I. PURPOSE/BACKGROUND

This policy and procedure establishes the payment process that University of Louisville faculty and staff must use to ensure compliance with subject privacy and IRS regulations when making payments related to human subjects who take part in University research studies. The Internal Revenue Service (IRS) requires human subject payments aggregating $600 or more paid to an individual during a calendar year be reported on Form 1099-MISC, Miscellaneous Income.

Research relating to individuals and groups may involve the collection and storage of information that, if disclosed to third parties, could cause harm or distress to the subject. Investigators should arrange to protect the confidentiality of such information by omitting information that might lead to the identification of individual subjects, limiting access to the information, anonymizing data, or other means. During the process of obtaining informed consent, the investigator should tell the prospective subjects about the precautions that the investigator will take to protect confidentiality.

An investigator should inform prospective subjects of the limits to the ability of the investigator to ensure strict confidentiality and of the foreseeable adverse social consequences of breaches of confidentiality. For example, some jurisdictions require the reporting to appropriate agencies of certain communicable diseases or evidence of child abuse or neglect. Food and Drug Administration authorities and other federal agencies have the right to inspect clinical-trial records of drug or device studies. A sponsor’s clinical-compliance audit staff may require and obtain access to confidential data. The Institutional Review Board (IRB), IRB support staff, and University financial personnel may see clinical study and payment records as a part of the University’s oversight of research conducted by University faculty. These and similar limits to the ability to maintain confidentiality should be anticipated and disclosed to prospective subjects.

If subjects get paid for participation in a project, parties providing compensation also need to be sensitive to concerns that the form of payment may contain information that would indicate to a third party a subject’s participation in a research project. For example, there may be information in the gift card payment process that could constitute a confidentiality breach, because it could be apparent to the person processing the payment that the recipient of the gift card is a research subject. While the possibility is remote, if the research is of a sensitive nature, this could lead to personal embarrassment, loss of employment and/or insurability.
II. DEFINITIONS

**Human Subject** - 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.

This person may or may not have an affiliation with the University of Louisville.

**Institutional Review Board (IRB)** - A Board whose members are appointed by the Executive Vice President for Research. The Board and its staff are responsible, in conjunction with administrative officers of the University of Louisville, for ensuring that University personnel and researchers comply with applicable federal regulations and guidelines.

**Research** - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalized knowledge.

**Subject Payments** - cash equivalent and tangible item payments to individuals (subjects) for their participation and time commitment in a clinical trial or social science survey, etc.

III. POLICY

The University of Louisville payment process will maintain research subject confidentiality, to the extent possible under the law, while meeting Internal Revenue Service (IRS) reporting requirements and conform to the University's standard accounting and payment practices. Individuals who take part in University research studies often receive payment for their participation as human subjects. University faculty and staff have a legal obligation to maintain confidentiality of those individuals. The University and the investigator will also take steps to maintain the confidentiality of human subjects when making payments to third parties that provide research-related services and/or products.

An investigator may adhere to confidentiality safeguards in the conduct of a study but there is a significant risk of breach of confidentiality when payments to subjects are involved. Therefore, the IRB requires that for payment purposes:

1. Only researchers and designated staff within the department sponsoring the study have access to the information.
2. Payments made to human subjects who are also employees of the University are treated the same as nonaffiliated subjects.
IV. PROCEDURE FOR POLICY

1. Prior to payment: Confirm the individual receiving payment is a valid human subject at the time of the research participation and that IRB approval was current at the time of subject contact.

2. Form of compensation: The University of Louisville utilizes the Swift Gift Card program for all human subject payments. This is a Visa branded, UofL gift card that can be used at any retailer that accepts Visa. The gift card policy can be found at http://louisville.edu/finance/controller/policies/prepaidcard.

3. Audit records should be maintained within the department to justify all payments made to participants.

V. ORGANIZATIONAL RESPONSIBILITIES

Principal Investigator – Ensures that confidentiality and proper protocol procedures are followed

Unit Business Manager (UBM) - Oversight, approve and review payment documents for confidentiality and accuracy

Document Preparer (Investigator or designee) - Ensures confidentiality and accuracy

Grants Management or Office of Industry Contracts - Approve Contracts for Professional Services review and accuracy

Financial Administration - Advise departments regarding standard University purchasing and payment processes.