HOWARD UNIVERSITY OFFICE OF REGULATORY RESEARCH COMPLIANCE (ORRC)

WHAT IS CONSIDERED RESEARCH: OHRP GUIDANCE AT 45 CFR 46.102(D); AND THE FDA GUIDANCE AT (21CFR 50.3(C), 21 CFR 56.103(C), 21 CFR 312.3(B), AND 21 CFR 812.3(H))

This document and questionnaire are intended to guide the determination of whether an activity meets any of the above referenced applicable federal regulation, and therefore, NOT Research. For activities that fall under designated ***"Exempt Categories" at 45 CFR 46.101(b),*** prospective investigators must complete **Form D1**. You are advised to read the entire document. For further clarification, you may visit the ORRC website at WWW.howard.edu/orrc

SECTION A: RESEARCH

OHRP Definition of Research

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Please note that:

- Activities that meet this definition constitute research for purposes of the federal policy.
    - This qualification is regardless of whether an activity is conducted or supported under a program that is considered research for other purposes.
    - For example, some demonstration and service programs may include research activities.
- **Systematic Investigation**: A systematic investigation is an activity that plans (prospectively) to incorporate 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 a theory.
- **Generalizable Knowledge:** Activities designed (with intent) 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 (e.g., publication or presentation).
    - The intent to develop or contribute to generalizable knowledge makes an activity research.
    - Results do not have to be published or presented, to qualify the activity as research.
- **Examples of activities that are typically considered systematic investigations**:
    - Interviews and focus groups
    - Surveys and questionnaires

- Analysis of data and specimen
- Observational studies
- Epidemiological studies
- Review of medical records as part of systematic investigation

- **Examples of activities that are typically NOT considered systematic investigation:**
  - Training activities when they are **NOT** intended to contribute to generalizable knowledge
  - Classroom activities where the objective of the activity is to teach proficiency in performing certain tasks or using specific tools or methods, when the activity is **NOT** intended to contribute to generalizable knowledge
- **Examples of activities that are typically NOT designed to develop or contribute to generalizable knowledge:**
  - Biographies
  - Oral histories designed exclusively to create a record of specific individuals/event
  - Service or course evaluations
  - Services, courses, or concepts where the results are **NOT** intended to be shared beyond the Howard University Community
  - Classroom exercises specifically designed to fulfill course requirements or to train students in the use of specific methods or devices
  - Quality assurance activities designed to continuously improve the quality or performance of a department or program, and there is **NO** intention to share the results beyond the Howard University Community

Food and Drug Administration (FDA) regulations Definition of Research

- **The FDA regulation defines a clinical investigation as any experiment that:**
  - Involves a test article and one or more human subjects, and that
  - Either subject to the requirements for prior submission to the FDA under section 505(i) or 520(g) of the Act, **or**
  - Need not subject to the requirements for prior submission to the FDA under relevant sections of the Act, but the results of which are intended to be later submitted or held for inspection by the FDA as part of an application for a research or marketing permit (21 CFR 50.3(c), 21 CFR 56.103(c), 21 CFR 312.3(b), and 21 CFR 812.3(h)).
- **A test article is any drug (including a biological product for human use):**
  - Medical device for human use
  - Human food additive
  - Color additive
  - Electronic product, or
  - Any other article subject to FDA regulations.
- **Examples of activities that are clinical investigations**:
  - Clinical trials that involve investigational drugs or devices
  - Research testing the safety and effectiveness of a device o Medical outcome studies comparing approved drugs or devices.

SECTION B: ORAL HISTORY AND OR JOURNALISTIC ACTIVITY

Exception Under 2018 Revised Common Rule:
https://www.federalregister.gov/documents/2017/01/19/2017-01058/federal-policy-for-the-protection-of-human-subjects#p-1354 The 2018 Requirements at 45 CFR 46.102(l) provide a definition of "research" and identify scholarly and journalistic activities that focus directly on ***specific individuals*** as one of four categories of activities deemed NOT to be research. Further, it defines 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.

For clarity on the 2018 OHRP "Exception" guidance, prospective Investigators must review the following OHRP publication: https://www.hhs.gov/ohrp/regulations-and-policy/requests-for-comments/draft-guidance-scholarly-and-journalistic-activities-deemed-not-to-be-research/index.html

While studies meeting the "Exception" threshold under the 2018 Revised Common Rule may provide an accurate and evidence-based portrayal of the individuals involved, they are not meant for developing generalizable knowledge. Specifically, the caveats include the following:

- Collected information is not intended/extended to draw generalizations about other individuals or groups.
- It is **NOT** the particular field that removes an activity from the definition, but rather that the purpose and design of the particular activity are to focus on specific individuals and not to extend the activity's findings to other individuals or groups.
- When the purpose and design of such studies or activities are to reveal something about the community or group – that is, to develop generalizable knowledge, it does not qualify for the exception under 45 CFR 46.

