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I. Draft your answers to the Pre-Protocol Diagnostic Survey

You will not need to answer all of the questions below. If your research is Exempt or Expedited, you will probably answer fewer than 10 questions.

To help you plan your answers, the questions below display routing directions. The routing directions will not be visible when you do the Pre-Protocol Diagnostic Survey in IRB Mentor.

For example, the options for Question 1 below are:

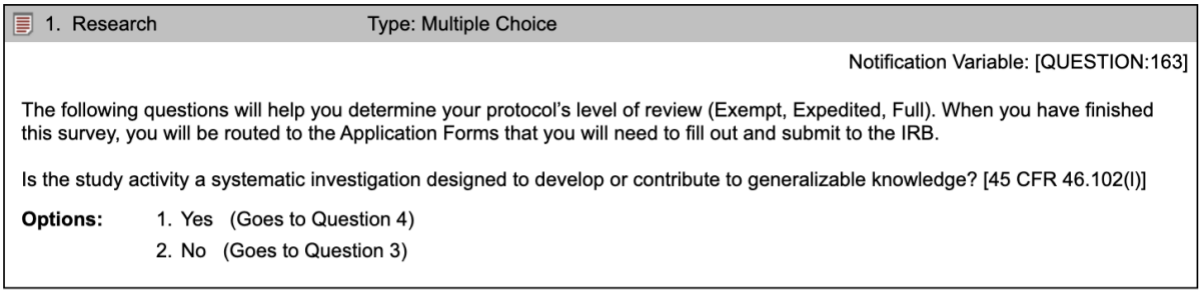
1. Yes (Goes to Question 4)
2. No (Goes to Question 3)

When you do the Pre-Protocol Diagnostic Survey in IRB Mentor, you will see:

1. Yes
2. No

IRB Mentor will route you appropriately (to either Question 4 or Question 3) based on the Yes/No option you select.

If you finish the survey and you think the review type assigned is incorrect, you can change it.



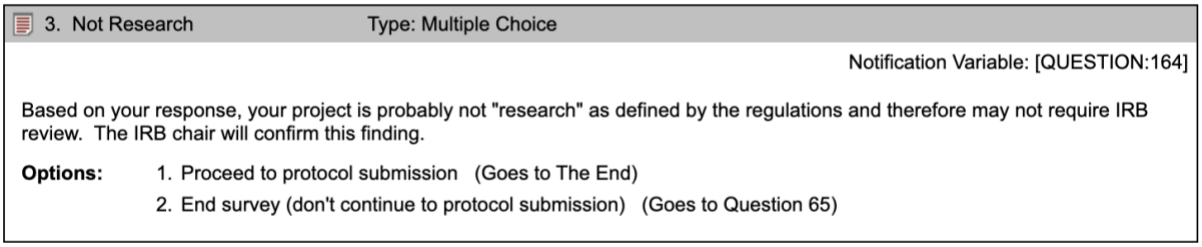
1. Research Type: Multiple Choice

Notification Variable: [QUESTION:163]

The following questions will help you determine your protocol's level of review (Exempt, Expedited, Full). When you have finished this survey, you will be routed to the Application Forms that you will need to fill out and submit to the IRB.

Is the study activity a systematic investigation designed to develop or contribute to generalizable knowledge? [45 CFR 46.102(l)]

Options:
1. Yes (Goes to Question 4)
2. No (Goes to Question 3)

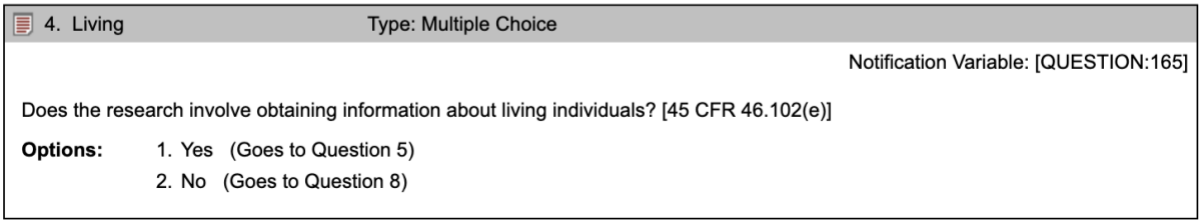


3. Not Research Type: Multiple Choice

Notification Variable: [QUESTION:164]

Based on your response, your project is probably not "research" as defined by the regulations and therefore may not require IRB review. The IRB chair will confirm this finding.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)



4. Living Type: Multiple Choice

Notification Variable: [QUESTION:165]

Does the research involve obtaining information about living individuals? [45 CFR 46.102(e)]

