improvement project** **(QA/QI)**: the project is limited to improvement activities specifically designed to bring about immediate, positive changes in the delivery of health care, programs, or business practices at LSUHSC-NO and associated institutions (e.g., UMC, Children’s hospital). The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.

**Example: Health care delivery improvement project** that is limited to improvement activities specifically designed to bring about immediate, positive changes in the delivery of health care, programs, or business practices at LSUHSC-NO and associated institutions (e.g., UMC, Children’s hospital). The intention of the project is not to generate conclusions that can be applied universally, outside of the immediate environment where the project occurred.**NOTE:** An improvement project is one that meets either of the criteria listed below: * Implementing an accepted practice to improve the delivery or quality of care or services (including, but not limited to education, training and changing procedures related to care or services) if the purposes are limited to altering the utilization of an accepted practice and collecting data to evaluate the effects on the utilization of the practice at LSUHSC-NO and associated institutions (local QI).
* Data collection and analysis, including the use of biospecimens, for LSUHSC-NO and associated institutions’ own internal operational monitoring and program improvement purposes (for existing services and programs and/or the development of new services or programs). The data/biospecimen collection and analysis is limited to the use of data/biospecimens originally collected for any purpose other than the currently proposedactivity, or is obtained through oral or written communications with individuals (e.g., teaching evaluations or customer services surveys/ interviews).

[Click here for additional guidance and examples](https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/)**NOTE:** If the project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project may also constitute human subjects research (HSR) under HHS regulations and requires IRB review and approval.  |
| 1. **Standard Medical Practice, Diagnostic or Therapeutic Procedures** – activities that consist of established and accepted medical practices, diagnostic, therapeutic procedures or instructional methods, performed only for the benefit of a patient or student but not for the purposes of research (*see case reports for exceptions*).

*Medical Practice*: Standard practice, innovative care, or off-label use of FDA-approveddrugs, biologics, devices and other articles or substances that are used in the normal course of medical practice, provided the activity does not involve systematic collection of safety or efficacy data, and is limited to prevention, diagnosis, mitigation, treatment, or cure of disease in affected individuals.**NOTE:** If the activity aims to disseminate or contribute to generalizable knowledge, it may require IRB review and approval. An alteration in patient care or randomization for research purposes will require IRB review and approval.  |
| 1. **Innovative procedures, treatments, or instructional methods for individual patient** - activities consist of an innovative intervention (e.g., procedures/treatment/instructional methods) designed solely to benefit an *individual* patient/client; although the result of the desired outcome is to some degree unproven, there is reasonable expectation of success. The intent of the intervention is to provide diagnosis, preventive treatment, or therapy to the *particular individual*.

**NOTE:** This activity does not qualify as NHSR if FDA regulations requiring IRB approval apply such as the use of: (1) articles (e.g., drugs, devices, and biologics) that have not been approved for use in humans; (2) articles requiring exemption from FDA oversight; (3) articles under an IND/IDE. |
| 1. **Use of publically available data sets:** The project is limited to analyzing **de-identified** data contained within a publicly available dataset.

 *Publicly available*: information shared without conditions on use (e.g., there are not requirements of payment/fee to gain access to the data). Some examples of data sources that qualify as not HSR, unless the researcher has received the restricted use data, include: data files from ICPSR (Interuniversity Consortium for Political and Social Research), Center for Disease Control, and Bureau of Economic Analysis.**NOTE:** IRB review and approval IS required if one of the following conditions is true: * Research will involve merging any of the public data sets in such a way that individuals might be identified.
* Researcher will enhance the public data set with identifiable, or potentially identifiable data.
* Researcher will use a restricted data set.

