

## Protocol for Coding Abstracts Using the ODP Prevention Taxonomy

### Background

The purpose of this protocol is to create a system to categorize prevention research and related activities (including training, career development and research-support/infrastructure) to allow the NIH Office of Disease Prevention (ODP) to identify and track various efforts in more detail than is possible using other methods. This document provides guidance, including definitions and examples, for categorizing research projects based on their titles, abstracts, and public health relevance using the accompanying taxonomy form.

The lettered items are categories for classification; the numbered items are topics within each category.

### General Instructions

- Read the entire title, abstract, and public health relevance (hereafter referred to as “abstract”) before doing any coding, marking passages relevant to each of the categories. Then, go back and read it again to code.
- It may be easier to code categories in the order they appear in the abstract, not the order they appear on the taxonomy form.
- For virtually all categories, select all topics that apply to the particular project. You will often need to select more than one topic within a category. There are a few exceptions:
  - If a project includes only basic science, selected only E.7 and F.6
  - If F.6 other/unclear is selected, no other topic in F can be selected
  - If G.6 is selected, no other topic in G can be selected
  - If F.5 is selected, E.2 must also be selected
  - If subtopics in A.1, A.2 or A.3 are selected (i.e., Air pollution A.7a, HIV/AIDs A.18a, Coronavirus A.18b), their primary topic must also be selected (i.e., Chemical/Toxin, Infectious Disease)
- Make coding decisions based on the content of the entire abstract, including the Public Health Relevance section, and on the guidance provided in this document. Do not use other resources (e.g., Google, Wikipedia, etc.).
- Make sure each category on the taxonomy form has at least one selection.
- As a general rule, code all specific aims for **A.2. Exposure** and **A.3. Outcome**. However, these categories may not apply for some specific aims because they may not describe an exposure or outcome. For example, sometimes a first aim refers to developing an intervention, which would not be coded, while the remaining aim(s) test the intervention that was developed; those remaining aims would typically be coded. Another example is when an aim refers to research capacity building (do not code – instead, select *G.2 Infrastructure*) or describe procedures that are part of the study design.
- If the abstract does not provide enough information to select a topic or there are unresolvable differences within the coding team, **do not make assumptions**, select *Other or unclear* for the category. If the abstract has no aims to code or is unclear, and it is not basic research, select *Other or unclear* all categories.
- Basic research studies are too distal to be considered primary or secondary prevention research. If a project includes only basic research, please select *Other or unclear* for **E. Study**

**design/purpose** and *Other or unclear* for **F. Prevention research category**; you do not need to code the other categories for these abstracts. However, if the abstract also includes another aspect of the project that is primary or secondary prevention research, do not code the basic research aspect of the project, but do code the topics that relate to the aspect that is primary or secondary prevention research and select the flag *G.1. Partial*.

- Basic research includes projects directed toward fundamental knowledge/basic discovery and/or greater understanding of biological structure, biological mechanisms, behavioral mechanisms, or physiology. Basic research often occurs in cells, tissues, or animals, but can occur in humans. In contrast, prevention research may also examine these processes, but always in the context of, or as predictors of, an identified health condition or risk/protective factor.
- Projects that do not identify a measured health condition (disease, disorder, injury, disability) or risk/protective factor as the outcome or context in which a biological or psychological process is being examined may be considered basic research. For example, a project examining pancreatic cell function would be considered basic research unless cell function was being examined as a predictor of diabetes, or among individuals with (pre)diabetes. Studies that examine cellular processes that are not disease specific (e.g., inflammation, cellular aging) are considered basic research.

## A. Study Focus

This category includes 3 subcategories, each indicated by a column on the taxonomy form. For each topic, three columns are provided: **A.1. Rationale**, **A.2. Exposure**, and **A.3. Outcome**. Every column should have at least one selection, so select *Other or unclear* when none of the other topics fit. Certain topics are blacked out because they are not relevant to the column, or because we are not interested in them.

**A.1. Rationale:** This category is used to code the health condition(s) (disease, disorder, injury, disability) or risk/protective factor(s) (that are not blacked out) that the abstract identifies as the motivation for the prevention research. This would be the health condition(s) which the project addresses. The rationale is often stated in the opening few sentences of the project abstract; in other cases, the abstract gives the rationale in the last few sentences.

Topics are blacked out if they are not conditions that could serve as the rationale for the project and therefore should be ignored. If a project cites a health condition that is not listed and is not blacked out, select *Other or unclear*. If the abstract does not identify a **health condition** as the rationale, select *Other or unclear*. Do not code unspecified health conditions (e.g., unnamed disability, "other health conditions," "other diseases") in **A.1. Rationale**.

For a project of physical activity, the abstract may say that physical activity is important because it is related to heart disease, cancer, and diabetes; in that case, select *Heart disease*, *Cancer*, and *Diabetes* in the **A.1. Rationale** column. A project to evaluate a new smoking cessation method may not refer to any specific disease and instead identify only smoking itself as the rationale for the project; in that case, select *Tobacco* as the rationale. Other projects may identify smoking and diseases such as cancer or heart disease together as the rationale – in that case, select *Tobacco* and *Cancer* or *Heart disease* as the rationale. In some cases, mortality (death) is mentioned without identifying the specific cause. For example, the abstract might state how many deaths per year are attributable to a health risk behavior – unhealthy eating, inactivity, tobacco use, alcohol use, etc. Or the abstract might refer to all-cause mortality. In these cases, select *Mortality* as the rationale, in addition to any other topics that may apply.

**A.2. Exposure:** This category is used to code the independent variable(s) for the project. There may be more than one exposure that serves as an independent variable for a given project, especially if the project includes several sub-projects. In general, the independent variables are found in the specific aims of the abstract.

Intervention studies. The intervention is the exposure, and the coding should reflect the nature of the intervention. An intervention refers to any kind of exposure designed or intended to have a specific, non-transient effect on a health condition (disease, disorder, injury, disability) or risk/protective factor; examples include surgery to remove cancerous tissue (select *Surgery*), health education programs to encourage smoking cessation (select *Education/counseling*), and medication to treat high blood pressure (select *Medication/device*). This includes interventions delivered under the control of the investigator as well as interventions that are part of a natural experiment. We are looking for the intervention component(s) that differ between the intervention and control group. If both groups get the same background treatment (for example medication or education), then that component of the treatment is not the independent variable. We are only interested in what differs between the groups because that difference is what is being tested. We do not code the control condition under **A. Study Focus** regardless of the content, code the control condition as appropriate for the other categories.

Observational Studies. Observational studies have no intervention; code for the exposure(s) being measured in the project. For example, groups of people who have different levels of exposure to some possible risk/protective factor for a disease may be compared to see if their health conditions differ.

Multiple exposures. If more than one exposure is being examined in the project, then select all the exposures. For example, if a project is examining the relationship of blood pressure, physical activity, and obesity to subsequent stroke, select all three (*Blood pressure*, *Physical activity*, and *Obesity*) for **A.2. Exposure** and *Stroke* for **A.3. Outcome**. If a project includes measures of attitude, knowledge, beliefs, or intentions about a certain topic as an exposure, but not a measure of the topic itself, select *Other or unclear* for **A.2. Exposure**. If a measure is described as a perceived exposure or outcome and it is equivalent to a self-report of that exposure or outcome, code the topic as appropriate.

Predictive models. Predictive models make an inference about the value of an outcome of interest, provided that there are data or information on certain input variables. For example, one or more risk factors can be used to predict a health condition. Predictive models should not be confused with animal models or theoretical or logic models and frameworks. Predictive models of any kind (e.g., statistical, mathematical, computational, simulation) can often be coded in **A. Study focus**. Code the predictor variables (inputs) as the exposures and the topic being predicted as the outcome. In some cases, the predictive models will be developed and validated for use by others who have their own input variables; for these projects, select *E.2* and *F.5* for *Methods research*.

Tools. Often, investigators are either using or developing new tools to measure disease or disease risk. An abstract may describe the development of a new tool as one of the objectives of a project. In general, do not code a tool itself as an exposure or outcome. Instead, code the health condition (disease, disorder, injury, disability) the tool is designed to measure in **A.3. Outcome**. If the way the health condition is being measured appears in the list, code it as the exposure; if it does not appear, select *Other or unclear*. For example, if cholesterol is used as a measure of heart disease, code *Cholesterol* in **A.2. Exposure**; if stress is measured as an indicator of a mental health condition, code *Stress* in **A.2. Exposure**; if genetics are used to measure musculoskeletal disease, select *Genetics* in **A.2. Exposure**.

Effect modifiers. The abstract may identify effect modifiers, also known as moderators, or describe analyses that will test interactions between the exposure and another variable to see if the effect of that exposure varies according to the level of the other variable. These are all different ways of talking about effect modifiers: variables that modify the effect of the exposure on the outcome. For example, if men respond more than women to the same exposure, then gender is an effect modifier of the relationship between the exposure and the outcome. The analysis of effects in subgroups, or subpopulations, is an example of effect modification, as the

purpose of the analysis is to determine whether the effect of the exposure depends on the subgroup or subpopulation. These subgroup analyses may also be referred to as stratified analyses, which also allow for the assessment of modifying effects. Analysis of the joint effect of two variables is also an example of effect modification, as its purpose is to determine if the effect of one variable depends on the level of the other. If a variable is being evaluated only as an effect modifier, do not select it as an outcome or as an exposure; however, if a variable is being evaluated both as a main effect and as an effect modifier, code its role as a main effect. For an aim or statement that is exclusively about moderators, do not code it under any category. An exception is gene-environment interactions, where the main effects need to be captured; for these projects, select *Genetics* and the appropriate topic(s) for the environmental exposure in **A.2. Exposure**.

**Confounders.** The abstract may identify confounders, which are variables that are related to the exposure and to the outcome but not on the causal pathway between them. For example, in a randomized trial to evaluate the effect of smoking cessation on the risk of a first heart attack, there might be more men in one arm of the study than in the other arm, so that gender is related to exposure just by chance. We know that men are more likely to have a first heart attack than women, so gender is also related to the outcome. As a result, gender is a potential confounder because the uneven distribution of gender across the levels of the exposure could artificially magnify or hide the true effect of the exposure on the outcome. If a variable is being evaluated as a confounder, do not select it as an outcome or as an exposure. For an aim or statement that is exclusively about confounders, do not code it under any category.

**Mediators.** The abstract may identify mediators, which are variables that are on the causal pathway between the exposure and the outcome. Research on disease or behavioral mechanisms usually involves mediation, as the goal of the research is to identify variables that are on the causal pathway between an exposure and an outcome. Mediators look just like potential confounders, but we have prior reason to believe that they may be on the causal pathway. For example, if the smoking cessation program works by changing the participant's self-efficacy for quitting, then we would see not only higher levels of quitting but also higher levels of self-efficacy for quitting in the intervention arm. So self-efficacy for quitting would be a potential mediator, because it would be related to the exposure and to the outcome, but it would be on the causal pathway between them. If a variable is being evaluated as a mediator, do not select it as an outcome or as an exposure. For an aim or statement that is exclusively about mediators, do not code it under any category.

- A.3. Outcome:** This category is used to code the dependent variable in the project, which may differ from the rationale and the exposure. In general, the dependent variables are found in the specific aims of the abstract. Sometimes a project starts by identifying people with the health condition of interest and looks to see what they have been exposed to. These are case-control studies and the health condition, though appearing first in this abstract, is the outcome.

Most of the topics under **A. Study Focus** could be exposures or outcomes, depending on the purpose of the project. For example, for a project examining the relationship between the level of physical activity and mortality, *Physical activity* is the exposure and *Mortality* is the outcome. For a project examining the effects of a counseling intervention on physical activity level, *Education/counseling* is the exposure and *Physical activity* is the outcome. The abstract may say "physical activity is important for heart disease, cancer, and diabetes," but if the project is not measuring any of those conditions, then do not select them as outcomes; instead, select them under **A.1. Rationale**.