Options:
1. Yes (Goes to Question 5)
2. No (Goes to Question 8)

5. Intervention Type: Multiple Choice

Notification Variable: [QUESTION:166]

Does the research involve intervention or interaction with the study subjects? [45 CFR 46.102(e)(2) & (3)]

Options:
1. Yes (Goes to Question 7)
2. No (Goes to Question 6)

6. Identifiable Type: Multiple Choice

Notification Variable: [QUESTION:167]

Is the information individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information)? [45 CFR 46.102(e)(5)]

Options:
1. Yes (Goes to Question 7)
2. No (Goes to Question 8)

7. Private Type: Multiple Choice

Notification Variable: [QUESTION:168]

Is the information private? (About behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, or provided for specific purposes by an individual and which the individual can reasonably expect will not be made public? [45 CFR 46.102(f)(2)]

Options:
1. Yes (Goes to Question 9)
2. No (Goes to Question 8)

8. NHSR Type: Multiple Choice

Notification Variable: [QUESTION:169]

Based on your responses, the project does not involve human subjects and therefore most likely does not require IRB review. The IRB chair will confirm this finding.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

9. Prisoners Type: Multiple Choice

Notification Variable: [QUESTION:170]

Are prisoners (individuals confined in a penal institution or sentenced to incarceration alternatives) a target population of your research?

Options:
1. Yes (Goes to Question 50)
2. No (Goes to Question 10)

10. Exemption Categories Type: Multiple Choice

Notification Variable: [QUESTION:171]

Please select one of the exemption categories below or "None of the above":

Options:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices. (Goes to Question 11)
2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior. (Goes to Question 16)
3. Research involving benign behavioral interventions with adults. (Goes to Question 22)
4. Secondary research uses of identifiable private information or identifiable biospecimens. (Goes to Question 32)
5. Research studying, evaluating, or examining public benefit or service programs conducted or supported by a federal department or agency. (Goes to Question 36)
6. Research involving taste and food quality evaluation or consumer acceptance studies. (Goes to Question 39)
7. Storage or maintenance for secondary research for which broad consent is required: Storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research use if an IRB conducts a limited IRB review and makes the determinations required by §46.111(a)(8). (Goes to Question 42)
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use. (Goes to Question 45)
9. None of the above. (Goes to Question 50)

11. Educational Setting Type: Multiple Choice

Notification Variable: [QUESTION:172]

Is the research conducted in an established educational setting?

Options:

1. Yes (Goes to Question 12)
2. No (Goes to Question 14)

12. Normal Ed Practices Type: Multiple Choice

Notification Variable: [QUESTION:173]

Does the project involve normal educational practices, such as research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods?

Options:

1. Yes (Goes to Question 13)
2. No (Goes to Question 14)

13. Adverse Impact Type: Multiple Choice

Notification Variable: [QUESTION:174]

Are the research activities unlikely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.

Options:

1. Yes (Goes to Question 59)
2. No (Goes to Question 14)

14. Exempt or Expedited1 Type: Multiple Choice

Notification Variable: [QUESTION:175]

Sorry, based on your answers, your study does not meet the definition of educational research that is exempt. You may proceed to:

Options:

1. Evaluate eligibility for the exemption for testing, surveys, interviews and observation of public behavior (Goes to Question 15)
2. Review the expedited review categories (Goes to Question 50)
3. End survey (don't continue to protocol submission) (Goes to Question 65)

15. Exemption 2 Type: Multiple Choice

Notification Variable: [QUESTION:176]

Does the research only involve any of the following activities: educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording)?

Options:
1. Yes (Goes to Question 16)
2. No, continue on to evaluate exemption 3, benign behavioral interventions in adults (Goes to Question 21)
3. No, continue on to evaluate expedited review (Goes to Question 50)
4. No, end survey (don't continue to protocol submission) (Goes to Question 65)

16. Exempt 2 Children Type: Multiple Choice

Notification Variable: [QUESTION:177]

Does the research involve children (individuals under the age of 18)?

Options:
1. Yes (Goes to Question 17)
2. No (Goes to Question 19)

17. Question 17 Type: Multiple Choice

Notification Variable: [QUESTION:178]

Does the research involve...