*Restricted data set: special files distributed by federal agencies and research organizations upon which use restrictions are imposed. These files often contain data such as Social Security numbers, names, or extensive life history markers that might enable an unauthorized user to identify a participant.** Researcher will use data from the NIH GWAS (Genome Wide Association Studies) data repository.
* The data host does require the researcher or the researcher’s institution to sign an agreement (e.g., a Data Use Agreement) or join a membership. The data is available to the public without any terms or conditions.
 |
| 1. **Establishing a database/registry strictly for clinical care or improvement projects**:

The purpose for creating this database/registry is for clinical care and quality improvement activities only, including outcomes evaluation and development of clinical guidelines, provided that the development of generalizable knowledge is not the primary purpose of any studies resulting from such activities; **however, if you wish to do “research” with data/specimens from this database, an additional IRB approval of a protocol may be required.** *Quality Improvement Activities*: aim to improve systems, current programs, and/or organization performance with the intention to improve outcomes to benefit current patients. The creation/use of the registry for performance measurements and reporting could include: * Helping the public make more informed choices regarding health care providers by communicating data regarding physician-specific surgical recovery data or infection rates.
* Practical or administrative uses of such data that might enable insurance companies or health maintenance organizations to make higher performing sites preferred providers, or allow other third parties to create incentives rewarding better performance.

**NOTE:** HIPAA Rule does not require a covered entity to secure individual authorization (nor a waiver) for use/disclosure of PHI for “health care operations” activities as defined by the HIPAA Privacy Rule ([45 CFR 164.501](https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/disclosures-treatment-payment-health-care-operations/index.html)), as long as the covered entity describes the activities in its Notice of Privacy Practices. However, HIPAA authorization is required if there is disclosure of PHI outside of the covered entity. A covered entity must develop policies and procedures that reasonably limit its disclosures of, and requests for, protected health information for payment and health care operations to the minimum necessary. |
| 1. **Receipt and/or analysis of coded private information/biospecimens:** The project is limited to the use of existing and/or prospectively collected coded private information and/or human biological specimens (hereafter referred to as “specimens”) and LSUHSC-NO affiliated investigators cannot readily ascertain the identity of the subjects to whom the information/specimens pertain.

 **From the Office for Human Research Protections (OHRP) guidance document, October 16, 2008:*****\*Coded***means that: (1) identifying information (such as name or social security number) that would enable the investigator to readily ascertain the identity of the individual to whom the private 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.“**Investigator**” includes anyone involved in conducting the research. OHRP and LSUHSC-NO IRB does not consider the act of solely providing coded private information or specimens (for example, by a tissue repository) to constitute involvement in research; however, if the provider of the coded information/ specimens collaborate on other activities related to this research with the investigators (recipients of information/specimens), that would constitute involvement in research. Examples include: (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.***ALL of the following conditions must be met for an activity with Coded information or specimens to be considered as NHSR*:**1. The private information or specimens were/are not collected specifically for the currently proposed project through an interaction or intervention with living individuals:
	* + 1. The person (source) providing the specimens/ data to the investigator will not otherwise be involved in this project, (e.g. not involved in interpretation or analysis of the data or creation and publication or presentation of research results);
			2. No results will be given back to the source of the specimens/data; **AND**
2. The investigators cannot readily ascertain the identity of the individual(s) to whom the coded private information or specimens pertain because, for example:
3. the investigators and the holder of the key (source) will enter into an agreement prohibiting the release of the key to the investigators under any circumstances, until the individuals are deceased *(note: Although HHS regulations do not require the IRB to review and approve this agreement, the signed agreement between the provider and recipient, stipulating that the key will not be released, must be executed prior to the exchange of data/specimens);* **OR**
4. there are IRB-approved written policies and operating procedures for a repository or data management center that prohibit the release of the key to the investigators under any circumstances, until the individuals are deceased; **OR**
5. there are other legal requirements prohibiting the release of the key to the investigators, until the individuals are deceased; **AND**
6. Specimens DO NOT include viable embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines; **AND**
7. Large-scale genomic data, including genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, will NOT used in this project; **AND**
8. Results of the activity will **NOT** be submitted to the FDA or held for inspection by the FDA

**NOTE:** If a researcher or any of the research study personnel listed on the protocol have direct knowledge of subjects or access to the code (possibility to readily ascertain the identity of the individual or of re-identifying subjects), the activity would be human research requiring IRB review. |
| 1. **Receipt and/or analysis of limited data sets:** The project is limited to analyzing a limited data set (LDS) as defined in [45 CFR 164.514(e](https://www.ecfr.gov/cgi-bin/text-idx?SID=56ac5b3575528a002716f06714b1d43d&mc=true&node=se45.1.164_1514&rgn=div8)) of PHI received by an LSUHSC-NO affiliated investigator (recipient) and there is a signed data use agreement (DUA) in place between the provider (or their institution) and the recipient (or their institution).