If an abstract says they will measure feasibility, acceptability, or a similar term, code those as *Other or unclear* in **A.3. Outcome**. An exception is if a project is measuring side effects, safety, or toxicities of a medication/device – these should be coded as *Medication/device* for **A.3. Outcome**. For these projects, also select *Pilot/feasibility/proof-of-concept/safety* under **E. Study design/purpose**. If a project includes measures of attitude, knowledge, beliefs, or intentions

about a certain topic as an outcome, but not a measure of the topic itself, select *Other or unclear* for **A.3. Outcome**. For example, if a project includes a measure of quitting tobacco self-efficacy as an outcome, select *Other or unclear* to represent that outcome instead of *Tobacco*; if the project also includes a measure of tobacco use as an outcome, select *Tobacco* as well as *Other or unclear*.

**Effect modifiers.** The abstract may identify effect modifiers, also known as moderators, or describe analyses that will test interactions between the exposure and another variable to see if the effect of that exposure varies according to the level of the other variable. These are all different ways of talking about effect modifiers: variables that modify the effect of the exposure on the outcome. For example, if men respond more than women to the same exposure, then gender is an effect modifier of the relationship between the exposure and the outcome. The analysis of effects in subgroups or subpopulations is an example of effect modification, as the purpose of the analysis is to determine whether the effect of the exposure depends on the subgroup or subpopulation. These subgroup analyses may also be referred to as stratified analyses, which also allow for the assessment of modifying effects. Analysis of the joint effect of two variables is also an example of effect modification, as its purpose is to determine if the effect of one variable depends on the level of the other. If a variable is being evaluated only as an effect modifier, do not select it as an outcome or as an exposure; however, if a variable is being evaluated both as a main effect and as an effect modifier, code its role as a main effect. For an aim or statement that is exclusively about moderators, do not code it under any category. An exception is gene-environment interactions, where the main effects need to be captured; for these projects, select *Genetics* and the appropriate topic(s) for the environmental exposure in **A.2. Exposure**.

**Confounders:** The abstract may identify confounders, which are variables that are related to the exposure and to the outcome but not on the causal pathway between them. For example, in a randomized trial to evaluate the effect of smoking cessation on the risk of a first heart attack, there might be more men in the one arm of the study than in the other arm, so that gender is related to exposure just by chance. We know that men are more likely to have a first heart attack than women, so gender is also related to the outcome. As a result, gender is a potential confounder because the uneven distribution of gender across the levels of the exposure could artificially magnify or hide the true effect of the exposure on the outcome. If a variable is being evaluated as a confounder, do not select it as an outcome or as an exposure. For an aim or statement that is exclusively about confounders, do not code it under any category.

**Mediators.** The abstract may identify mediators, which are variables that are on the causal pathway between the exposure and the outcome. Research on disease or behavioral mechanisms usually involves mediation, as the goal of the research is to identify variables that are on the causal pathway between an exposure and an outcome. Mediators look just like potential confounders, but we have prior reason to believe that they may be on the causal pathway. For example, if the smoking cessation program works by changing the participant's self-efficacy for quitting, then we would see not only higher levels of quitting but also higher levels of self-efficacy for quitting in the intervention arm. So self-efficacy for quitting would be a potential mediator, because it would be related to the exposure and to the outcome, but it would be on the causal pathway between them. If a variable is being evaluated as a mediator, do not select it as an outcome or as an exposure. For an aim or statement that is exclusively about mediators, do not code it under any category.

## Topics

Below are examples and definitions for each of the topics for **A. Study Focus**. A number of health conditions are available as possible rationales for the prevention research. These include the 10 leading causes of death based on 2015 CDC data and several of the actual causes of death identified by Mokdad et al. (2018). All topics except *Maternal/paternal/child health* and *Mortality* are available as

possible exposures, as death cannot be a precursor to another health condition. Additionally, *Maternal/paternal/child health* cannot be an outcome. Often abstracts will refer generally to the disease burden, or to morbidity and mortality, as part of the rationale for the project. If the abstract names mortality or death in this way, then select *Mortality* under **A.1. Rationale**. But do not select other topics in lieu of “morbidity.” All topics are available as possible outcomes (i.e., under **A.3. Outcome**).

An abstract may identify disease risk as an exposure or outcome. Select the topic that represents that disease as the exposure or outcome only when risk is based on a measure of the health condition itself (i.e., incidence or prevalence of the condition). Otherwise, select *Other or unclear* for disease risk. If a project is examining prevalence or incidence of a health condition (disease, disorder, injury, disability) or risk/protective factors as one of its aims, select *Other or unclear* as the exposure and the health condition, as the outcome. If a project describes symptoms that are not diagnostic of a disease or condition (e.g. depressive symptoms, psychiatric symptoms, diabetes symptoms, coughing as a symptom), select *Other or unclear* as appropriate for exposure or outcome. An abstract may study self-management of a disease (e.g. diabetes self-management, severe mental illness self-management); in these cases, select the health condition or disease as appropriate for **A.2 Exposure** or **A.3. Outcome**. If a project is using an established and validated proxy measure as an exposure or outcome, select the topic being measured and the topic for which the measure is a proxy for exposure or outcome, as appropriate.

In methodological studies, when an investigator is using an established and validated screening tool, the screening tool is classified as the disease for which it is intended to screen. For example, select *Neurological disease* for an established and validated screening tool for autism spectrum disorders or *Suicide* for an established and validated screening tool that assesses suicidal ideation. If a methodological study is developing, evaluating, and/or validating a new screening tool/measure or applying an established screening tool in a new population, select *Other or unclear* for the exposure or outcome, as appropriate.

#### 1. *Alcohol*

Alcohol use/misuse is a leading cause of death and is a diagnosable condition, so it can be a rationale. Alcohol use/misuse can cause liver disease, motor vehicle crashes, and other conditions that cause morbidity (e.g., injuries) or are fatal. This topic includes measures of alcohol use/misuse such as age of onset, number of drinks per day or week, and blood alcohol level. It could be an exposure if, for example, a project is interested in whether alcohol use is related to risk of stomach cancer or some other health condition. It could be an outcome if a project is interested, for example, in whether an intervention program reduces binge drinking or some other measure of alcohol use by college students. For projects that examine alcohol dependence disorder as an exposure or outcome, select *Alcohol* and do not select *Mental Health*. If a project is related to Fetal Alcohol Syndrome (FAS), select both *Alcohol* and *Maternal/paternal/child health* for rationale.

#### 2. *Alzheimer's disease*

Alzheimer's disease is a leading cause of death and can be a rationale. Because of its prominence, we are interested in it separately from other neurological conditions. It could be an exposure if we are interested, for example, in whether Alzheimer's disease increases the risk of another health condition. It could be an outcome if we are interested, for example, in whether another exposure increases the incidence of Alzheimer's disease. If the abstract is about Alzheimer's Disease and Related Dementia (ADRD), code only Alzheimer's Disease and not Neurological Disease.

#### 3. *[Removed]*

4. *Blood disorder*

This includes blood disorders like anemia, hemophilia or sickle cell anemia. For blood cancers like leukemia, select *Cancer* instead. Blood pressure is not a blood disorder. Blood disorders are health conditions, so they can be the rationale. Blood disorders could be an exposure if we are interested, for example, in whether those with sickle cell anemia are more likely to develop a particular cancer. Blood disorders could be an outcome if we are interested, for example, in whether those with a particular genetic variation are more likely to have sickle cell anemia. For projects that examine sepsis as an exposure or outcome, select *Infectious disease* and do not select *Blood disorder*.

5. *Blood pressure (BP)*

High blood pressure is a leading actual cause of death and is a diagnosable condition. This category includes both hypertension and the measurement of blood pressure. The terms malignant hypertension/hypertensive emergency describe an acute episode of hypertension and are also included in this topic. Hypertension is a health condition, so it can be a rationale. Select both Blood pressure and Maternal/paternal/child health if the abstract mentions hypertensive conditions during pregnancy (e.g., gestational hypertension, preeclampsia, eclampsia). It can be an exposure if the project is looking at, for example, how BP is related to subsequent disease, or an outcome if a project is looking at, for example, what factors or interventions influence BP or hypertension.

6. *Cancer*

Cancer is a leading cause of death and can be a rationale. This topic includes screening or diagnosis of any form of cancer (including blood cancers like leukemia), malignancies/malignant tumors, or neoplasms. **This topic does not include precancerous conditions/lesions (e.g., ductal carcinoma in situ (DCIS) or CIN1-3 cervical dysplasia); select *Other or unclear* instead.** For lung cancer, select *Cancer*, not *Lung disease*. It would be an exposure if the researchers are interested, for example, in whether diagnosis with a particular cancer increases the risk of another health condition. It would be an outcome if we are interested, for example, in whether exposure to a toxin increases the incidence of cancer. For projects that examine family history of cancer as an exposure, select *Other or unclear* and not *Cancer*.

7. *Chemical/toxin*

This topic includes toxicants, air pollution, water pollution, environmental radiation (e.g., radon), metals, endocrine disruptors, dietary toxins, and others. It is not a health condition, so it cannot be a rationale. It includes measures of exposure to chemical/toxins, such as mercury levels in the blood. This topic does not include UV radiation (select *Other or unclear* instead) because a form of electromagnetic radiation that everyone is exposed to. It can be an exposure, for example, in projects examining the association between exposure to a particular chemical and risk of developing a health condition. It can be an outcome, for example, in projects examining the relationship between dietary intake and levels of a certain toxin in the blood. If a project is examining a specific toxin or chemical, select *Chemical/toxin* as an exposure or outcome and not the source of a toxin. If the project is examining the source of the toxin and not the individual components, select the source(s) of the toxin (e.g., *Diet* for dietary intake, *Other or unclear* for environment, *Tobacco* for tobacco smoke) as an exposure or outcome. If a project is examining toxicities of medications, select *Medication/device*. If the source is an important motivation for the project then it may be appropriate to select it as the rationale if it is a health condition (e.g., *Tobacco* or *Substance use*). If, for example, a project examines allergies to latex, then select *Chemical/toxin* as the exposure and *Other or unclear* as the outcome. Air pollution is of special interest as it is an actual cause of death. If a project is examining air pollution as an exposure or outcome, select both 7. *Chemical/toxin* and 7a. *Air pollution*.

## 8. *Cholesterol*

This topic is about blood cholesterol, not dietary cholesterol. Elevated blood cholesterol is a risk factor for (not a diagnostic measure of) heart disease, stroke, and other vascular diseases. This topic includes all forms and measures of cholesterol found in the blood, including LDL cholesterol, HDL cholesterol, lipoproteins, triglycerides, LDL size, blood lipid panels, etc. We do not consider it separately to be a health condition, so it cannot be a rationale. It can be an exposure if we are interested, for example, in whether those with elevated cholesterol are at risk for a health condition. It can be an outcome if we are interested, for example, in whether those who are very active physically have lower cholesterol.

## 9. *Diabetes*

Diabetes is a leading cause of death and so it can be a rationale. This topic includes both type 1 or type 2 diabetes mellitus and gestational diabetes mellitus, but it does not include pre-clinical states of this condition such as metabolic syndrome, glucose intolerance, insulin resistance, or prediabetes. For these conditions, select *Other/Unclear* instead. This topic also includes measurements of self-management in diabetic patients. It can be an exposure if the study is asking, for example, whether diabetes increases the risk of another disease, such as a cardiovascular disease. It can be an outcome if the study is asking, for example, whether an exposure like a lifestyle intervention reduces the rate of diabetes. If a glucose measurement test is mentioned as part of the study (glycemic control on diabetic patients, fasting blood glucose levels, glucose tolerance test, or glycated hemoglobin [HbA1c] levels), select *Diabetes* only if these measurements are being done to determine the participants' diabetic status or if they are being done on patients with a previous diagnosis of diabetes. Do not select *Diabetes* if these tests will be only used to measure pre-clinical states in the study population or if the intention for the use of these tests is unclear.

