



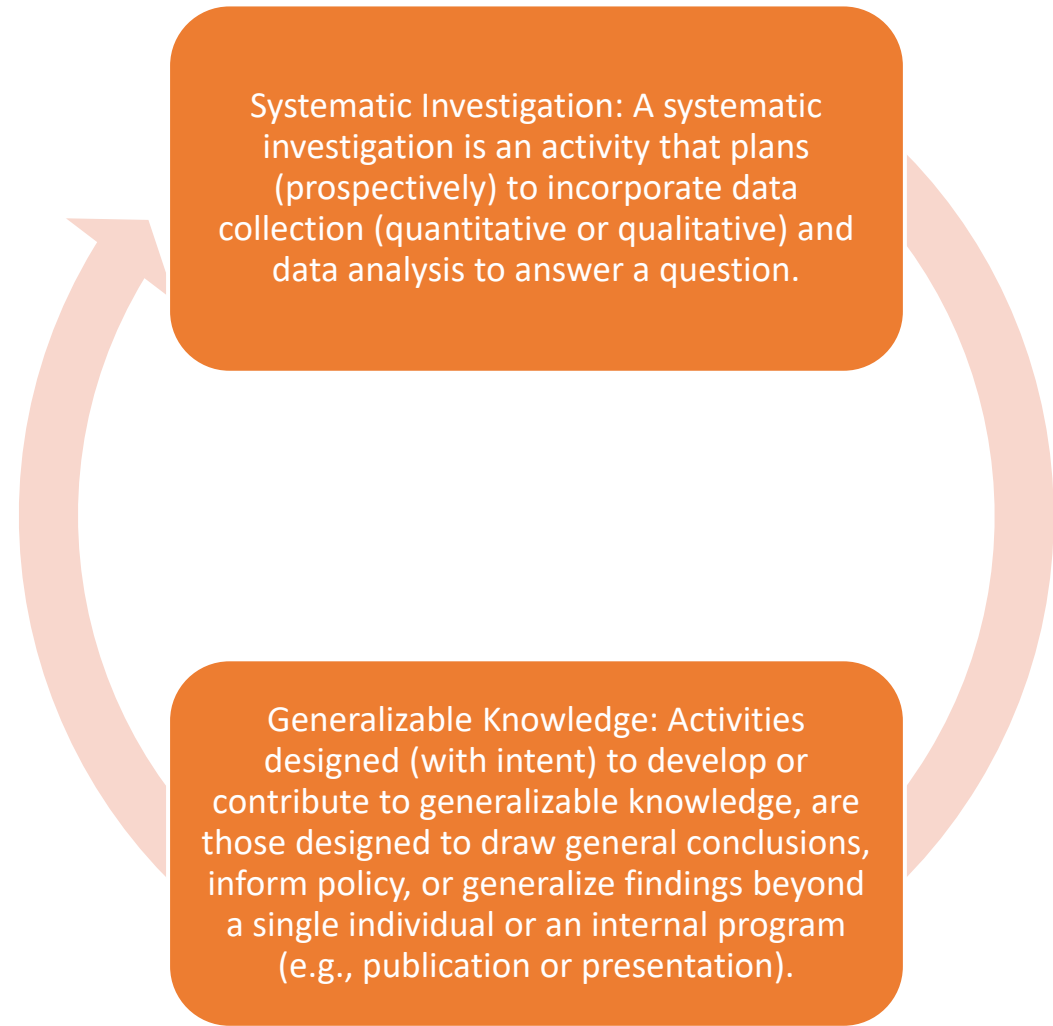
RESEARCH EXCLUSION DETERMINATION

GRADUATE SCHOOL

OFFICE OF GRADUATE STUDIES

Exclusion Review Process: IS IT RESEARCH?

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



Examples of activities that are typically considered systematic investigations



Interviews and focus groups



Surveys and questionnaires




Analysis of data and specimen



Observational studies o 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

ORAL HISTORY AND OR JOURNALISTIC ACTIVITY

- The 2018 requirements at 45 CFR 46. 102(1) 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.
- 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.

General Research Determination Questions

Yes or No

- **Yes or No. If YES to any question, research does not typically meet the exclusion determination approval.**
 - 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?

Determination on Whether Oral History and Journalistic Activities Meets the Threshold for Exception

Yes or No

- 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?



Graduate School's Exclusion Determination Process

- If an exclusion determination is being requested, follow the process below:
 - Send the request to the Office of Graduate Studies in the Graduate School via the Senior Associate Dean for Graduate Studies.
 - Attach to the request:
 - Proposal/Prospectus
 - Exclusion Determination Signed Form
- Once a determination has been decided, a formal letter will be sent outlining if the exclusion determination has been approved or disapproved.
- If the proposal/prospectus does not meet the exclusion determination criteria, then it must be sent to ORRC for review.

Exclusion Criteria

- Exclusion Criteria
 - The project is not a “systematic investigation”
 - Conclusions will not contribute to “generalizable knowledge”
 - Does not involve data collection through “intervention or interaction” with individuals
 - Does not involve the collection of private information that is directly or indirectly individually identifiable
- Please note that an approved letter of exclusion determination for the reviewed project applies only to the activities described in the documentation submitted for review. It does not apply should any changes be made to the project.
- If changes are being considered and there are questions about whether IRB review is needed, please submit a modification of the project to the ORRC/IRB for another determination. In iMedRis select the non-medical option.

Overview of IRB Submission

<i>Action</i>	<i>Exclusion</i>	<i>Exempt</i>	<i>Expedited</i>	<i>Full Board</i>
<i>Risk</i>	N/A (Does not involve the use of human participants or human data, biohazardous materials, animals.	Fits exemption categories, presumed minimal risk (low or less risk)	Fits expedited categories, AND minimal risk	Greater than minimal risk, or does not fit expedited categories
<i>Type of Review</i>	Exclusion determination review.	ORRC Administrative Staff Review.	Member designated by IRB to review.	Review by Full Board.
<i>Initial Submission Requirement</i>	Exclusion form and proposal (if applicable) to Office of Graduate Studies in the Graduate School	Submit IRB application through the iMedRIS ECP (electronic compliance platform)	Submit IRB application through the iMedRIS ECP (electronic compliance platform)	Submit IRB application through the iMedRIS ECP (electronic compliance platform)
<i>Review and Approval Time</i>	1-5 business day depending on submission and level of determination.	2 weeks. Applications that require revisions may take longer.	2-3 weeks. Applications that require revisions may take longer.	4-6 weeks. Applications that require revisions may take longer.
<i>Proposal/Research Changes</i>	Must report.	Must report. Possible new exempt application submission.	Must report. Possible new expedited application submission.	

* Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

** Studies that do not qualify as "minimal risk" nor for expedited review under the federal regulations are usually considered greater than minimal risk. Greater than minimal risk studies usually involve medical procedures or devices or create some high degree of discomfort for participants. This discomfort can be physical, emotional, social, or psychological.