A LDS is PHI that **excludes** the following direct identifiers of the individual or of relatives, employers, or household members and may be used or disclosed for research purposes without authorization from the research subject or a waiver of authorization from a Privacy Board:* Names, including initials
* Postal address information, other than town or city, State, and zip code
* Telephone or fax numbers
* Electronic email addresses
* Social Security numbers, medical records numbers, health-plan beneficiary numbers, Account numbers
* Certificate/license numbers
* Vehicle identifiers and serial numbers, including license plate numbers
* Device identifiers and serial numbers
* Web Universal Resource Locators (URLs)
* Internet Protocol (IP) address numbers
* Biometric identifies including fingerprints and voice prints
* Full-face photographic images and any comparable image

For any research use of a LDS, the covered entity disclosing the LDS must enter into a Data Use Agreement (DUA) with the recipient of the information. The DUA permits uses and disclosures of the LDS by the recipient, consistent with the purposes of the research, and places limits on which personnel can use or receive the data.**The following conditions must be met for an activity using LDS to be NHSR:** * The data/specimens being used were/are **NOT** collected specifically for the currently proposed project through an interaction or intervention with living individuals, for example:
	+ The data/specimens was collected solely for clinical purposes; or
	+ Data/specimens were collected for unrelated research purposes with no “extra” data collected for use in this project.
	+ If data/specimens were collected with the use of a consent form, the supplier of the secondary use data/specimens agrees with the language in the consent under which the data/specimens were obtained.
* The data/specimens meet the criteria of a Limited Data set per HIPAA regulations
* Data/specimens are not readily identifiable (e.g., project does NOT include large-scale genomic data such as genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data;
* The person (source) providing the data/specimens to the LSUHSC-NO affiliated investigator will not otherwise be involved in this project, (e.g. not involved in interpretation or analysis of the data or creation and publication or presentation of research results).
* A DUA will be duly executed prior to receipt of the LDS, and the data/specimens will be used or disclosed only for the specified purposes.
* Specimens DO NOT include viable human embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines
* Results of the activity will **NOT** be submitted to the FDA or held for inspection by the FDA

**NOTE**: Information is still protected health information or “PHI” under HIPAA. It is not de-identified information and is still subject to the requirements of the Privacy Regulations and the use must agree to the same restrictions, terms and conditions listed in the DUA.  |
| 1. **Receipt and/or analysis of fully de-identified data or specimens**: The project is limited to the use of existing and/or prospectively collected **de-identified** private information and/or human biological specimens (hereafter referred to as “specimens”).

 IRB Approval is not required if **ALL** of the following conditions apply to the project:* The private information or specimens were/are not collected specifically for the currently proposed project through an interaction or intervention with living individuals; **AND**
* If applicable, the investigator(s) can confirm that the use of the information or specimens is not in violation of the terms of use under which the information or specimens were/will be collected (e.g., use of data/specimens agrees with the language in the original consent under which the data/specimens were obtained); **AND**
* The investigator will only receive information or specimens that are **fully de-identified;**

*De-identified* means that the materials to be studied are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers. **To be considered de-identified, nobody, including individuals who are not involved in the conduct of the project, should be able to link the information or specimens back to identifiers**; **and*** The specimens DO NOT include viable human embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines; **and**
* Large-scale genomic data, including data from genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data, will **NOT** be used; and
* Activity is NOT regulated by the Food and Drug Administration (FDA),

**Examples include:** * Analysis of data gathered for a previous research protocol (secondary use data) not related to current proposal and the investigator has no access to identifying data.
* Analysis of specimens from a repository that is completely de-identified (identifiers do not exist).
* Human cells lines obtained from commercial entity and the identifiers were irreversible stripped (de-linked).
* Unidentifiable biospecimens/information obtained from a provider that is prohibited from releasing identifiers by established regulations or policies.