## 10. *Diet*

Diet is a leading actual cause of death. It is not a health condition, so it cannot be a rationale. This topic includes dietary composition (e.g., macronutrients, micronutrients, calorie/energy intake), diet quality scores and dietary patterns, dietary supplements, dietary behaviors (excluding anorexia and bulimia, which are disorders and included in *Mental Health*), food or beverage purchases, and compliance to a specific diet or dietary supplement, etc. Dietary supplements include vitamins, minerals, herbs or other botanicals, amino acids, and other dietary ingredients or their constituents; they exclude tobacco products. Dietary supplements are intended for a healthy consumer population, whereas medications are specially formulated for a diseased patient population and make health claims. Studies examining omega-3 fatty acids or caffeine metabolites are included in this topic. *Diet* does not include malnutrition (select *Other or unclear*) or ingested toxins (select *Chemicals/toxin*). We are interested in diet as it relates to disease; therefore, the disease(s) of interest is the rationale. It can be an exposure, for example, in a project examining whether a specified diet will reduce risk of cardiovascular disease. It can be an outcome, for example, in projects that investigate whether a certain intervention will lead to people choosing to eat healthier food. It may be appropriate to select *Diet* for the exposure, or for the outcome, or both. If, for example, a project examines allergies to nuts, then it may be appropriate to select *Diet* as the exposure and *Other or unclear* as the outcome. If, for example, a project is examining the effect of lactose intolerance on gastrointestinal diseases, then it may be appropriate to select *Diet* as the exposure and *Gastrointestinal disease* as the outcome. If a project includes measures of attitude, knowledge, beliefs, or intentions about diet, select *Other or unclear*.

## 11. *Education/counseling*

This topic includes conveying knowledge, advice, or information; providing social support as an intervention or a component of one; or providing behavioral counseling or skills training,



regardless of the delivery mode (could be in person, over the phone [e.g., quit lines], by internet, by smart phone, in groups, individually, etc.). Other indications that a project is examining an education/counseling intervention include terms such as training, feedback, or therapy (e.g., behavior modification, psychotherapy, psychoanalysis, hypnosis, motivational interviewing, cognitive or cognitive-behavioral therapy, mindfulness, self-help materials, peer-led interventions, or school-based curriculum). If a project is examining contingency management or providing rewards/incentives, select *Other or unclear*, unless another part of the intervention leads you to select *Education/counseling*. *Education/counseling* cannot be a rationale because it is not a health condition. Instead, *Education/counseling* can be an exposure for an observational study, or a type of intervention for an intervention study. It can be an outcome if the project is looking at how to improve an educational system (e.g., changing a curriculum), what factors are associated with the delivery of education, or what factors impact academic performance. If a project is examining attitudes, intentions, beliefs, or examining *but not providing* social support, select *Other or unclear* as appropriate. If a project is measuring retention of knowledge resulting from an intervention, select *Education/counseling* as the outcome. Screening, Brief Intervention, and Referral to Treatment (SBIRT) interventions, as the name suggests, include a screening component, a brief, education/counseling intervention, and a referral to treatment component. For projects examining the effect of SBIRT interventions, select *Education/counseling* as the exposure. In addition, if a validated screener is being used as part of the SBIRT intervention, select the health condition that is being screened as the exposure (e.g., *Alcohol*, *Substance use*, *Tobacco*).

Please note - This category is not applicable to career development and training awards where the researcher is undergoing training or additional coursework.

#### 12. *Firearms*

Firearms are not a health condition so cannot be a rationale. This topic includes carrying, making threats with, or using firearms. Firearms can be an exposure that causes mortality or injuries, or an outcome if a project is looking at how to reduce use of firearms. If a project includes measures of attitude, knowledge, beliefs, or intentions about firearms as outcomes, select *Other or unclear* to represent those outcomes. If a project about firearms also has specific aims related to violence without firearms, select *Violence* for the exposure or outcome as appropriate.

#### 13. *Gastrointestinal disease (GI)*

GI diseases include conditions of or related to the GI system (i.e., esophagus, stomach, intestines, liver, pancreas, gall bladder, spleen), such as duodenal ulcers, GI bleeding, Barrett's esophagus, Crohn's disease, inflammatory bowel disease, etc. For GI cancers, select *Cancer* instead. For virus- or bacteria-induced GI disorders (e.g., hepatitis, ulcers caused by *H. pylori*), select *Infectious disease* instead. Diarrhea and ulcers of unclear/non-specified etiology are included in this topic. GI diseases are health conditions, so this topic can be a rationale. GI disease can be an exposure if, for example, a project is interested in whether people with stomach ulcers are more likely to develop anemia. GI disease can be an outcome if a project is interested in, for example, whether people who take a particular dietary supplement are more likely to develop duodenal ulcers. If, for example, a project is examining lactose intolerance, then it may be appropriate to select *Diet* as the exposure and *Gastrointestinal disease* as the outcome.

#### 14. *Genetics*

Relevant project types include genome-wide association studies (GWAS), genomics, and epigenetics (i.e., the study of processes that regulate how and when certain genes are turned on and off). Genetics are not a health condition, so cannot be a rationale. Genetics can be an exposure, for example, in a project that evaluates a genetic variant as a possible risk factor for developing a disease (e.g., *BRCA1/BRCA2* for breast cancer, *ApoE* for Alzheimer's disease). For GWAS, which seek to identify genetic variants that are associated with health conditions, select

*Genetics* as the exposure and the disease or health condition as the outcome. *Genetics* could be an outcome, for example, in a project examining the effects of an intervention on indicators of epigenetic processes such as DNA methylation. *Genetics* should not be selected just because the project is using genetic material to identify the entities studied. For example, do not select *Genetics* for a project about the microbiome where genetic material is being used only to identify the individual microbes in the microbiome (select *Microbiome* for the rationale, exposure, or outcome) as appropriate. Select *Other or unclear* for projects involving congenital diseases that affect multiple organ systems (e.g., Down syndrome or cystic fibrosis) as the rationale, exposure, or outcome as appropriate, unless the study focus is on screening for or incidence of congenital diseases; in those cases, select *Maternal/paternal/child health* for rationale. For projects examining gene-environment interactions, select *Genetics* and *Other or unclear* for the environmental component, unless the environmental component is specified in the abstract (e.g., *Tobacco, Chemical/toxin*).

Terms often used in genetic research include gene expression (i.e., the process by which the information encoded in a gene is used to direct the assembly of a protein molecule); gene regulation (i.e., the process of turning genes on and off); gene modulation (i.e., the practice of altering the expression of a gene); and single nucleotide polymorphisms (SNPs) (i.e., the most common type of genetic variation among people). Other common terms associated with genetic research include alleles, chromatin, cloning, codon, DNA, exome, genome, heterozygous, histone modification, homozygous, imprinting, inherited, messenger RNA (mRNA), mutation, oncogene, polymorphism, promoter, RNA, recessive, and telomere. Terms that should not be coded in this topic (select *Other or unclear* instead) include amino acid, antibody, enzyme, histone, metabolome/metabolomics, phenotype, protein, proteome/proteomics, transcription factor, and microbiome. Note: Proteins are the product of gene translation and should not be coded under *Genetics*. Exosomes/liposomes are cellular vesicles that may contain genes but should not be coded under *Genetics* unless genes are measured.

#### 15. *Healthcare delivery*

This topic includes access to healthcare services, utilization of healthcare services, healthcare financing and costs (e.g., health insurance payments and out-of-pocket expenses such as deductibles and co-payments), organization of care, and quality of care. It also includes projects about clinical practice or aspects of the healthcare system such as patient-centered medical homes, decision-support systems, and healthcare teams. This topic also includes patient navigation, which is defined as the individualized provision of different support services (communication, appointment scheduling, transport, education, legal assistance, among others) with the intention of increasing a person's access or use of healthcare services, independently of who is providing them. If a patient navigation exposure or outcome mentions the provision of education or information to patients, select both Education/counseling and Healthcare Delivery. It may include studies of electronic health records if they are used to measure healthcare utilization. *Healthcare delivery* cannot be a rationale; the disease/condition for which the care is delivered is the rationale. This topic does not include studies of medical devices or pharmaceuticals (select *Medication/device*) or cost-effectiveness of interventions (select *Other or unclear*).

It can be an exposure, for example, if the project is asking whether providing a certain healthcare service is associated with improved utilization and/or better patient outcomes. For example, in a project examining whether physicians are using a risk calculator to determine patients' risk for a stroke is associated with fewer strokes, select *Healthcare delivery* as the exposure. Select this topic, for example, as an exposure for a project testing the use of a clinical decision support tool to improve screening for diabetes. For a study to assess whether using a team approach to reduce cardiovascular risk in patients with diabetes works better than not using a team approach, select *Healthcare delivery* for the exposure. For a project to ascertain whether changes in health insurance or patient cost sharing impact patient outcomes, select this topic as the exposure. This topic does not include testing interventions that are only educational or counseling, even if they are delivered by healthcare personnel (select *Education/counseling*), except where it is the mode

of delivery that is being tested (e.g., all study participants receive the education/counseling intervention, but it is delivered in one arm by trained lay staff and in another arm by nurses or physicians); for these projects, select only *Healthcare delivery* for the exposure.

*Healthcare delivery* can be an outcome, for example, if a project is testing an intervention to improve the availability, utilization, cost, or quality of healthcare services. Select this topic as an outcome for a project measuring utilization of healthcare services (e.g., medical procedures, screenings, vaccinations) delivered by a clinician (e.g., physicians, nurses, other registered/licensed/trained healthcare professionals). For example, screenings that are always performed by a clinician such as mammograms, sigmoidoscopies, and colonoscopies are included in this topic. Tests that do not involve or are not ordered by a clinician are not considered *Healthcare delivery* (e.g., select *Genetics* for at-home genetic tests, select *Other or unclear* for home pregnancy tests).

If a project refers to a specific type of service utilization, then select both *Healthcare delivery* and the topic associated with the type of service as exposure or outcome as appropriate (e.g., *Kidney disease* for dialysis service use, *Infectious disease* for HIV testing). Projects about healthcare service utilization can be in traditional health care settings (e.g., doctors' offices, hospitals, clinics) as well as in nontraditional health care settings (e.g., health fairs, churches, pharmacies). For a project evaluating the effectiveness of an intervention in promoting increased utilization of mental health services, select both *Healthcare delivery* and *Mental health* for the outcomes. In a study of the impact of an intervention on patient out-of-pocket costs, select *Healthcare delivery* for the outcome. Select this topic, for example, as an outcome for a project testing whether providing flu shots reduces hospitalizations. For a project to assess whether an intervention increases referrals to care, select *Healthcare delivery* as the outcome. This topic does not include routine clinical measurements such as height, weight, or blood pressure.

#### 16. *Heart disease*

Heart disease is a leading cause of death and can be a rationale. This topic includes cardiac conditions such as heart attacks (myocardial infarction), heart failure, arrhythmias, atherosclerosis of the heart, heart valve conditions, angina, cardiac or cardiovascular events, and structural abnormalities/defects of the heart. For projects about heart disease mortality or sudden cardiac death, it may be appropriate to select *Heart disease* as the rationale and *Mortality* as the outcome. Heart disease can be an exposure, for example, in a project to find out if patients with a prior heart attack are more likely to develop a particular form of dementia. Heart disease is often an outcome, for example, in a project examining the relationship between dietary factors and heart attacks. If a project cites cardiovascular disease (CVD) or peripheral artery disease (PAD) as a rationale, exposure, or outcome, select both *Heart disease* and *Stroke*; but select only *Heart disease* if a project cites coronary heart disease (CHD) as a rationale, exposure, or outcome. Cardiometabolic disease should not be coded as a rationale; if cardiometabolic disease is cited as an exposure or outcome, select *Other or unclear*. This topic does not include pre-clinical or subclinical cardiovascular disease (e.g., cardiac remodeling, which includes changes in size, shape, or function of the heart in response to disease); in these cases, select *Other or unclear* instead.

#### 17. *HRQOL (Health-related quality of life)*

This topic refers to quality of life, usually associated with aging or a specific medical condition (e.g., HRQOL specific to breast cancer patients). HRQOL is a multi-dimensional concept that includes domains related to functional status and/or performance such as physical, mental (i.e., cognitive, intellectual, neurocognitive), emotional, and social functioning, as well as disability and dysfunction/impairment. This topic does not include cognitive decline (select *Other or unclear*). It goes beyond direct measures of population health, life expectancy, and causes of death, and focuses on the impact health status has on quality of life. Key elements used to measure HRQOL include activities of daily living (ADL), instrumental activities of daily living (IADL), quality-adjusted

life years (QALYs), and disability-adjusted life years (DALYs). DALYs and QALYs are composite measures that include death in their calculation, so select both HRQOL and *Mortality* when DALYs or QALYs are measured. HRQOL is not a health condition, so it cannot be a rationale. Sometimes a project measures HRQOL as one of its outcomes, rarely as an exposure.