Note: In this context, Oral History and Journalistic Activities are examples of such exceptions. However, the exception may not be applicable to "ALL" intellectual activities in the Department of History and Journalism.

A Perspectives of the Oral History Association:

The Oral History Association (Oral History, Human Subjects, and Institutional Review Board https://www.oralhistory.org/about/do-oral-history/oral-history-and-irb-review/) acknowledges that**:** "Within the last several years, egregious violations of requirements for human subjects review in biomedical research have led to the suspension of all human subjects research at several major institutions." *"One of the consequences of criticizing human subjects' regulations is the imputation of ethical insensitivity or arrogance. Yet, there is a deep ethical narrative in oral history and numerous examples of the sorts of ethical dilemmas oral historians have faced in practice. These dilemmas cannot be resolved by the formulaic prescriptions of the Common Rule but rather by the informed judgment of the interviewer, operating within the context of a specific interview relationship. Educating students, faculty, and staff in these real ethics would serve everyone well."* (*http://www.historians.org/perspectives/issues/2007/0703/0703vie3.cfm*)

Further, the publication notes that "the dictates of professional integrity in the practice of

history requires awareness of one's own biases and a readiness to follow sound method and analysis wherever they may lead" and appropriately so. Yet, "oral historians must remain aware of the potential risk of criminal or civil liability, damage to financial standing, employability, or reputation of the narrator." *Of significant relevance to the Common Rule at 45 CFR 46 is the risk of group harm and the potential for "reinforcement of thoughtless stereotypes beyond individuals involved in the activity (oral history or journalistic activity)."*

Additional Important Cautionary Notes

Funding Agencies and Applicability: Please note that while about seventeen Federal Agencies are subject to 45 CFR 46, there are notable exceptions *(e.g., Office of the Director of National Intelligence and the Central Intelligence Agency (follows CR because of EO 12333, as amended).* Research supported by Federal Agencies that are not subject to 45 CFR 46 may require a different standard. If your activity is supported by a Federal Agency, please ensure that you are familiar with the Agency regulations on Human Subject Protection: https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html

Local and Tribal Laws: Also, note that the 2018 Revised Common Rule now recognizes Tribal Laws in addition to the Local requirements. Because of the nature of historical events, it is imperative that investigators are familiar with the applicable Local and Tribal Laws. *Per the regulation at §__.116(i), Tribal governments can develop laws related to the protection of human subjects that are more protective than the Common Rule, and that these laws must be followed by federally funded research activities involving these populations:* https://www.ncai.org/policy-research-center/research-data/prc-publications/ResearchPolicyUpdate.pdf

Summary

Consistent with the regulation at 45 CFR 46, the ORRC will exclude "Oral history" through limited assessment (per HU Policy and Procedure) as long as it falls under the category of "***scholarly and journalistic activities that collect and use information about deceased or a specific living individual***." On the other hand and per the regulation at 45 CFR 46, studies using methods such as participant observation and ethnographic studies, in which investigators gather information from individuals in order to understand the beliefs, customs, and practices, not only of those individuals but also of the community or group to which they belong would represent generalizable knowledge, and therefore, not excluded from IRB review under the Revised Common Rule. Nonetheless, when aspects of oral history are excluded from IRB oversight, oral historians must continue to hold themselves to the highest professional and ethical standards as spelled out by the Oral History Association's Principles and Best Practices: https://www.oralhistory.org/information-about-irbs/

PLEASE, COMPLETE SECTIONS "C" THROUGH "E" BELOW

SECTION C: General Research Determination Questions	Yes	No
Is your activity a systematic investigation?	☐	☐
Is your activity intended to contribute to generalizable knowledge?	☐	☐
Does your activity involve the prospective collection of data (qualitative or quantitative)?	☐	☐
Does your activity involve data analyses to answer a question?	☐	☐
Is your activity designed/intended to draw general conclusions?	☐	☐
Is your activity intended to inform policy?	☐	☐
Is your activity intended to generalize findings beyond a single individual or an internal program?	☐	☐
Do you intend to publish or present your findings beyond the Howard University community?	☐	☐
Are you testing an article such as a drug, including a biological product for human use?	☐	☐
Is your proposed activity a case report?	☐	☐
If a case report, how many subjects are included in the report?	☐	☐
Is your proposed activity for quality assurance?	☐	☐
Does your activity involve living humans and or identifiable private information?	☐	☐

Note: Complete **section C** (above) to determine whether your activity is research in a very general sense. For oral history and journalistic activity, you must additionally complete **section D**.