**NOTE**: The investigator must have no subject/donor contact and no access to identifying data.If the investigator is obtaining the data/specimens directly (e.g., through subject contact or process like a chart review where identifiers will be viewed but not necessarily written down) or, the criteria for this activity is not meet and IRB Review and Approval is required.  |
| 1. **Providing data/biospecimens outside of LSUHSC-NO for research**: The activity is limited to providing existing information and/or human biological specimens (hereafter referred to as “data” and/or “specimens”) outside of LSUHSC-NO and/or its affiliates.

**The following conditions must be met for the provision of data/specimens to be NHSR:*** The data/specimens, in its entirety, were collected for purposes other than the proposed project to be done by those with whom the data/specimens will be shared.
* These data/specimens are “on the shelf” (e.g. in medical records/ Pathology at the time the not human subjects research protocol is submitted).
* No results will be given back to the provider of the specimens/data if the provider has access to private information associated with coded data/specimens
* The individuals (LSUHSC-NO affiliated personnel) releasing the data/specimens (providers/source) are NOT working in collaboration with the recipients (investigators) on the research project. **The provider is not an “investigator.”**

*“****Investigato****r” includes anyone involved in conducting the research. Providing coded private information or specimens (for example, by a tissue repository) does not constitute involvement in research; however, if the provider of the coded information/ specimens collaborate on other activities related to the conduct of this research with the investigators (recipients of information/specimens), that would constitute involvement in the conduct of the research. Examples include: (1) the study, interpretation, or analysis of the data resulting from the coded information/ specimens; and (2) authorship of presentations or manuscripts related to the research.** *If original data/specimens were collected for research purposes*, the recipient should obtain assurance from the provider that the data/specimens were obtained with a valid informed consent form under an IRB-approved protocol and that the secondary use of the data/specimens is within the scope of the research described in the original consent. Disagreement exists or may exist if the consent states tissue will be discarded after the original study is completed/ consent states data will not be used for future studies/ consent states no genetic research will be conducted on the specimens.
* Data/specimens must either meet the HIPAA criteria of Limited Data Set, be completely de-identified, or be provided as coded data/specimens so that the investigators cannot readily ascertain the identity of the subjects to whom the data/specimens pertain at the time of release.
* Limited Data Set (LDS) – see detailed requirements listed above for receipt/analysis. DUA must be fully executed prior to issuing the LDS.
* Coded private information/biospecimens – see detailed requirements listed above for receipt/analysis. There must be a safeguard in place prohibiting the release of the key to the code to the investigator (either through an executed agreement, written policies and procedures, or other legal requirements).
* De-identified – see detailed requirements listed above for receipt/analysis. De-identified means that the materials provided are devoid of any of the 18 Protected Health Information elements set forth in the Privacy Rule, as well as any codes that would enable linkage of the information or specimens to individual identifiers.
* The specimens DO NOT include viable human embryos, human fetal tissue, human embryonic stem cells (HESC), induced pluripotent stem cells (IPSC) or human embryonic cell lines.
* Large-scale genomic data, including data from genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, epigenomic, and gene expression data, will not be provided and used in proposed project.
* Activity is NOT regulated by the Food and Drug Administration (FDA

**NOTE:** If recipients (investigators) have direct knowledge of subjects or access to the code (possibility to readily ascertain the identity of the individual or of re-identifying subjects), the activity would be human subjects research requiring IRB review. |
| 1. **Public Health Surveillance Activities**: Activities involving 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).