A distinct but related concept is well-being, which assesses the positive aspects of a person's life, such as positive emotions and life satisfaction. Well-being is a relative state where one maximizes his or her physical, mental, and social functioning in the context of supportive environments to live a full, satisfying, and productive life. Select *Other or unclear* for projects that examine well-being. If a non-specific problem or aspect of development (e.g., cognitive development) is an exposure and/or an outcome select *Other or unclear for* as the exposure and/or outcome, respectively.

#### 18. *Infectious disease*

This topic includes any infectious disease or agent, whether viral, bacterial, or parasitic. Examples include HIV/AIDS, other sexually transmitted infections, tuberculosis, hepatitis, measles, human papillomavirus (HPV), schistosomiasis, otitis, periodontitis or periodontal disease, tropical infectious diseases, zoonotic or potentially zoonotic infectious diseases, and diarrheal disease caused by an infectious disease agent. The topic includes two sub-topics representing conditions of interest for ODP: *HIV/AIDS* and *Coronaviruses*. If a project has a rationale, exposure, or outcome focusing on these sub-topics select both *18. Infectious disease* and *18a. HIV/AIDS/18b. Coronaviruses* as the appropriate sub-topic. The *Coronaviruses* sub-topic includes infections caused by any of the seven known types of coronaviruses that can infect humans: 229E, NL63, OC43, HKU1, MERS-CoV, SARS-CoV and SARS-CoV-2. Terms such as MERS, SARS, and COVID-19 refer to health conditions caused by these viruses and should also be coded under this topic.

If the project involves pneumonia/influenza, select that topic instead of *18. Infectious disease*. This topic also includes testing for infectious diseases (e.g., PCR, antigenic, and antibody tests for COVID-19 testing; HIV/AIDS testing) and measures of infectious disease (e.g., viremia, antibodies, viral blood count) indicating natural infection or immunity, not vaccine-induced immunity. For projects using measures of infectious disease that indicate vaccine-induced immunity, select *Vaccine* to represent these measures. Select *Infectious disease* if a project is examining a mutation of the infectious disease agent that leads to drug-resistance or vaccine escape.

Infectious disease is a health condition, so it can be a rationale, even if no specific infectious disease is named. It can also be an exposure, for example, in studies of whether persons with a particular virus are more likely to develop congestive heart disease. Antibodies are typically a marker for being infected with an infectious disease, so if a project investigates antibodies in this context, select *Infectious disease*. It can be an outcome, for example, in a project testing a possible vaccine against malaria. If the project is examining a vaccine, candidate vaccine, or vaccine components to protect against an infectious disease, it may be appropriate to select *Vaccine* as the exposure and *Infectious disease* as the outcome and/or as the rationale. For projects that examine sepsis as an exposure or outcome, select *Infectious disease* and do not select *Blood disorder*. Studies of immune response are not necessarily coded as *Infectious disease* unless the overall goal of the project focuses on one or more specific infectious diseases. For studies of allergies or immunocompetence as an exposure or outcome, select *Other or unclear*. If a project is examining the impact of antiretroviral therapy (ART) in the prevention of HIV transmission, it may be appropriate to select A2.22 *Medication/device* as the exposure and A3.18 *Infectious disease* and A3.18.a *HIV/AIDS* as the outcomes.

#### 19. *Kidney disease*

Kidney disease is a leading cause of death and can be a rationale. It includes conditions of the urinary system such as chronic kidney disease, nephritis, renal failure, urinary tract infections, and kidney stones. It may also include studies of bladder function, kidney function, and dialysis. It can be an exposure, for example, in a project looking at the risk for hepatitis C infection among persons with and without a history of urinary tract infections. It can be an outcome, for example, in projects looking at the relationship between a dietary supplement and nephritis. For projects measuring utilization of dialysis services, select *Kidney disease* and *Healthcare delivery*. For cancers involving the kidney, select *Cancer* instead. Tests of Kidney function that are not diagnostic of a disease or disease progression should be coded at *Other or Unclear*.

#### 20. *Lung disease*

Chronic lung disease is a leading cause of death and can be a rationale. This includes emphysema, chronic obstructive lung disease (COLD), chronic obstructive pulmonary disease (COPD), chronic lower respiratory disease, pulmonary fibrosis, asbestosis, and asthma. It also includes measures of lung disease such as forced expiratory volume (FEV<sub>1</sub>) as measured by spirometry or exhaled nitric oxide (eNO) for asthma. *Lung disease* does not include pneumonia/influenza, infectious disease (e.g., tuberculosis, bronchitis, pertussis), or cancer; select the appropriate topic. It can be an exposure, for example, in a project looking at whether having asthma affects physical fitness or physical activity. It can be an outcome, for example, in projects looking at whether e-cigarette use is associated with asthma. Tests of lung function that are not diagnostic of a disease or disease progression should be coded at *Other/Unclear*.

#### 21. *Maternal/paternal/child health*

Although this topic is not a specific health condition, it can be a rationale. If a project uses exposures or outcomes that are included in this topic, select this topic as a rationale. This topic includes projects of normal and abnormal growth, development, and adjustment during pregnancy, postpartum, infancy and childhood (i.e., age 5 and under), addressing the health of the mother or the fetus/child. It also includes projects related to male/female fertility and reproductive health, including contraception, and diseases of the reproductive system (aside from cancers). It includes projects of health conditions that are characteristically diagnosed during childhood/pregnancy/puerperium (e.g., neonatal illnesses; congenital malformations; pre-eclampsia; obstetric complications; and the screening for or incidence of cystic fibrosis, inborn errors of metabolism, or genetic disorders), but does not include diseases that can appear during adulthood and happen to be studied in children (e.g., childhood obesity, childhood cancer, childhood asthma). Select Maternal/paternal/child health if the project is assessing the mother-child transmission of a risk factor or health condition (e.g. mother-child transmission of HIV, effects of maternal drug use/stress/diet during pregnancy). Select Maternal/paternal/child health if the project is studying parenting practices, breastfeeding, and projects about child maltreatment, but do not select this topic if the project is about parental decisions in medical care (e.g., vaccinations, surgery).

For projects that examine fetal death, miscarriage, abortion, and pregnancy termination, select Maternal/paternal/child health for rationale and Other or unclear for outcome and not Mortality since these data are compiled separately by the CDC National Center for Health Statistics. Select Maternal/paternal/child health and Mortality for rationale for projects of infant death which occurs before the first birthday (e.g., Sudden infant death syndrome, also known as SIDS).

#### 22. *Medication/device*

This topic includes any medication, or strategy of using multiple medications, as well as medical devices such as defibrillators, artificial valves, screening devices such as a colonoscope, etc., and their side effects or toxicities. It includes medical use of marijuana and nicotine when

delivered as a medical product (e.g., nicotine replacement products such as nicotine patch, nicotine inhaler, nicotine lozenge, nicotine nasal spray, nicotine gum). Note: Other tobacco products, such as e-cigarettes, are not medical products and cannot be marketed as such and so do not qualify as medications or medical devices; in these cases, select *Tobacco*.

*Medication/device* does not include dietary supplements (select *Diet*), radiation treatment or imaging (if radiosurgery, select *Surgery*, otherwise select *Other or unclear*), or *Vaccines*. If a project is examining drug-resistance or uses a similar term, select *Infectious disease*, or *Pneumonia/influenza* if it is examining that disease as the rationale, exposure, or outcome as appropriate, because the drug-resistance is caused by changes in the infectious agent.

Medications or devices are not health conditions and so cannot be a rationale. This topic can be an exposure, for example, if a project is evaluating the efficacy of a new medication or medical device in preventing a health condition. Medications are specially formulated for a diseased patient population and make health claims. If a project is examining the effectiveness of a new type of condom, select *Medication/device* as the exposure. This topic can be an outcome, for example, if a study is looking at what exposures or interventions influence the delivery of medications; the use of a medical device in clinical practice; or the sensitivity, pharmacokinetics, or pharmacodynamics of a medication or drug. Another example of *Medication/device* as an outcome is a project that examines measures of medication or device compliance/adherence. If a project uses contraception methods that are medications or devices (e.g., IUD, birth control pill/patch, Depo-Provera), select *Medication/device* as the exposure or outcome and *Maternal/paternal/child health* as the rationale, if appropriate. If a project is examining the impact of antiretroviral therapy (ART) in the prevention of HIV transmission, it may be appropriate to select *Medication/device* as the exposure and *Infectious disease* as the outcome. If it is clear the medication/device has not yet been approved by FDA or already in general use, select *Other/unclear* for this medication/device. Projects evaluating the side effects or toxicities of a medication/device are evaluating the safety of the medication/device; select *Medication/device* or *Other/unclear* (if not FDA approved or in general use) for the **A.3. Outcome** and *Pilot/feasibility/proof-of-concept/safety* under **E. Study design/purpose** for these projects. For example, if a project is investigating allergies to penicillin, then it may be appropriate to select *Medication/device* as the exposure and outcome. If an abstract says the project will measure feasibility, acceptability, or a similar term, code those as *Other or unclear* outcomes.

### 23. *Mental health*

This topic includes mental health disorders such as mood disorders (e.g., major depressive disorder, anxiety disorders), post-traumatic stress disorder (PTSD), attention deficit disorder, eating disorders (e.g., anorexia, bulimia), conduct disorder, schizophrenia, etc. Select this topic if the investigator uses the term “mental health,” “mental illness,” “depression”, “psychiatric or psychological disorder,” “psychopathology,” or similar terms but not “psychological health” or “depressive symptoms.” *Mental health* includes self-care or self-management of psychiatric or mental health disorders. It does not include mental states that are not disorders such as moods (select *Other or unclear*), neurological disorders and dementia (select *Neurological disease*), or Alzheimer’s disease (select *Alzheimer’s disease*). It is a health condition, so it can be a rationale. It can be an exposure, for example, in projects of whether people with a particular mental illness are more likely to abuse drugs or become HIV-infected. It can be an outcome, for example, in a project examining environmental or genetic exposures to the development of a certain mental illness. *Mental health* does not include cognitive decline (select *Other or unclear*) or cognitive functioning (may be appropriate to select *HRQOL [Health-related quality of life]*). For projects that examine substance use addictive behavior disorders as an exposure or outcome, select *Alcohol*, *Substance use*, or *Tobacco* as appropriate and do not select *Mental health*. Note: *Suicide* is a separate topic and therefore is not included as part of *Mental health*.

#### 24. *Microbiome*

These are communities of microbes (e.g., bacteria, fungi, archaea, viruses) found at many sites on the human body. These microbes often exist in a symbiotic relationship with their human hosts. *Microbiome* includes analysis of the role of these microbes in human health and disease. Therefore, the microbiome would be considered an exposure for projects that examine the relationship between microbiomes and disease. For example, if a project is examining the effect of the microbiome on colorectal cancer, select *Microbiome* as the exposure and *Cancer* as the outcome. This topic can be an outcome if a project is examining the changes of the microbiome due to a health condition, environmental, or other exposure. For example, if a project is examining the effect of physical activity on changes of the gut microbiome, select *Physical activity* as the exposure and *Microbiome* as the outcome. This topic excludes the study of pathogenic or infectious microbes; for these projects, select *Infectious disease*. Projects that are only examining the content of the microbiome (i.e., the individual microbes within the microbiome) with no relation to a health condition or risk factor are considered basic research.

#### 25. *Mortality*

Mortality and death are synonymous. This topic includes the term “survival” but not necessarily “survivor” or “survivorship.” It also includes the terms “longevity” and “lifespan” if used in the context of mortality. It does not include projects that use survival analysis to analyze data unless death is a measured outcome. Measures that use death in their calculation, such as quality-adjusted life years (QALYs) and disability-adjusted life years (DALYs), are included in this topic. *Mortality* can be a rationale if, for example, an abstract or Public Health Relevance statement includes a statistic about deaths per year. *Mortality* cannot be an exposure because mortality cannot be a precursor to another health condition. *Mortality* can be an outcome, whether due to a specific condition or all-cause mortality. For projects of disease-specific mortality as an outcome, select both the disease and *Mortality* as outcomes. Note: *Suicide* is a separate topic and therefore is not included as part of *Mortality*. For projects that examine fetal death, miscarriage, abortion, or pregnancy termination, select *Maternal/paternal/child health* and not *Mortality* for rationale since these data are compiled separately by the CDC National Center for Health Statistics.

