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| **The purpose of this form is to request a determination that IRB review is not required because this project is not research or not research involving human subjects. Please answer all questions and submit in IRBNet as submission type “Other.”****If you wish to apply for IRB review, see our website for guidance on how to submit a New Project for initial review.** |
| **Project Title:** |       |
| **Primary Contact Name, Email, Phone:** |       |
| **Yes** | **No** | **Research Determination Questions** |
|[ ] [ ]  1. Has the project received funding (e.g. federal, industry) to be conducted as a human subjects research study?

If a project has received funding to be conducted as research, the IRB will consider if human subjects protections must be in place. If a project has received funding for other purposes, such as program evaluation or process improvement, the IRB may issue a not research determination. If you are unsure, contact your program officer to determine whether the funding source requires a specific level of IRB review and oversight. |
|[ ] [ ]  1. Do you plan to use the information generated from this project to draw conclusions that have scientific merit and can be applied to populations outside of the specific study population or contribute to a body of knowledge?

When answering, consider both the intent and design of the project. Does the design of the project take into account internal validity to ensure the results are trustworthy as well as external validity to ensure the outcomes can be generalized beyond the individual participants?If the intent of this project is to create knowledge that can be generalized beyond the study participants and the design of the research supports this goal, answer "Yes". If the intent is to report facts or outcomes without extrapolation, then answer "no". |
|[ ] [ ]  1. Will the project involve testing an [experimental drug, device (including medical software or assays), or biologic](https://research.ucdavis.edu/policiescompliance/irb-admin/researchers/project-guidance/investigational-drugs-or-devices/)?

The purpose of this question is to determine whether federal regulations beyond the Common Rule, such as FDA regulations, need to be applied to a project. |
|[ ] [ ]  1. Does the study involve any of the following:
* A release of identifiable data from a State of California Agency
* A release of information from the Framingham Institute[[1]](#footnote-1)
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|[ ] [ ]  1. Is the project intended to improve or evaluate a practice or process within a particular institution or a specific program?

If the only purpose of this project is to improve or evaluate a practice or process at a single site or for a specific program, then the response should be “Yes”. Quality assessment or improvement projects done without the intention to generalize findings are generally not research. |
|[ ] [ ]  1. Is this a multi-site project (indicators of multi-site projects: there is a coordinating or lead center, more than one site participating, and/or a study-wide protocol)?

Projects completed at multiple sites are more likely to create generalizable knowledge. For example, the outcomes of a quality improvement program at a single site may only apply to that site. A quality improvement project done across multiple sites is more likely to yield outcomes that can be applied broadly. |
| Yes | No | Research Determination Questions |
|[ ] [ ]  1. Will the results of the project be published, presented or disseminated outside of the institution conducting it?

The act of publishing or presenting information does not make a project research; however, if the intention is to disseminate information to a larger group, it is more likely that the goal is to create generalizable knowledge. Not distributing results is a strong indicator that this project does not meet the definition of research. |
|[ ] [ ]  1. Will the project occur regardless of whether individuals conducting it may benefit professionally from it?

If this project is being completed to meet the requirements of a program, a funding agency, or some other outside obligation, then select “Yes”. If the project is being done to advance individuals’ career path or grow a research portfolio, then select “No”. The purpose of this question is to determine if this project is being conducted to meet requirements or if the project is being conducted for professional growth through research. |
| Yes | No | Human Participants Determination Questions |
|[ ] [ ]  1. Does this project involve any interactions or interventions to collect information about living individuals?

Interaction: Communication or interpersonal contact between investigator and subject (e.g. interviews, questionnaires, online surveys, intercept surveys, focus groups, anthropometry).Intervention: Physical procedures by which information or biospecimens are gathered (e.g. taking vitals, venipuncture, clinical assessements) and manipulations of the subject or the subject’s environment that are performed for research purposes.When information is collected about living individuals for research purposes, they become human research participants. The purpose of this question is to determine if this project involves human participants. |
|[ ] [ ]  1. Does this project invole access and use of private identifiable information or identifiable biospecimens?

Private Information: Information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g. a medical record, student record, or research record).Identifiable Information: Information for which the identity of the subject is or may be readily ascertained by the investigator or associated with the information.Identifiable Biospecimen: A biospecimen for which the identity of the subject is or may be readily ascertained by the investigator or associated with the biospecimen.When private identifiable information or identifiable biospecimens are used for research purposes, the individuals become human subjects in research. The purpose of this question is to determine if this project involves human participants. Select “Yes” if this project involves analysis of records or specimens collected for other purposes AND there is a way the project team can link the data to an individual person. For data that is coded, select “Yes” if the project team has acess to the key that links the data set to individual identifiers.NOTE: Research that is subject to FDA oversight and involves the use of biospecimens will require IRB review, even when the biological samples are not labeled with identifying information. |
| Briefly describe the project objectives and procedures: |
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| * By submitting this application, I certify that this information is accuate and complete.
* I understand that there may be requirements beyond IRB review and certify that all applicable requirements will be followed when conducting this project.
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1. <https://biolincc.nhlbi.nih.gov/studies/framcohort/>

**The Framingham Heart Study Group requires that the requestor must obtain full or expedited IRB/Ethics Committee review and approval to obtain these data. Waivers or a determination that the research is exempt from ethical regulations do not suffice.** [↑](#footnote-ref-1)