

# D2d Ancillary Study Application



*Office Use*

Ancillary Study Number \_\_\_\_\_

Date Submitted (MM/DD/YYYY) \_\_\_\_\_

Title of Proposal  
(81 character limit)

Principal Investigator \_\_\_\_\_

Institutional Affiliation \_\_\_\_\_

Street Address 1 \_\_\_\_\_

Street Address 2 \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

Co-Investigator 1 \_\_\_\_\_

Institutional Affiliation \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

Co-Investigator 2 \_\_\_\_\_

Institutional Affiliation \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_ Email \_\_\_\_\_

*If Principal Investigator is not a member of the D2d study group, please specify:*

D2d Co-Investigator \_\_\_\_\_

Institutional Affiliation \_\_\_\_\_

*Other Key Persons (biosketch is not required)*

Name \_\_\_\_\_ Ancillary Study Role \_\_\_\_\_

Name \_\_\_\_\_ Ancillary Study Role \_\_\_\_\_

Name \_\_\_\_\_ Ancillary Study Role \_\_\_\_\_

Name \_\_\_\_\_ Ancillary Study Role \_\_\_\_\_

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## ***D2d Ancillary Study Subcommittee Use Only***

Ancillary Studies Subcommittee Action

Date

Steering Committee Action

Date

DSMB Action

Date

*Approved Applications*

Consent form required?

## Part 1: Research Plan

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### 1a. Anticipated Timeline and Enrollment

Planned Start Date \_\_\_\_\_

Planned End Date \_\_\_\_\_

Anticipated Enrollment \_\_\_\_\_

### 1b. Hypothesis and Specific Aims

*Please describe the question(s) you are asking and what you expect to happen (3/4 page limit).*

## 1c. Significance and Brief Background

*Please describe the scientific relevance (1 page limit).*

## 1d. Innovation & Impact

*Please describe the research innovation and potential impact (1/2 page limit).*

## 1e. Research Approach

*Please address the following: (1 and 1/2 page limit)*

- *Study type (e.g. interventional or observational)*
- *Population and setting (inclusion/exclusion criteria)*
- *Study design (e.g. details of study procedures, outcome assessments, confounders, bias)*
- *Schedule of assessments*
- *Sample size (power) calculations*
- *Data analysis plan*

*Please continue Research Approach on next page.*



## 1f. References Cited

Please attach a list of references (PDF format document) with the application.

## Part 2: Description of Data

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### 2a. Required Sources of Data

Please select all that apply:

Existing data collected as part of D2d study

If yes, please complete **D2d Ancillary Study Data Request Form**

New data derived through use of stored biological specimens collected as part of D2d study

If yes, please complete **D2d Ancillary Study Specimen Request Form**

New data derived through direct contact with D2d participants (e.g. procedure, survey, observation)

If yes, please complete question 2b

**If available, please include a copy of the proposed protocol with your application.**

### 2b. New Data Acquisition, if applicable

Please describe the additional procedures, interventions or surveys required for new data acquisition and address the need for additional visits and/or the prolongation of existing visits. (1/2 page limit).

## Part 3: Facilities & Resources

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### 3a. D2d Collaborating Clinical Sites

**Please note:** By marking the box next to a site(s), the ancillary study PI has secured the commitment of the site(s) to the proposed ancillary study to allow generation of new data by direct contact with D2d participants at the site.

Please select all D2d collaborating clinical sites that have agreed to participate in the proposed Ancillary Study.

- |   |   |
|---|---|
| Atlanta VA Medical Center                         | Northwestern University                         |
| Baylor College of Medicine                        | Pennington Biomedical Research Center           |
| Duke University Medical Center                    | Stanford University Medical Center              |
| Florida Hospital Translational Research Institute | Tufts Medical Center                            |
| HealthPartners Research Foundation                | Tulane University Health Sciences               |
| Los Angeles Roybal                                | University of Cincinnati VA Medical Center      |
| Maine Medical Center Research Institute           | University of Kansas Medical Center             |
| Medical University of South Carolina              | University of Nebraska Medical Center           |
| MedStar Health Research Institute                 | University of Tennessee Health Science Center   |
| NIDDK Phoenix                                     | University of Texas Southwestern Medical Center |

### 3b. Description of Clinical Laboratory Facilities, *if applicable*

Please describe clinical laboratory facilities and where and how bio-specimens will be handled (e.g. storage, shipping of biological material; laboratory staff experience).