#### 26. *Motor vehicle crash (MVC)*

This topic includes all types of motor vehicle crashes and all types of motor vehicles: cars, buses, airplanes, etc. It is not a health condition, so it cannot be a rationale. It can be an exposure, for example, in a project of unintentional injuries resulting from motor vehicle crashes. It can be an outcome, for example, in projects examining the effect of a change in policy governing drinking ages on nighttime single vehicle crashes.

#### 27. *Musculoskeletal disease*

This topic includes conditions of the muscles or skeleton (including teeth). Examples include osteoarthritis, osteoporosis, rheumatoid arthritis, other joint problems, myositis, myopathy (though cardiac myopathy is included in *Heart disease*), and dental caries. It is a health condition, so it can be a rationale. It can be an exposure, for example, in a study of whether history of rheumatoid arthritis increases the risk of unintentional injuries. It can be an outcome, for example, in a project to identify genetic risk factors for osteoarthritis. *Musculoskeletal disease* does not include fractures; for these projects, select *Unintentional injuries*.

#### 28. *Neurological disease (not Alzheimer’s)*

This topic includes conditions of the nervous system and neurological disorders, e.g., Parkinson’s, neuropathies, autism, dementia, epilepsy, cerebral palsy, multiple sclerosis, Mild Cognitive Impairment (MCI) and neurodegenerative conditions. For projects evaluating developmental delays

due to autism during childhood, select *Maternal/paternal/child/health* and *Neurological disease* as rationale. Note: *Alzheimer's disease* is listed separately because it is a leading cause of death. *Neurological disease* is a health condition, so it can be a rationale. It can be an exposure, for example, in a case-control study of whether Parkinson's disease patients are more likely to suffer from falls. It can be an outcome, for example, in a project about the development of neurological disorders such as early-onset dementia in football players with a history of traumatic brain injury. *Neurological disease* does not include cognitive decline; for these projects, select *Other or unclear*.

#### 29. *Obesity*

Obesity is considered a disease, so it can be selected as a rationale. This topic includes overweight and studies of energy balance in the context of overweight and obesity. It includes measures of obesity, such as body mass index (BMI), adipose tissue, sustained weight loss, or waist circumference in projects clearly studying overweight or obesity. It does not include physical activity projects or studies of energy balance unless the projects also focus on overweight/obesity. Projects that involve weight measures as exposures or outcomes that are outside the context of obesity or overweight should not be included in this topic (e.g., in a project examining BMI as a measure of wasting in seriously ill patients). If a project examines the relationship between BMI (as a measure of obesity) or body composition and subsequent disease, then select *Obesity* as an exposure. If a project tests approaches to reduce obesity, then select *Obesity* as an outcome.

#### 30. *Physical activity*

Physical activity, including aerobic activity, resistance training, activity patterns, sedentary behavior, or inactivity, is a leading actual cause of death. It is not a health condition, so it cannot be a rationale. Projects about yoga, including those types of yoga that incorporate meditation, are included in *Physical activity*. For studies of meditation alone, select *Other or unclear*. *Physical activity* can be an exposure, for example, in projects examining the relationship between physical activity or inactivity and subsequent disease. It can be an outcome, for example, in projects evaluating the effect of an intervention on subsequent physical activity levels. If a project includes measures of attitude, knowledge, beliefs, or intentions about physical activity or exercise, select *Other or unclear*. If a project is examining an educational intervention or therapy that engages participants in physical activity, select both *Education/counseling* and *Physical activity* as the exposure.

#### 31. *Policy/built environment*

This topic includes projects that examine the effects of existing policies established by laws/regulations or by organizations such as school policy, worksite policy, household policy, or healthcare policy. It also includes projects involving indoor/outdoor environmental structures in the community such as sidewalks, billboards, parks, tobacco and alcohol retail outlets, and other manmade environments. It also includes features of those environments such as land use, walkability and the availability of fruits and vegetables. This topic does not include examinations of social norms/networks, nor projects of environmental health generally (e.g., projects examining the source or impact of environmental toxins). It is not a health condition, so it cannot be a rationale. It can be an exposure in a project examining the relationship between a policy or environment and a health condition. For example, if a project is evaluating how a higher sales tax on cigarettes influences smoking, it may be appropriate to select *Policy/built environment* as the exposure and *Tobacco* as the outcome. It can be an outcome if a project is examining approaches that could be used to change a health-related environment or policy. If the content of the policy focuses on another topic listed under **A. Study Focus** – e.g. *Alcohol*, *Substance use*, *Obesity*, *Tobacco* – it may be appropriate to select *Policy/built environment* and the other topic as the exposure and/or outcome. For example, for a project designed to change economic policy to influence tobacco control, select *Tobacco* as the outcome and *Policy/built environment* as the exposure and outcome.



### 32. *Pneumonia/influenza*

Pneumonia/influenza is a leading cause of death. These conditions are listed together because death generally occurs from influenza if it progresses to pneumonia. This topic includes diagnostic measures of pneumonia/influenza, such as chest x-ray or plasma proteins. It is a health condition, so it can be a rationale. It can be an exposure, for example, in a project looking at whether previous exposure to pneumonia increases risk for chronic lung disease or cancer. It can be an outcome, for example, in projects examining interventions, medications, or other methods to prevent these infections. If the project is about pneumonia/influenza, select this topic instead of *Infectious disease*. This topic also includes testing and measures of pneumonia or influenza (e.g., viremia, antibodies, viral blood count) indicating natural infection or immunity, not vaccine-induced immunity. For projects using measures of pneumonia or influenza that indicate vaccine-induced immunity, select *Vaccine* to represent these measures. If a project about pneumonia or influenza is examining drug-resistance or uses a similar term, select this topic because the drug-resistance is caused by changes in the infectious agent.

### 33. *Sexual behavior*

This includes risky sexual behaviors like failure to use condoms outside of a stable monogamous relationship and sexual contact with people who have a sexually transmitted disease like HIV/AIDS or other sexually transmitted infections (STI). This topic includes other sexual behaviors that can also increase risk of disease under some circumstances. This topic includes measures of sexual behavior such as age at first sexual encounter or number of partners and the use of behavioral contraceptive methods such as condoms, abstinence, withdrawal method, or rhythm method. It does not include sexual identity. It is not a health condition, so it cannot be a rationale. It can be an exposure, for example, if a project is examining specific sexual behaviors increasing the risk for infectious disease like HIV or Hepatitis B or D. It can be an outcome, for example, in a study examining social or familial effects on sexual behaviors. If a project includes measures of attitude, knowledge, beliefs, or intentions about sexual behaviors, select *Other or unclear*.

### 34. *Stress*

Stress is not a health condition, so it cannot be a rationale. Stress is the body's reaction to a stressor. Stressors can be anything (physical or psychological) that triggers a stress response in the body. Distress refers to stress induced by an unwelcome event or stress that exceeds the body's mechanisms for coping and is coded as *Stress*. Stress is of interest as a potential factor that influences health as an exposure (e.g., stress related to hypertension) or as an outcome (e.g., of an intervention study). This includes distress, psychosocial stress, and stressors but not resistance training (select *Physical Activity*), molecular/cellular stress (select *Other or unclear*), or PTSD (*Mental health*).

### 35. *Stroke*

Stroke is a leading cause of death, and includes hemorrhagic or ischemic stroke, cardiovascular events, and transient ischemic attacks (TIAs). It is a health condition, so it can be a rationale. It can be an exposure, for example, in a project that examines the risk of heart attacks in those who have already had a stroke. It can be an outcome, for example, in a project using physical activity interventions to prevent a second stroke. If a project cites cardiovascular disease (CVD) or peripheral artery disease (PAD), select both *Heart disease* and *Stroke*; but select only *Heart disease* if a project cites coronary heart disease (CHD). This topic does not include pre-clinical or subclinical cardiovascular disease; for these projects, select *Other or unclear* instead.

### 36. *Substance use*

Illicit drug use is a leading actual cause of death and is a diagnosable condition, so it can be a rationale. This includes use of illegal substances or abuse of prescription or legal substances (other than tobacco or alcohol) that could harm health. It also includes overdose and withdrawal from those substances and addiction to those substances. This topic includes measures of substance use/abuse such as age of onset or frequency of use as well as measures of substance use, such as drug-specific metabolites. It can be an exposure, for example, in a project examining the relationship of cocaine use and subsequent ischemic stroke. It can be an outcome, for example, in a project of interventions to prevent opioid use disorder. For projects about alcohol or tobacco use, select those topics instead of *Substance use*. This topic does not include the medical use of marijuana (select *Medication/device*) but does include recreational use of marijuana. If a project includes measures of attitude, knowledge, beliefs, or intentions about substance use, select *Other or unclear*.

### 37. *Suicide*

Suicide is a leading cause of death and includes suicidal ideation or intent as well as suicidal behavior (actual and attempted suicide by any means). It is a health condition, so it can be a rationale. It can be an exposure, for example, in a project that examines whether a prior suicide attempt leads to a previously undiagnosed mental disorder. It can be an outcome, for example, in projects testing suicide-prevention interventions or examining risk factors for suicide. If a project includes measures of attitude, knowledge, or beliefs, about suicide, select *Other or unclear*.

### 38. *Surgery*

This topic includes any kind of surgery (e.g., by scalpel, laparoscope, radiosurgery) and the immediate pre-operative preparation for surgical procedures (e.g., using antibiotic wash on the patient, starting an intravenous line). Surgery is not a health condition, so it cannot be a rationale. It does not include long-term preparation for surgery that takes place outside of the surgical setting (e.g., taking prophylactic antibiotics, preparing organs for implant). Examples of surgery include circumcision, appendectomy, tonsillectomy, laparoscopy, biopsy, and skin grafting. This topic includes organ transplantation procedures, but it does not include complications resulting from the transplant (e.g., graft versus host disease [GVHD], primary graft dysfunction [PGD], organ rejection); select *Other or unclear* for these conditions. *Surgery* can be an exposure (e.g., a project testing effects of bariatric surgery effects on risk of diabetes), but it also can be an outcome (e.g., a project looking at factors that influence, or interventions to influence, the use of surgical procedures in practice).

### 39. *Tobacco*

Tobacco use includes smoking, smokeless tobacco, e-cigarettes, other products derived from tobacco (e.g., lozenges, lollipops), tobacco addiction, smoking cessation, and regulatory science related to tobacco use. This topic includes self-reported measures of tobacco use such as age of onset or number of cigarettes smoked per day, as well as objective measures of tobacco exposure through either secondhand smoke exposure or active smoking, such as cotinine or exhaled carbon monoxide. It can be a rationale because it is a diagnosable condition and does influence numerous health conditions. Tobacco use can be an exposure (e.g., a project to find out whether tobacco use is a risk factor for cancer) or a project outcome (e.g., a project to encourage smokers to quit, where smoking status would be the outcome). If a project is examining the effect or impact of toxins from tobacco smoke, select *Chemical/toxin* as the exposure or outcome instead (in this case, it may be appropriate to select *Tobacco* as the rationale). This topic includes exposure to secondhand smoke from tobacco unless the project is measuring specific chemicals/toxins, in which case select *Chemical/toxin*. For a project designed to change economic policy to influence tobacco control, select *Tobacco* as the rationale and outcome and *Policy/built environment* as the exposure and

outcome. For projects that examine nicotine dependence disorder as an exposure or outcome, select *Tobacco* and do not select *Mental health*.

Nicotine replacement products marketed with health claims should be coded under *Medication/device*, not under *Tobacco*. This would include nicotine replacement gum, nicotine patches, nicotine inhalers, nicotine nasal spray, or nicotine lozenges. Other products that deliver nicotine (e.g., e-cigarettes) cannot be marketed with health claims and so *Tobacco* should be selected for those products. If a project includes measures of attitude, knowledge, beliefs, or intentions about tobacco use, select *Other or unclear*. Note: Tobacco plants may be used as a production platform for a drug that has nothing to do with nicotine or tobacco use as described here; in such cases, do not select *Tobacco* as a topic.

