**Does my study require Institutional Review Board (IRB) review?**

Federal regulations require an Institutional Review Board to review research involving human subjects. This checklist is designed to assist you in determining if your study meets the federal definition of human subjects research and should be submitted CCSU’s Institutional Review Board (IRB).

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| **1. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge?** *A* ***systematic investigation*** *involves a plan to study a specific topic, answer a specific question, test a specific hypothesis, or develop a theory. It incorporates the collection of quantitative or qualitative data, or specimens, and analysis.****Generalizable knowledge*** *is knowledge gained from a study that may be applied to populations beyond the specific study population, used to inform policy, and/or may be disseminated through presentations and/or publications.* | **YES**□Continue to #2 | **NO**□STOP IRB review is not required |
|  | If you answer yes to any of the following questions, your research may meet the definition of contributing to generalizable knowledge:* **Is the project a thesis or dissertation?**
* **Do you anticipate that the results of the research will be presented at a meeting or conference, or submitted for publication in a journal or Internet posting?**
* **Do you anticipate the activity to be listed as scholarly or scientific activity on your professional vita or resume?**
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|  | However, if your research involves any of the following activities, you do not require IRB review:* **Data will be collected from oral histories to create a historical record of specific personal events and experiences but NOT to draw conclusions, inform policy or generalize findings.**
* **Data will be comprised of a case history and be limited to a description of clinical features and/or outcome of a single patient.**
* **Research will be conducted in an educational setting and involve quality assessment or quality improvement of instructional techniques, curricula, or classroom management methods AND NOT contribute to generalizable knowledge beyond your academic or professional institution.**
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| **2. Does the research involve obtaining information about living individuals, directly or indirectly?** | **YES**□Continue to #3 | **NO**□STOP IRB review is not required |
|  | If you answer yes to any of the following questions, your research does not involve living individuals:* **Will the research focus on collecting information on things such as processes, policies or business procedures and not collect information about living individuals?**
* **Is the research limited to searching existing literature, news articles, and/or publicly accessible websites?**
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| **3. Does the research involve intervention or interaction with human participants?** | **YES**□STOP*Submit IRB application* | **NO**□Continue to #4 |
| **4. Does the research involve the collection of individually identifiable information?***Information is* ***individually identifiable*** *if the identity of the participant is or may be readily ascertained by the investigator or associated with the information.* | **YES**□Continue to #5 | **NO**□STOP IRB review is not required |
|  | If you answer yes to any of the following questions, your research does involve identifiable information:* **Does the data contain information that could lead to the identification of individuals through direct or indirect means (e.g., collecting specific demographic information)?**
* **Will data or specimens be coded with a link that could allow individuals to be re-identified?**
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| **5. Is the information private?***A* ***private behavior*** *is one that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public.* | **YES**□STOP*Submit IRB application* | **NO**□STOP IRB review is not required |
|  | If you answer yes to any of the following questions, your research does not involve private behavior:* **Will the research solely involve the use of surveys, interviews, or observation of public behavior of senior elected or appointed public officials or candidates for public office?**
* **Is the information posted on publicly accessible websites or forum?**
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*Still unsure? Submit IRB application for official determination***. *Submit to irb@ccsu.edu***