## Part 4: Potential Burden on the D2d study

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*Please describe the potential burden of the ancillary study **on the D2d study** in relation to the following and provide ways to minimize the burden:*

### 4a. Participant Burden and Potential for Compromising Participant Retention

### 4b. Participant Safety and Confidentiality

*Please describe measures taken to ensure participant safety and confidentiality and address plan for data management (secure storage, monitoring etc.).*

### 4c. Burden on Collaborating Clinical Sites

## 4d. Regulatory Requirements

*Please describe how informed consent will be obtained and describe plan for local IRB approval. If available, please attach a copy of the informed consent form.*

## Part 5: D2d Support

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**Please note:** The costs associated with the use of resources (D2d or other) must be included in the plans for funding the ancillary study. All negotiated services must be documented in a letter of commitment from the provider of such services.

*Please select resources at the D2d Coordinating Center or D2d Central Laboratory that will be required. There will be a fee associated with these services:*

- Data extraction and transfer
- Specimen selection and transfer
- Data analyses (*depending upon staff availability, proposed analyses may be conducted by the analytical team at the D2d Coordinating Center*)
- Other study-specific services for studies that will collect new data in real time

## Part 6: Funding

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### 6a. Funding Source(s)

*Please describe ancillary study funding source(s) or plans to apply for funding.*

**6b. Planned Date of Submission to Funding Agency** \_\_\_\_\_

## Part 7: NIH Biosketch

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*Please attach NIH Biosketches **for PI only** with your application upon submission.*

## D2d Ancillary Study Application



### Part 8: Acknowledgement of D2d Ancillary Studies Policies & Procedures

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I have read and agree to abide by the policies and procedures for D2d Ancillary Studies as described in the document titled: *D2d Ancillary Studies Policies and Procedures & Instructions for Submission of Proposals*, and specifically regarding the presentation and publication of ancillary study results and data sharing policies.

Principal Investigator Signature  
(e-signature accepted)

*James M. Dallywan*

Date

*7/17/13*

### Part 9: Attachments

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Please indicate all documents that are included with your application:

- NIH Biosketches for PI only (*required for all applications*)
- References Cited (*required for all applications*)
- D2d Ancillary Study Data Request Form
- D2d Ancillary Study Specimen Request Form

Please note: The following forms are not required with application, but are required prior to study initiation:

- Ancillary Study Proposal
- Ancillary Study Manual of Procedures
- Informed Consent Form (*required for studies involving generation of new data via direct contact with D2d participants*)
- IRB Approval Letter

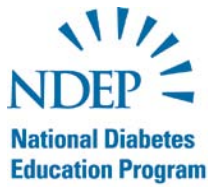
#### Final steps to submission:

Save a copy of this form to your computer.

Click on the "Submit" button, which will open an email and automatically attach application. In that email, attach additional documents checked above to complete application then send.



Thank you for your interest in the D2d Study



A program of the National Institutes of Health and the Centers for Disease Control and Prevention

ID: \_\_\_\_\_

## Vitamin D and Type 2 Diabetes (D2d) Study

### NDEP Questionnaire #1

#### Introduction

Your answers to the questions below will help the National Diabetes Education Program (NDEP) create better materials for people at risk for diabetes. Answering the questions is voluntary, and your answers will not be shared with anyone other than the research study staff. You have the right to stop answering these questions at any time. There is no penalty or loss of benefits to you if you do not complete the questions.

It should take you about 10 minutes to complete these questions. If you don't know the answer, leave it blank.

#### Questions

**1. How can you prevent or delay type 2 diabetes?**

*(Please mark one.)*

- a. Lose as much weight as you can
- b. Eat fruits and vegetables every day
- c. Eat less sugar
- d. Lose anywhere from 5 to 10 percent of your body weight

**2. If you have prediabetes, your blood glucose levels are:**

*(Please mark one.)*

- a. Below normal
- b. Normal
- c. Above normal

**3. Which of the following are important steps you should take to lose weight?**

*(Please mark all that apply.)*

- a. Take in fewer calories than you burn during the day
- b. Skip meals
- c. Eat less fat (especially saturated fats and trans fats) than you currently eat
- d. Eat smaller portions of high fat and high calorie foods than you currently eat

**4. Which of the following is the least (or smallest) amount of physical activity you should do to help prevent type 2 diabetes?**