#### 40. *Unintentional injuries*

Unintentional injuries are a leading cause of death. This is a health condition, so it can be a rationale. This topic includes unintentional injuries or death from falls, fires, or unintentional drowning (if deaths are being studied, also select *Mortality*). It includes fractures, traumatic brain injuries, concussions, and spinal cord injuries. It can be an exposure, for example, in a project examining the risk of developing osteoarthritis after suffering an ankle fracture. It can be an outcome, for example, in projects examining interventions or risk factors for falls in the elderly. This does not include injuries from motor vehicle crashes or firearms; for these projects, select *Motor vehicle crash* or *Firearms*, respectively.

#### 41. *Vaccine*

Traditional vaccines contain either parts of microbes or whole microbes that have been killed or weakened so that they don't cause disease. When administered, the body develops antibodies so that if later confronted with the same microbe, the body is able to defeat it. Increasingly, the term vaccine is also used to describe drugs that induce the immune system to block the psychoactive and behavioral effects of nicotine and other addictive drugs. This topic is used broadly to include both traditional and newer types of vaccines. If *Vaccine* is selected, do not also select *Medication/device*.

*Vaccine* includes immunizations, vaccine delivery, projects of population-level immunity, adjuvants and other vaccine ingredients, and vaccine development. It also includes measures of immune response (e.g., antibodies) if those markers are used to indicate immune response to the vaccine. It is not a health condition, so it cannot be a rationale. It can be an exposure, for example, in projects testing the efficacy of a new vaccine. It can be an outcome, for example, in vaccine development projects or projects seeking to increase use of vaccines (e.g., vaccine initiation, vaccine-related behaviors). If a project includes measures of attitude, knowledge, beliefs, or intentions about vaccines, select *Other or unclear*. If, for example, a project is examining allergic reactions to the flu shot among people with an egg allergy, then it may be appropriate to select *Vaccine* as the exposure and *Other or unclear* as the outcome; do not select *Diet*. This topic does not include vaccine escape phenotypes; because these projects are about viruses, select *Infectious disease*.

Some projects may examine cancer vaccines for prevention. Cancer prevention vaccines are similar to traditional vaccines because they protect against infectious agents, so it is appropriate to select *Vaccine* as exposure or outcome; they are not medications because they induce an immune response and do not treat cancer. For example, in a project examining the efficacy of a human papilloma virus (HPV) vaccine in protecting against incident cervical cancer, select *Infectious disease* (for HPV) and *Cancer* as the **A.1. Rationale**, *Vaccine* as the **A.2. Exposure**, *Cancer* as the **A.3. Outcome**, and *Preventing a new health condition, promoting health, or identifying risk factors* as the **F. Prevention research category**. Cancer treatment vaccines are intended to treat an existing cancer, and it would be appropriate to select *Vaccine* as exposure or outcome, and *Other or unclear* under **F. Prevention research category**.

#### 42. *Violence*

Violence includes any threatening act or aggression such as assault, bullying, homicide (also select *Mortality*), sexual violence, elder abuse, and carrying or making threats (e.g., physical, verbal) with weapons other than firearms. It is not a health condition, so it cannot be a rationale. It can be an exposure, for example, in a project examining children who are bullied and their risk for developing mental health conditions as adults. This can be an outcome, for example, in violence prevention interventions. This does not include motor vehicle crashes or firearms; for these projects, select *Motor vehicle crash* or *Firearms*, respectively. *Violence* includes child maltreatment or child abuse only if physical or sexual abuse is specifically being studied; for these projects, also select *Maternal/paternal/child health* for rationale. If a project includes measures of attitude, knowledge, beliefs, or intentions about violence, select *Other or unclear*.

#### 43. *Other or unclear*

Select this topic as the rationale if the health condition serving as the rationale is not listed in **A.1 Rationale**. Do not select this topic as the rationale for a blacked-out topic. Select this topic as the exposure or outcome when none of the topics listed apply (e.g., cost and cost-effectiveness, attitudes, intentions, social norms). This topic should be selected for disease risk unless the risk is based on a measure of the health condition itself (e.g., incidence or prevalence). If a project is examining prevalence or incidence of a health condition, disease, or risk/protective factor, select *Other or unclear* as the exposure and the health condition, disease, or risk/protective factor as the outcome. If a project describes symptoms that are not diagnostic of a disease or condition (e.g., depressive symptoms, psychiatric symptoms, diabetes symptoms, coughing as a symptom), select *Other or unclear* as appropriate for exposure or outcome.

#### **B. [Removed]**

#### **C. [Removed]**

#### **D. Population focus**

The population groups listed below should be selected only if explicitly stated as being studied in the abstract and/or title (i.e., recruited, measures taken, interventions delivered). Other sources of information (other than the project abstract) will be available to provide information on race/ethnic and gender distributions, so they are not included in this list. More than one population may be selected if applicable; sometimes this information can be found when the abstract refers to recruitment sources. In a project with multiple population groups, select all that apply; if there is any group that does not fit, select *Other or unclear* to represent that group. If the abstract uses an indecipherable symbol followed by an age (e.g., “e60”, “¿10”), then treat the symbol as equivalent to an “=” (equal sign). Special populations of interest are based on demographic characteristics, not disease status. They include the following:

##### 1. *Incarcerated/institutionalized*

This topic refers to residential populations in prisons, mental health institutions, rehabilitation facilities, nursing homes, and/or hospice care facilities. It includes participants who are recruited, measured, or given an intervention while they are incarcerated/institutionalized, even if they are not incarcerated/institutionalized for the duration of the project. It also includes participants who were released from incarceration/institutionalization if the focus of the project is on that population. Note: This topic focuses on those who are incarcerated/institutionalized long-term, so

the terms “hospitalized patients” or “inpatients” are not sufficient to justify selecting *Incarcerated/institutionalized*.

2. *Sexual or Gender Minorities*

This topic includes but is not limited to individuals who identify or are described in the research project as lesbian, gay, bisexual, asexual, transgender, two-spirit, queer, and/or intersex. It also includes individuals with same-sex or -gender attractions or behaviors (e.g., men who have sex with men (MSM)), or those with a difference in sex development. These populations also encompass those who do not self-identify with one of these terms but whose sexual orientation, gender identity or expression, or reproductive development is characterized by non-binary constructs of sexual orientation, gender, and/or sex.

3. *Low income*

Use this topic when the investigator states “poor,” “impoverished,” “low wage,” “low socioeconomic status,” or similar term. This topic includes individuals who participate in assistance programs (e.g., Medicaid, food stamps, WIC, SNAP, etc.) or are served by healthcare safety net providers (e.g., federally qualified health centers). This does not include child welfare, which is the equivalent of child protective services and distinct from financial welfare. Note: A disadvantaged population is not considered *Low income*, but an economically disadvantaged population (e.g., homeless) is considered *Low income*.

4. *Military/veterans*

This topic includes all branches of the military and their reserves: Army, Air Force, Coast Guard, Marine Corps, and Navy, as well as the National Guard. The Commissioned Corps of the U.S. Public Health Service is a non-military uniformed service and therefore not included in this topic. This topic also includes military dependents as well as retired military and military veterans who are serviced by the medical facilities, clinics, and benefits offices of the U.S. Department of Veteran Affairs.

5. *Older adults/elderly*

Use this topic when the investigator states, “older adults” or the “elderly” or “geriatric” population and gives no specific ages, or when the age range may include age 65 and older. If the project also examines adults below age 65 then also select *Other or unclear* unless another topic is selected that describes the study population. This topic includes Medicare beneficiaries since a majority of this group is 65 and older.

6. *People with disabilities*

Use this topic when the investigator uses the term “disability” or if the project includes people with an impairment that substantially limits one or more major life activities. This includes hearing impairments/deafness, vision impairments/blindness, developmental disabilities (e.g., autism spectrum disorder, Asperger’s Syndrome), intellectual disabilities (e.g., Down syndrome, Prader-Willi syndrome, Fragile X syndrome, Angelman syndrome), learning disabilities (e.g., dyslexia, dyspraxia, dysgraphia), and physical disabilities (e.g., amputation, paralysis, cerebral palsy, spinal cord injury, multiple sclerosis). Note: Not all people with mental illness are considered disabled; if the abstract gives context that those with mental illnesses have a disability, then it may be appropriate to select this topic.

7. *Pregnant and/or post-partum persons*

Use this topic when the investigator uses “pregnant,” “post-partum,” “lactating” or a similar term that indicates pregnant women or women (or persons) within one year of giving birth.

8. *Rural*

Use this topic when the investigator uses “rural,” “agricultural,” “village,” “tribal” or a similar term.

9. *Urban*

Use this topic when the investigator uses “urban” or “inner city” or other similar term; or when a specific city is named (names of Universities or Hospitals should not be used for this category). Note: When a project is a community-based study conducted in a city, select *Urban*. This topic does not include counties, even if they are known to be urban (ex: Los Angeles County).

10. *Youth*

Use this topic for studies of fetuses, infants, children, or adolescents (<18 years), or “pediatric” population. If the project also examines adults age 18 and older, then select *Other or unclear* unless another topic can describe the study population.

11. *Other or unclear*

Use this topic when a study population is not listed above or when there are no human subjects. For example, if the population is women only and in an urban setting, select *Urban* only, do not also select *Other or unclear*. Another example would be a study of men who have sex with men; select only *Sexual or Gender Minorities* and do not select *Other or unclear*.

## E. Study design/purpose

Below are descriptions of the most common study designs used in prevention research. Select all that apply for the particular abstract. More than one study design may be possible in an abstract. For example, an abstract could have a first phase that is an *Observational study* and a second phase that is a *Randomized intervention study*. If *Analysis of existing data*, *Methods research*, or *Pilot/feasibility/proof-of-concept/safety study* are selected, it may be appropriate to select another topic to describe the study design.

An abstract describing a clinical trial to evaluate a medication, device, or treatment may use the following terminology referring to the phases of clinical trials:

- Pre-clinical: Research using animals to find out if a medication, device, procedure, or treatment is safe and likely to be useful. Pre-clinical studies take place before any testing in humans is done. Note: Pre-clinical studies precede Phase I studies; for projects that are entirely pre-clinical studies, select only *Other or unclear* for the **E. Study design/purpose** and *Other or unclear* for the **F. Prevention research category**. However, if there is a second phase of the project, it may be appropriate to select another **E. Study design/purpose**. In those situations, do not code the pre-clinical part of the project.
- Phase I: Testing a new medication, device, or treatment in a small group of people to evaluate its safety and identify side effects. For these projects, select *Pilot/feasibility/proof-of-concept/safety*. Note: Select *Other or unclear* under **F. Prevention research category** for Phase I clinical trials.
- Phase II: Testing a new medication, device, or treatment in a larger group of people to see if it is effective and further evaluate its safety. For these projects, select *Pilot/feasibility/proof-of-concept/safety*. Note: Select *Other or unclear* under **F. Prevention research category** for Phase II clinical trials.
- Phase III: The medication, device, or treatment is given to a larger group of people to confirm its effectiveness, compare it to commonly used treatments, and collect information that will

allow the medication, device, or treatment to be used safely. If the project is designed as a randomized study, select *Randomized intervention study*. Otherwise, select *Non-randomized intervention study*.

- Phase IV: Projects done after the medication, device, or treatment has been marketed to gather information on the drug's effect in various populations and any side effects associated with long-term use. For these projects, select *Observational study*.

An abstract describing prevention research more generally may use the following terminology:

- Hypothesis development: These projects are often classified as *Analysis of existing data* or *Observational studies*.
- Methods development: These projects are often classified as *Methods research*.
- Controlled intervention trials, also called efficacy trials, or explanatory trials: An intervention refers to any kind of exposure designed or intended to have a specific, non-transient effect on a health condition (disease, disorder, injury, disability) or risk/protective factor. Examples include provision of a new vaccine to prevent malaria infection, universal vs. targeted HIV screening in the emergency department, health education programs to encourage smoking cessation, and medication to treat high blood pressure. These projects are often classified as *Randomized intervention studies*, or if randomization was not used, as *Non-randomized intervention studies*.
- Defined population studies: These projects are often classified as *Randomized intervention studies*, or if randomization was not used, as *Non-randomized intervention studies*.
- Implementation projects, also called effectiveness trials, or pragmatic trials: These studies are often classified as *Randomized intervention studies*, or if randomization was not used, as *Non-randomized intervention studies*. They can also be *Observational studies*.