SECTION D: Determination on Whether Oral History and Journalistic Activities Meets the Threshold for Exception		
Is your investigation/activity on Oral History and or Journalistic Activity?	☐	☐
Do you plan to study living individuals?	☐	☐
Do you plan to study deceased individuals?	☐	☐
If your proposed activity includes only deceased individuals, do you plan to later extend the study to the relatives, associates, or the community of the dead person?	☐	☐
If your proposed activity included someone alive, have you obtained or plan to obtain a legal release from the narrator?	☐	☐
If your activity includes someone alive, can your proposed activity pose the risk of criminal or civil liability, damage to financial standing, employability, or reputation of the narrator?	☐	☐
If you plan to study more than one person, how many people do you plan to include in the proposed study (deceased or alive): _____?		
Does your proposed activity(s) include more than one person (deceased or alive)?	☐	☐
Does your proposed activity(s) involve Children?	☐	☐
Does your proposed activity involve Prisoners?	☐	☐
Does your proposed activity(s) involve Tribal Groups?	☐	☐
Does your proposed activity(s) involve the National Intelligence or Central Intelligence Agency?	☐	☐
Does your proposed activity(s) include an internationally component?	☐	☐

Note: Complete **section D** (above) only if your activity involves oral history or journalistic activity and you intend to obtain "Research Exception." If you are requesting standard "Exempt", please complete the exempt application in iMedRIS.

SECTION E: STUDY DESCRIPTION (**All must complete this section**)
Provide the abstract/brief description of your proposed activity
Location of the activity:
Estimated duration of the activity:
Involved individual(s):
In the space below, please provide other relevant information, if any:
▪ **Attach as relevant:** o Copy of dissertation o Other relevant documents (surveys, questionnaires, etc.) o Legal release agreement if applicable

SECTION D: PRINCIPAL and or STUDENT INVESTIGATOR ASSURANCE

NAME: **DEPARTMENT**:

PROJECT TITLE:

I, as The Investigator, give my assurance that I will conduct this activity according to the rules and regulations governing this scholarly activity and the rights of humans participating (as applicable) in my activities as stipulated in the Howard University's Federal Wide Assurance (FWA) which is on file with the Office for Human Research Protections (OHRP) of the United States Department of Health and Human Services (DHHS). Additionally, I will comply with the Howard University Institutional Review Board (HU-IRB) and the Howard University Office of Regulatory Research Compliance (HU-ORRC) Policies and Procedures.

If my activity includes **human subjects**, properly executed informed consent forms will be kept as part of the records of this project. The Chairman of the Howard University Institutional Review Board (IRB) will be immediately notified of any adverse reaction(s) or events that may occur and of the measures employed to correct them. The Chairman of the IRB/the ORRC will be apprised of any changes to the approved activity, and the IRB/ORRC approval will be obtained before implementing any changes.

If my activity meets the OHRP and HU-IRB/ORRC "**Exempt**," "**Exception**," or "**Exclusion**" threshold (deemed NOT to be humans subject research or Research); I will not make any changes to the scope of approved activity without notifying the IRB/ORRC of the changes, and I will obtain approval before initiating any changes on my approved activity.

If my activity is approved under "**Full Board**" or "**Expedited**" Review, Annual Reports will be submitted to the Chairman of the IRB, which will contain the following: (**1**) The number of participants recruited for this project; (**2**) The number and location of executed informed consent forms; (**3**) Any adverse reactions or events that may have occurred and the measures taken to correct them; and (**4**) Any changes in the protocol of this project.

My signature below affirms that I will comply with the terms of this activity as proposed and approved.

_____ _____

Signature Student Investigator **Date**

_____ _____

Signature of Principal Investigator **Date**

Note: A signed copy of this page must be included in all protocols submitted for IRB review

ATTESTATION

I confirm that my response to the questions on the determination form, the abstract and other information provided by me are accurate.

_____ _____

Signature Student Investigator (If applicable) **Date**

_____ _____

Signature of Principal Investigator **Date**

REVIEW OUTCOME

Approved as presented**:** _____ **(Exclusion: _____) (Exception: _____)**

Request additional information**:** _____

Recommend: Submit "Exempt" Review Application**:** _____

Recommend: Submit "Expedited" Review Application**:** _____

Recommend: Submit "Full Board" Review Application**:** _____

_____ _____

ORRC – Compliance Officer/IRB **Date**