*(Please mark one.)*

- a. 30 minutes of activity, five times a week (or 150 minutes per week)
- b. 10 minutes of activity, seven days a week (or 70 minutes per week)
- c. 45 minutes of activity, six days a week (or 270 minutes per week)
- d. 60 minutes of activity, three days a week (or 180 minutes per week)

**5. Which of the following health problems is not usually linked to diabetes?**

*(Please mark one.)*

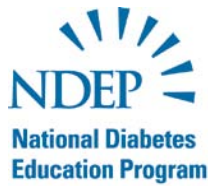
- a. Vision problems
- b. Heart problems
- c. Allergy problems
- d. Kidney problems

**6. Please circle the number that best describes your knowledge of each statement. (Please circle one number for each line.)**

How sure are you that you know:	Extremely unsure	Somewhat unsure	Neutral	Somewhat sure	Extremely sure
a. How many calories you should eat each day?	1	2	3	4	5
b. How many grams of fat you should eat each day?	1	2	3	4	5
c. How much physical activity you should get each week?	1	2	3	4	5
d. How to make healthy food choices?	1	2	3	4	5
e. How to get as much physical activity as you should?	1	2	3	4	5
f. How many calories are in the foods and drinks you have most often?	1	2	3	4	5
g. The serving (portion) size of the foods and drinks you have most often?	1	2	3	4	5

**7. For each statement, please circle the number that best describes your behaviors. (Please circle one number for each line.)**

Have you:	I do not intend to	I am considering doing so within the next 6 months	I plan to within the next month	I started this less than 6 months ago	I started this 6 months ago or longer
a. Increased the number of times you are physically active each week?	1	2	3	4	5
b. Increased how hard you work during physical activity? (That is, you have added an activity that makes you sweat more, or spent more time doing such an activity.)	1	2	3	4	5
c. Reduced the amount of fat in your diet?	1	2	3	4	5
d. Reduced the number of calories you consume?	1	2	3	4	5
e. Set a weight loss goal?	1	2	3	4	5
f. Set a physical activity goal?	1	2	3	4	5
g. Kept track of what you eat and drink, and the activity you get, most days of the week?	1	2	3	4	5



## Vitamin D and Type 2 Diabetes (D2d) Study

### NDEP Questionnaire #2

A program of the National Institutes  
of Health and the Centers for  
Disease Control and Prevention

### Introduction

Your answers to the questions below will help the National Diabetes Education Program (NDEP) create better materials for people at risk for diabetes. Answering the questions is voluntary, and your answers will not be shared with anyone other than the research study staff. You have the right to stop answering these questions at any time. There is no penalty or loss of benefits to you if you do not complete the questions.

It should take you about 10 minutes to complete these questions. If you don't know the answer, leave it blank.

### Questions

**1. How can you prevent or delay type 2 diabetes?**

*(Please mark one.)*

- a. Lose as much weight as you can
- b. Eat fruits and vegetables every day
- c. Eat less sugar
- d. Lose anywhere from 5 to 10 percent of your body weight

**3. Which of the following are important steps you should take to lose weight?**

*(Please mark all that apply.)*

- a. Take in fewer calories than you burn during the day
- b. Skip meals
- c. Eat less fat (especially saturated fats and trans fats) than you currently eat
- d. Eat smaller portions of high fat and high calorie foods than you currently eat

**5. Which of the following health problems is not usually linked to diabetes?**

*(Please mark one.)*

- a. Vision problems
- b. Heart problems
- c. Allergy problems
- d. Kidney problems

**2. If you have prediabetes, your blood glucose levels are:**

*(Please mark one.)*

- a. Below normal
- b. Normal
- c. Above normal

**4. Which of the following is the least (or smallest) amount of physical activity you should do to help prevent type 2 diabetes?**

*(Please mark one.)*

- a. 30 minutes of activity, five times a week (or 150 minutes per week)
- b. 10 minutes of activity, seven days a week (or 70 minutes per week)
- c. 45 minutes of activity, six days a week (or 270 minutes per week)
- d. 60 minutes of activity, three days a week (or 180 minutes per week)

**6. Please circle the number that best describes your knowledge of each statement. (Please circle one number for each line.)**