#### 1. *Analysis of existing data*

This topic is often called secondary data analysis. Select this topic when the project is analyzing data collected by others or collected in a previous project by the same investigators, such as for analysis of an existing dataset or of synthetic data, meta-analyses, simulation studies, development of risk prediction equations, or similar activities. If a project names an existing clinical trial, community trial, or epidemiologic study as a source of data, select *Analysis of existing data*. If the project is recruiting subjects or taking samples or biological specimens from the named trial or project, select *Analysis of existing data*. This topic includes projects that abstract information from existing records such as electronic health records, patient charts, claims records, etc., when the data are used in their existing form. The data need to exist only at the time the investigator accesses them. This topic does not include primary data collection. If the abstract proposes to use point estimates from existing data for validation, that is not considered *Analysis of existing data*. For example, a project may use information about prevalence of a certain condition, gathered from an existing project, to validate a survey tool – this is not considered *Analysis of existing data*. Document-based research is not necessarily considered *Analysis of existing data*. For example, a project may analyze documents such as cigarette ads, press releases, or newspaper articles to identify and categorize common marketing messages used by the tobacco industry – this is not considered *Analysis of existing data* because the data must be manipulated in order to analyze it. Conversely, if a project uses patient charts or electronic health records to extract the weight and height of each patient in the sample, this project is considered *Analysis of existing data*. Selecting this topic does not preclude selecting other topics in **E. Study design/purpose**.

#### 2. *Methods research*

Select this topic for projects that are developing and/or validating new methods or improving existing methods. Examples include developing and/or evaluating different study designs,

statistical analysis approaches, measurement approaches (including the development of new measures for risk or prognosis), recruitment strategies, survey instruments, surveillance tools, screening methods, etc. This topic includes projects examining the sensitivity, specificity, and/or predictive value of a screening tool. It should not be selected just because the project uses different or unusual methods or adapts an existing method to a new population. It also does not include the development of interventions. Selecting this topic does not preclude selecting other topics in **E. Study design/purpose**.

This topic does not include the development or testing of diagnostic tools, unless they are explicitly used for screening or are explicitly described as screening tools. Projects that identify or discover biomarkers are not included in this topic; however, projects that develop and/or validate biomarkers are considered *Methods research*. If a project is developing a predictive model, it may be considered *Methods research*; however, using an existing predictive model is not considered *Methods research*.

This topic includes simulation studies to compare different study design options or different statistical analysis approaches applied to prevention research questions; such projects generate new data and so are not examples of *Analysis of existing data*. It is not appropriate for all simulation studies, for example, where the project uses simulation methods to compare the effects of two possible policy choices on morbidity or mortality rates. Nor would it be appropriate for a molecular simulation study to develop a new medication.

Do not select *Methods research* if a project is only conducting basic science research or testing basic research methods. Selection of *Methods research* under **E. Study design/purpose** is independent of whether a project is conducting prevention research. Whether the methods research includes prevention research will only be considered under **F. Prevention research category**.

### 3. *Non-randomized intervention study*

Select this topic for projects examining causal effects of interventions but that do not randomize participants to receive, or not receive, the intervention. An intervention refers to any kind of exposure designed or intended to have a specific, non-transient effect on a health condition (disease, disorder, injury, disability) or risk/protective factor. If the terms “randomized,” “randomly assigned,” or “random assignment” are not used, select this topic for intervention projects where it is not clear how the participants were assigned. These include the following type of studies:

- a. Quasi-experiments. Intervention and control groups are determined by the investigators, but participants are not assigned randomly; includes pre-to-post or time series designs with a comparison group but no randomization.
- b. Pre-post study without an external control/comparison group. One measurement of project outcome occurs before and one occurs after an intervention is delivered; there is a within-subjects comparison.
- c. Natural experiments where interventions are not delivered by the investigators but are being delivered by others or through policy or environmental changes, not under control of the investigator. Examples of this type of study may include measurements that are taken before and after a policy intervention (also called a pre-post study).
- d. Multiple baseline or time series designs. Multiple measurements of project outcomes occur before, during, and after an intervention is delivered; there may or may not be a comparison group.
- e. External comparison. A comparison group is not recruited or assigned by the investigators, but one outside the project is used. For example, county, state, or national data collected by others or historical data previously collected is used to form the comparison group.



- f. Regression discontinuity design. Individuals are assigned to intervention or comparison on the basis of a quantitative score, with all participants on one side of a cutpoint assigned to the intervention arm and all participants on the other side of that cutpoint assigned to the comparison arm. There is no randomization of participants to study arms.
- g. Other projects conducted to follow participants after completion of a non-randomized intervention study where the non-randomized design is maintained or used in the comparison.
- h. If the project has an intervention but does not describe a design consistent with the six designs described above, select *Other or unclear*.

#### 4. *Observational study*

Select this topic for projects where naturally occurring exposures and outcomes are measured and analyzed, and no intervention is delivered. An intervention refers to any kind of exposure designed or intended to have a specific, non-transient effect on a health condition (disease, disorder, injury, disability) or risk/protective factor. This topic includes the following study designs:

- a. Case-control study. Starts with cases who have the condition/disease, identifies controls (often by matching on age, gender, etc.), and compares prior exposures to predict the condition/disease.
- b. Cohort study. Starts with people who do not have the condition/disease, measures exposures, and follows the people over time to identify onset of the condition/disease or health conditions in those exposed compared to not exposed.
- c. Cross-sectional study. Exposures and outcomes are measured at the same time; includes prevalence studies and population surveys.
- d. Ecological study. Observational study where the unit of analysis is groups of people or geographic areas such as counties, states, or nations.
- e. Other observational study designs, such as case-control studies nested in a cohort study, observational studies conducted to follow participants after completion of a randomized controlled trial where the randomized design is no longer maintained or used in the comparison, or other designs.
- f. This topic includes the following study designs: Genome-wide association studies (GWAS) as well as Whole Exome and Whole Genome studies.

#### 5. *Pilot/feasibility/proof-of-concept/safety study*

Select this topic when the project description uses “pilot,” “feasibility,” “proof-of-concept,” “safety,” or similar terms (e.g., acceptability, usability) in the context of testing a procedure. The project can be observational or an intervention. This topic includes projects that are testing whether an intervention is culturally acceptable to a population but does not include projects that are only using a “culturally acceptable” intervention. Projects testing the effectiveness or efficacy of an intervention are not included in this topic. Note: Side effects of medications/devices may be used to evaluate safety and/or toxicity; it may be appropriate to select *Medication/device* under **A. Study Focus** and *Pilot/feasibility/proof-of-concept/safety*. Selecting this topic does not preclude selecting other topics in **E. Study design**.

Select this topic for career development awards if a specific research project is included among the activities undertaken in addition to mentoring and training activities.

## 6. *Randomized intervention study*

Look for the terms “randomized,” “randomly assigned,” or “random assignment.” Note: This is not the same as random selection/sampling or a randomization test.

Randomized controlled trials where the intervention is delivered by investigators includes the following study designs:

- a. Individually randomized controlled trials (RCT). Individual subjects are randomly assigned to an intervention or control group.
- b. Group randomized trials (GRT). Groups of people, organizational entities (such as schools or worksites), or entire communities are randomly assigned to intervention or control group; also called cluster randomized trials.
- c. Individually randomized group-treatment trials (IRGT). Individuals are randomized to intervention or control arms but receive at least some portion of their intervention in small groups or from a shared interventionist (e.g., instructor, surgeon).
- d. A few designs are almost always randomized designs, even though the abstract may not refer to randomization. These should be coded under this category and include controlled clinical trials, factorial designs, and stepped wedge designs. In the case of cross-over studies, select this category only if the abstract mentions randomization.
- e. Follow-up studies involving participants from a randomized trial where the investigators will continue to compare the intervention and control arms for long-term effects of the intervention. These studies may appear to be observational studies, because there is no plan for any further intervention, but as long as there is comparison between the intervention and control arms (randomization is maintained), these follow-up studies should be coded as Randomized intervention studies. If at least one aim qualifies as an Observational study, these follow-up studies may also be coded as Observational studies.
- f. This topic does not include simulation studies, even if they used randomization.

## 7. *Other or unclear*

Select this topic if the design/purpose is not listed in one of the categories above or if you cannot tell from the abstract whether the project fits into one of the above options. For example, select this topic for projects where an intervention is being delivered, but there is no indication of randomization or the use of a comparison group. For basic research, select *Other or unclear*. Basic research whose purpose is an understanding of biological structure, biological mechanisms, or behavioral mechanisms should be coded *Other or unclear*.

## F. **Prevention research category**

This category groups projects into topics of prevention research that should enable people interested in subtypes of prevention research to identify projects within that subtype and to allow for consideration of what is considered prevention. Therefore, the topics are designed to accommodate various definitions of prevention.

Think about the research as described in the abstract and select one or more of the following categories of prevention. If you are not sure, select *Other or unclear*.

1. *Preventing a new health condition, promoting health in the general population, or identifying risk factors for a new health condition*
  - a. This topic is often called primary prevention or health promotion.

- b. Factors of interest include health behaviors, environmental exposures, and biological risk or protective factors (including biomarkers) that may increase or reduce risk of a new health condition or promote health.
- c. Includes observational studies that identify risk and/or protective factors for onset of a new health condition or for promoting optimal health. Includes risk prediction projects including genetic risk and other factors that may increase risk of a health condition.
  - i. This topic does not include identification of risk factors for disease recurrence; for those projects, select *Preventing progression of disease, preventing recurrence in those with a known health condition, identifying risk factors for progression or recurrence*.
- d. Includes development and evaluation of interventions to reduce risk of a new health condition, such as improving health behaviors and decreasing identified risk factors.
- e. Includes intervention studies that are testing prevention or health-promotion interventions in apparently healthy people without an existing health condition.
- f. Includes preventing a new health condition in people who already have a health condition that may increase risk of the new condition.
- g. Examples include: promoting physical activity and healthy diet in the general population; preventing smoking initiation; preventing first heart attacks; preventing new primary cancer after remission for a different cancer; tobacco control policies to prevent smoking initiation; preventing high blood pressure; preventing injurious motor vehicle crashes; preventing injuries from falls; preventing CVD in cancer survivors; preventing the progression of precancerous conditions/lesions to cancer; prevention of the development of Barrett's esophagus, as well as the development of esophageal cancer in patients with Barrett's esophagus; preventing suicide in people with depression; promoting healthy diet and exercise in people with diabetes to prevent CVD; provision of metformin or dietary interventions to prevent pre-diabetes from developing into diabetes; evaluating vaccines to prevent infectious disease in humans through an efficacy trial; mastectomy to prevent breast cancer in someone who has never had it before but is at high risk; ART treatment in people with HIV to prevent transmission of HIV; preventing incidence or transmission of drug resistant infectious disease.

## 2. *Screening for risk factor*

- a. Screening is defined as testing for known risk or protective factors in people not previously known to have a certain health condition to identify individuals or groups at risk for that health condition.
- b. This topic is considered part of primary prevention.
- c. Includes screening to detect asymptomatic and unidentified risk factors, and/or asymptomatic risk conditions. The project may be looking at effects or outcomes from an existing screening test. However, not all projects involving screening for a disease mean that the project is about screening. For example, a project may be screening patients for eligibility and then assigning eligible patients to an intervention. In contrast, if participants are assigned to an SBIRT intervention where screening is part of the intervention, then select this topic or *Screening for early disease* depending on the purpose of the screening.
- d. Excludes methods research that is developing a screening tool or method (select *Methods research*) unless the screening tool or method is being applied after it has been validated. Also excludes basic research projects examining biological mechanisms that may ultimately lead to a screening test, because they do not have immediate relevance for primary or secondary prevention research (select *Other or unclear*). Also excludes basic research that may use the term "screening," such as high throughput screening (HTS) of molecules for drug development.