***Public Health Authority****: An agency or authority of the United States, a state, a territory, a political subdivision of a state or territory, an Indian tribe, or a foreign government, or a person or entity acting under a grant of authority from or contract with such public agency, including the employees or agents of such public agency or its contractors or persons or entities to whom it has granted authority, that is responsible for public health matters as part of its official mandate.***Examples include:**  Monitoring of diseases when mandated by a public health authority such as the CDC or the Louisiana Department of Health) and program evaluation (e.g., immunization coverage or use of clinical preventive services such as mammography). Specific example - U.S. influenza surveillance system, which allows CDC to find out when and where influenza activity is occurring, track influenza-related illness, determine what strains of influenza virus are circulating, detect changes in influenza viruses, and measure the impact influenza is having on hospitalizations and deaths in the United States.See OHRP Guidance titled “[Activities Deemed Not to be Research: Public Health Surveillance 2018 Requirements](https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-activities-deemed-not-be-research-public-health-surveillance/index.html)” for additional information.**NOTE:** IRB approval is required for surveillance activities that are not driven by a public health authority (e.g., epidemiological research, including secondary research evaluating health outcomes, interventions, and disease states; subsequent research using information collected during a public health surveillance activity (e.g., genetic analysis of biospecimens).  |
| 1. **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.

**For Example:** A blood drive, where the goal of the activity is to benefit others in a predictable way, with no intention of conducting research. **NOTE:** If human subjects data are collected during the activity to be used for research protocols, submission to the IRB is required.  |
| 1. **Research on organizations**: Information gathering about organizations, including information about operations, budgets, etc. from organizational spokespersons or data sources.

**NOTE:** The information must not include identifiable private information about individual members, employees, or staff of the organization. If it does, IRB review and approval is required.  |
| 1. **Oral history:** The project is limited to oral history activities, such as open ended interviews, that only document a specific historical event or the experiences of individuals without the intent to draw conclusions or generalize findings.

**NOTE:** IRB approval is required when the oral history activities are intended to produce generalizable conclusions (e.g., that serve as data collection intended to test economic, sociological, or anthropological models/theories). |
| 1. **Scholarly and Journalistic Activities** (e.g., journalism, biography, literary criticism, legal research, and historical scholarship)**:** Activities are limited to the collection and use of information that focus on specific individuals about whom the information is collected or investigations and interviews that focus on specific events, views, trends or individuals involved in such events or issues. The activities can lead to publication in any medium (including electronic), documentary production, or are part of training that is explicitly linked to journalism. There is no intent to test a hypothesis.

**NOTE:** IRB approval may be required when journalists conduct activities normally considered scientific research intended to produce generalizable knowledge (e.g., systematic research, surveys, and/or interviews that are intended to test theories or develop models). Instructors have an obligation to ensure students meet professional and ethical standards.  |
| 1. **Criminal justice activities:** Activities are limited to the collection and analysis of information, biospecimens, or records by or for a criminal justice agency. They must be authorized by law or court order and done solely for criminal justice or criminal investigative purposes. These activities are ones necessary for the operation and implementation of the criminal justice system.

**Example:** The FBI is charged by law with setting standards governing the collection and processing of fingerprints and related biographical information taken from federal and state criminal suspects or offenders and certain sensitive civil employment applicants.**NOTE**: Activities must be performed by or on behalf of an authorized (Federal, State or local) government authority and therefore is unlikely to apply to activities at LSUHSC-NO. Activities that would require IRB approval and review are those not authorized by the law/court order (e.g., social and behavioral studies looking at the causes of criminal behavior).  |
| 1. **Authorized operational activities in support of national security missions:** The project is limited to authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.

Operational activities may include routine outbreak investigations and disease monitoring and studies for internal management purposes, such as program evaluation, quality assurance, quality improvement, fiscal or program audits, marketing studies or contracted for services.**NOTE:** This activity must be performed by or on behalf of an authorized (Federal, State or local) government authority and therefore is unlikely to apply to activities at LSUHSC-NO. |

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| **Version Number** | **Revision Date** | **Summary of Changes** |
|  |  |  |
| 1.0 |  | Implemented May 27, 2020 |