How sure are you that you know:	Extremely unsure	Somewhat unsure	Neutral	Somewhat sure	Extremely sure
a. How many calories you should eat each day?	1	2	3	4	5
b. How many grams of fat you should eat each day?	1	2	3	4	5
c. How much physical activity you should get each week?	1	2	3	4	5
d. How to make healthy food choices?	1	2	3	4	5
e. How to get as much physical activity as you should?	1	2	3	4	5
f. How many calories are in the foods and drinks you have most often?	1	2	3	4	5
g. The serving (portion) size of the foods and drinks you have most often?	1	2	3	4	5

**7. For each statement, please circle the number that best describes your behaviors. (Please circle one number for each line.)**

Have you:	I do not intend to	I am considering doing so within the next 6 months	I plan to within the next month	I started this less than 6 months ago	I started this 6 months ago or longer
1. Increased the number of times you are physically active each week?	1	2	3	4	5
2. Increased how hard you work during physical activity? (That is, you have added an activity that makes you sweat more, or spent more time doing such an activity.)	1	2	3	4	5
3. Reduced the amount of fat in your diet?	1	2	3	4	5
4. Reduced the number of calories you consume?	1	2	3	4	5
5. Set a weight loss goal?	1	2	3	4	5
6. Set a physical activity goal?	1	2	3	4	5
7. Kept track of what you eat and drink, and the activity you get, most days of the week?	1	2	3	4	5

At an earlier visit, you received the materials shown below:

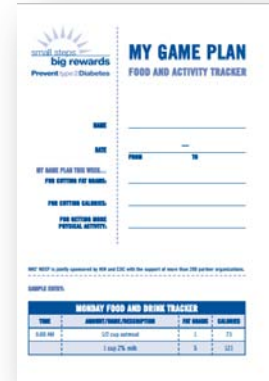
Your GAME PLAN to Prevent Type 2 Diabetes Information for Patients Booklet



Your GAME PLAN to Prevent Type 2 Diabetes Fat and Calorie Counter



MY GAME PLAN Food and Activity Tracker



8. The GAME PLAN materials were given to you as booklets. In what format would you prefer these materials? (Please mark all that apply.)

	Paper booklet	Smartphone/ Mobile app	Computer website
Information for Patients booklet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fat and Calorie Counter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Food and Activity tracker	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

9. Which of the following statements best describes your use of these materials? (Please mark one.)

- a. I never looked at them. (*Skip the remaining questions. Thank you.*)
- b. I skimmed them, but didn't use them.
- c. I started to use them to make changes in what I eat or how active I am, but stopped and went back to my old habits.
- d. I used them to make some changes in what I eat or how active I am, and I am continuing those changes.

10. For each statement, please circle the number that best describes how much you agree or disagree with it. (Please circle one number for each line.)

	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
a. The materials gave me enough information to <u>set a weight loss goal.</u>	1	2	3	4	5
b. The materials gave me enough information to <u>plan healthier meals.</u>	1	2	3	4	5
c. The materials gave me enough information to <u>start a physical activity program.</u>	1	2	3	4	5
d. The materials gave me enough information to <u>set a physical activity goal.</u>	1	2	3	4	5

11. How much of the Information for Patients (left image) did you read? (Please mark one.)

- a. None of it
- b. A few pages
- c. About half of it
- d. Most of it
- e. All of it

12. The Information for Patients booklet had: (Please mark one.)

- a. Too little information
- b. The right amount of information
- c. Too much information

13. What other information would you have liked to see in the Information for Patients booklet?

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14. How often did you use the Fat and Calorie Counter (center image)? (Please mark one.)

- a. Never
- b. Once
- c. A few times
- d. A few days
- e. For one to four weeks
- f. For more than four weeks

15. The Fat and Calorie Counter was: (Please mark one.)

- a. Too small
- b. Just right
- c. Too large

16. The Fat and Calorie Counter had \_\_\_\_\_ of the foods and drinks I usually have. (Please mark one.)

- a. All
- b. Most
- c. About half
- d. Some
- e. None

17. What foods and drinks would you like to see added to the Fat and Calorie Counter?

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18. How often did you use the Food and Activity Tracker (right image)? (Please mark one.)

- a. Never
- b. Once
- c. For a few days
- d. For one to four weeks
- e. For more than four weeks

19. The Food and Activity Tracker was: (Please mark one.)

- a. Too small
- b. Just right
- c. Too large

20. What changes would you like to see made to the Food and Activity Tracker?

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*Thank you for your time!*