- e. Includes projects establishing the incidence or prevalence of risk or protective factors in a population or subpopulation.
- f. Examples include: detection of elevated blood pressure by routine BP measurement (a risk factor for stroke), screening for physical inactivity or poor diet in people without a diagnosis, and screening for cervical dysplasia by Pap smear.

### 3. *Screening for early disease*

- a. Screening for early disease is defined as testing people not previously known to have a certain health condition to identify individuals or groups who have early, pre-clinical disease, for which they have not sought care and are asymptomatic. However, not all projects involving screening for a disease mean that the project is about screening. For example, a project may be screening patients for eligibility and then assigning eligible patients to an intervention. In contrast, if participants are assigned to an SBIRT intervention where screening is part of the intervention, then select this topic or *Screening for risk factor* depending on the purpose of the screening. If the screening is not explicitly for early disease, then select *Screening for risk factor*.
- b. This topic is considered part of secondary prevention. Note: If the project subjects have sought care for symptoms or a condition, then it is not screening; it is diagnostic testing or evaluation.
- c. Excludes methods research that is developing a screening tool or method (select *Methods research*) unless the screening tool or method is being applied after it has been validated. Also excludes basic research projects examining biological mechanisms that may ultimately lead to a screening test, because they do not have immediate relevance for primary or secondary prevention research (select *Other or unclear*). Also excludes basic research that may use the term “screening,” such as high throughput screening (HTS) of molecules for drug development.
- d. Examples include: detection of breast cancer by routine mammography; detection of colon cancer by routine colonoscopy; and detection of HIV infection through screening of high-risk persons.
- e. Includes projects establishing the incidence or prevalence of early disease in a population or subpopulation.

### 4. *Preventing progression of disease, preventing recurrence in those with a known health condition, identifying risk factors for progression or recurrence*

- a. Identification of, or intervention for, behaviors and risk/protective factors (including biomarkers) that affect risk for progression of disease or recurrence of a known health condition.
- b. Includes observational studies to identify health behaviors or other potential risk or protective factors for progression or recurrence as well as intervention studies to evaluate interventions to improve health behaviors or other risk/protective factors in order to prevent progression or recurrence. This also includes screening to identify progression or recurrence or risk/protective factors for progression or recurrence.
- c. Some people consider this primary prevention, whereas others consider it secondary prevention.
- d. This topic does not include treatment or management of a diagnosed health condition unless that treatment is being evaluated in that project for its effect on progression or recurrence. There are six exceptions: treatment for HIV, tobacco use disorder, substance use disorder, alcohol use disorder, weight loss treatment for overweight/obese populations, and preventing those with suicidal ideation or behaviors from committing suicide. Substance use disorder treatment to prevent overdose deaths is also considered an exception under treatment for

substance use disorder and should be coded under this category. Preventing the progression of any other disease to death is considered treatment and should be coded as *Other or unclear*. For projects that involve other treatment situations or chronic conditions with predictable episodic recurrence (e.g., mental health, asthma, diabetes), select *Other or unclear*.

- e. Examples include: prevention of spontaneous mutation from non-resistant infectious disease to drug resistant infectious disease; promotion of heart-healthy nutrition in subjects who have had a heart attack to reduce risk of another heart attack; promotion of exercise to reduce risk of a recurrent cancer; exercise rehabilitation to reduce risk of another heart attack; treatment of high blood pressure to reduce risk of another stroke; antiretroviral therapy (ART) to prevent progression from HIV to AIDS; prevention of diabetic retinopathy; prevention of development of AIDS-related malignancies; tobacco control policies for smoking cessation; behavioral interventions to prevent relapse for alcohol use disorder or substance use disorder; preventing smoking relapse; treatment for opioid use disorder to prevent overdose deaths; aspirin to prevent another stroke in subjects who already had a stroke; adjuvant treatment using tamoxifen or radiation to prevent recurrence of breast cancer after breast cancer treatment; mastectomy to prevent another breast cancer; behavioral interventions to reduce risk of reinfection of an infectious disease that has been previously treated; promoting weight loss in overweight/obese populations; repeat bone scans to monitor progression of osteoporosis, either as a form of screening or to evaluate an intervention to prevent progression; repeat carotid ultrasounds to monitor progression of atherosclerosis, either as a form of screening or to evaluate an intervention to prevent progression; preventing those with suicidal ideation or behaviors from committing suicide.

#### 5. *Methods research*

Select this topic for projects that are developing and/or validating new methods or improving existing methods. Examples include developing and/or evaluating different study designs, statistical analysis approaches, measurement approaches, recruitment strategies, survey instruments, screening methods, etc. This topic includes developing and validating predictive models, which should not be confused with animal models or theoretical or logic models and frameworks. This topic includes projects examining the sensitivity, specificity, and/or predictive value of a screening tool. It should not be selected just because the project uses different or unusual methods or adapts an existing method to a new population. It also does not include development of interventions.

Select only *Methods research* if the investigator is developing and/or validating a method but does not apply it beyond the validation stage. If the method is applied beyond the validation stage (e.g., to identify a risk/protective factor, prevent a specific disease or condition, or screen for a risk/protective factor or early disease), then it may be appropriate to select another topic in **F**.

**Prevention research category.** For example, if a project is developing a predictive model, it may be considered *Methods research*; however, using an existing predictive model is not considered *Methods research*.

This topic does not include development or testing of basic research methods. It also does not include development or testing of diagnostic tools, unless they are explicitly used for screening or explicitly described as screening tools.

Projects that identify or discover biomarkers are not included in this topic; however, projects that develop and/or validate biomarkers are considered *Methods research*. For projects that identify or discover biomarkers that mark the onset of disease or disease progression/recurrence, select *Preventing a new health condition, promoting health in the general population, or identifying risk factors for a new health condition* or *Preventing progression of disease, preventing recurrence in those with a known health condition, identifying risk factors for progression or recurrence*, as appropriate. For projects of biomarkers for treatment response or prognosis as it relates to treatment, select *Other or unclear*.

This topic includes simulation projects to compare different study design options or different statistical analysis approaches applied to prevention research questions. It is not appropriate for all simulation projects, for example, where the project uses simulation methods to compare the effects of two possible policy choices on morbidity or mortality rates. Nor would it be appropriate for a molecular simulation project to develop a new medication.

Methods projects must have immediate relevance for prevention research (i.e., the results could be applied in new prevention projects without further development) and not be an early step that will eventually lead to application in prevention research.

#### 6. *Other or unclear*

Select this topic when you cannot reasonably place the project into a topic above.

If any of topics 1–5 or 7 in **F. Prevention research category** are selected, do not select *Other or unclear*. Basic research whose purpose is an understanding of biological structure, biological mechanisms, or behavioral mechanisms should be coded *Other or unclear* because it is too distal to be considered primary or secondary prevention research. Just as biological mechanisms are those biological processes that underpin biological phenomena, behavioral mechanisms are the processes that explain or underlie observed behavioral phenomena. Behavioral mechanisms could include but are not limited to: executive control, emotion regulation, metacognition, interoception, social regulation of behavior, and decision-related processes such as valuation, risk perception, temporal discounting, and social influence.

Treatment, including management of chronic conditions such as asthma, HIV/AIDS, and diabetes; projects investigating sequelae or complications of treatment; treatment to prevent progression of disease to death; rehabilitation studies; projects about palliative care; and projects developing new medications or therapies for treatment and rehabilitation should be coded *Other or unclear*. There are six exceptions: projects investigating sequelae or complications of treatment for HIV, tobacco use disorder, substance use disorder and alcohol use disorder, weight loss treatment for overweight/obese populations, and preventing those with suicidal ideation or behaviors from committing suicide. Substance use disorder treatment to prevent overdose deaths is also considered an exception. These should be coded *Preventing progression of disease, preventing recurrence in those with a known health condition, identifying risk factors for progression or recurrence*. For projects developing medications, vaccines, or devices that may eventually be used in prevention research, select *Other or unclear*. For Phase I and Phase II clinical trials, select *Other or unclear*.

#### 7. *Prevention type unspecified*

It may be applicable to select this topic for awards that include career development, training awards and research-support/infrastructure.

If the abstract or PHR include goals and/or activities related to “preventing a new health condition”, or “understanding risk factors”, “health promotion” or health screening” and/or treatment of any of the six exceptions listed in the taxonomy protocol, code prevention (F1-F5) as applicable. If prevention type as indicated in the abstract or PHR are unclear (only mentions training in “prevention research”), code new “**F7 prevention type unspecified**”. If no mention of prevention and/or treatment of any of the six exceptions listed in the taxonomy protocol, code F6.

### G. Flags

A project may cover topics or have study design elements that are not captured in another category. For example, a project may be conducted outside of the U.S. and U.S. territories, have a basic research aim, or focus on establishing project infrastructure. In these cases, it may be

appropriate to select one of the following flags for the abstract. It may be appropriate to select more than one flag for an abstract. Not every abstract will require a flag and, in cases where a flag is not needed, select *G6. Unclear or None*. Flags can only be added if there is at least one fully codable aim in the project.

1. *Partial*

This flag should be used when an abstract contains one or more basic science aims and at least one aim that can be fully coded (this flag should not be selected for grants coded E7F6 only). Examples include: A project that will test the use a new medical device in an animal model and then conduct a pilot test in humans; a project that validates a biomarker for a disease in a human cohort and describes the mechanisms of this condition in cell lines; a project that will study the characteristics of disease-carrying vectors in a specific area and then determine the prevalence of the disease in a human population; or a project that will study predictors of a psychological process, such as self-control, in Aim 1, and how self-control is related to exercise, diet, or another behavior in Aim 2.

2. *Infrastructure*

This flag should be used if an abstract contains infrastructure aims that are related to applied research (e.g., investigator training, capacity building, creating a new cohort for future studies, establishment of a data center, coordinating center, a biobank, call centers). The collection of a new wave of data from an existing cohort, the addition of new members into an existing cohort, or the collection of additional tests from an existing cohort are not considered part of this topic. Additionally, aims related to the dissemination or implementation of research should not be coded in this topic.

3. *International research*

This flag is used to identify grants that specifically mention that the research is occurring in a country other than the U.S. This flag may be selected if research is happening both within and outside the U.S. This flag may also be selected if the project uses existing data collected outside the U.S. (e.g., survey data, EMRs collected internationally).

4. *Occupational risks*

An occupational disease is any health condition contracted because of exposure to risk factors arising from work activity. Select this flag if the abstract mentions the exposure to an event/risk factor or the occurrence of a health condition that is caused by the work activities of the studied population. Only the following risks are included in this category: occupational asbestos (e.g., asbestos exposure or mesothelioma), occupational asthmagens, occupational carcinogens (e.g., arsenic, acid, benzene, beryllium, cadmium, chromium, diesel, formaldehyde, nickel, polycyclic aromatic hydrocarbons, second-hand smoke, silica, trichloroethylene), occupational injuries (fatal and non-fatal), occupational ergonomic factors (e.g., lower back pain), occupational noise, and occupational particulates. Other occupational risks such as biological (e.g., tuberculosis infections in health workers, avian influenza in farmers), psychological (e.g., PTSD in war veterans or emergency workers), or violence risks are not considered in this category. Illegal occupations (e.g., drug trafficking, illegal mining, sex work) are not considered a part of this category. Do not select this flag for health interventions that occur at a worksite but are not related to an occupational risk (e.g., lifestyle modification interventions in the workplace).

5. *Health economics*

This flag is used to identify grants that use cost effectiveness analyses, cost-utility analyses, cost-benefit analyses, healthcare financing and costs (e.g., health insurance payments and out-of-pocket expenses such as deductibles and co-payments) or return on investment analyses when

evaluating health interventions. Interventions that test the effect of financial incentives are included in this flag, but do not select it for projects that mention providing financial incentives for enrollment. Cost-effectiveness analyses are frequently used in prevention research. The most common metric is an incremental cost effectiveness ratio (ICER), which is the ratio of change in costs to the change in effects, also called the cost per quality-adjusted life year (QALY). To select this flag, the economic measurement should be assessed in at least one of the aims of the project. Do not select this flag if a project is only describing an intervention or test as being cost-effective; rather, it must be studying the project as a whole.

6. *Unclear or None*

Select this category if none of the research flags appear in a project or if it is unclear if one of them should be coded. This category does not need to be selected if only E7F6 (basic research) is selected.