Options:
1. ...any survey procedures, interview procedures, or observation of public behavior where the investigator PARTICIPATES in the activities being observed? [45 CFR 46.401(b)(3)] (Goes to Question 18)
2. ...only educational tests or observation of public behavior where the researcher DOES NOT PARTICIPATE in the activities being observed? (Goes to Question 60)

18. Children-Not Exempt Type: Multiple Choice

Notification Variable: [QUESTION:179]

Sorry, based on your answers, your study does not meet the definition of for exemption #2. You may proceed to:

Options:
1. Proceed to evaluate expedited review categories (Goes to Question 50)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

19. Identifiers & Risk Type: Multiple Choice

Notification Variable: [QUESTION:180]

Is the information obtained recorded in such a manner that human subjects CAN BE IDENTIFIED, directly or through identifiers linked to the subjects;

AND

could any disclosure of the human subjects responses outside the research reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation?

Options:
1. Yes (Goes to Question 20)
2. No (Goes to Question 60)

20. Limited Exempt 2 Type: Multiple Choice

Notification Variable: [QUESTION:181]

Your protocol may be eligible for exemption with *limited IRB review* to ensure that adequate measures to protect subject privacy and the confidentiality of the data are in place.

Options:
1. Proceed with exemption and limited IRB review (Goes to The End)
2. Proceed to evaluate expedited review (Goes to Question 50)
3. End survey (don't continue to protocol submission) (Goes to Question 65)

21. Benign Behavioral — Type: Multiple Choice

Notification Variable: [QUESTION:182]

Does the research involve only benign behavioral interventions with associated data collection with adults?

Options:
1. Yes (Goes to Question 22)
2. No, proceed to evaluate expedited review (Goes to Question 50)
3. No, end survey (don't continue to protocol submission) (Goes to Question 65)

22. Benign - Children — Type: Multiple Choice

Notification Variable: [QUESTION:183]

Does the research involve children (individuals under the age of 18)?

Options:
1. Yes (Goes to Question 23)
2. No (Goes to Question 24)

23. Exempt or Expedited3 — Type: Multiple Choice

Notification Variable: [QUESTION:184]

Sorry, because your study involves children, it does not meet the definition of the benign behavioral interventions on adults exemption category. You may...

Options:
1. Proceed to evaluate expedited review (Goes to Question 50)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

24. Benign Behavioral — Type: Multiple Choice

Notification Variable: [QUESTION:185]

Does the research involve benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording and will the subject prospectively agree to the intervention and information collection?

Options:
1. Yes (Goes to Question 26)
2. No (Goes to Question 50)

25. Harm — Type: Multiple Choice

Notification Variable: [QUESTION:186]

Do the intervention or methods of data collection introduce risks of harm, physical or emotional discomfort, offense or embarrassment?

Options:
1. Yes (Goes to Question 50)
2. No (Goes to Question 26)

26. Capacity — Type: Multiple Choice

Notification Variable: [QUESTION:187]

Will the participants all have adequate decision-making capacity to agree to participate in the proposed research?

Options:
1. Yes (Goes to Question 27)
2. No (Goes to Question 50)

27. Prospective — Type: Multiple Choice

Notification Variable: [QUESTION:188]

Does the nature of the research allow participants to agreement to the study procedures in advance, and if so, is the agreement required?

Options:
1. Yes (Goes to Question 29)
2. No (Goes to Question 50)

28. Brief — Type: Multiple Choice

Notification Variable: [QUESTION:189]

Is the intervention brief in duration (can be completed within one day)?

Options:
1. Yes (Goes to Question 29)
2. No (Goes to Question 50)

29. Deception — Type: Multiple Choice

Notification Variable: [QUESTION:190]

If the proposed research involves deception of the participants, will the prospective agreement (consent prior to commencement of the research procedures) include an explicit statement that the participant agrees to the planned deception?

Options:
1. Yes (Goes to Question 30)
2. No (Goes to Question 50)
3. Study does not involve deception (Goes to Question 30)

30. Intervention Types — Type: Multiple Choice

Notification Variable: [QUESTION:191]

Is the proposed research limited to one (or more) of the following categories?

- Communication or interpersonal contact with the participant.
- The performance of a cognitive, intellectual, educational or behavioral task.
- Manipulation of the subject's physical, sensory, social or emotional environment.

Options:
1. Yes - the proposed research ONLY involves procedures described in the list above. (Goes to Question 31)
2. No - the proposed research includes additional procedures with participants that do not fit in the categories listed above. Continue to evaluate expedited review. (Goes to Question 50)

31. Data Types — Type: Multiple Choice

Notification Variable: [QUESTION:192]

Are the means of collecting data limited to one or more of the following categories:

- Verbal (oral) or written responses by the participant.
- Data entry by the participant.
- Observation of the participant, including audiovisual recording.

Options:
1. Yes (Goes to Question 61)
2. No (Goes to Question 50)

32. Secondary Use — Type: Multiple Choice

Notification Variable: [QUESTION:193]

Does the research involve only secondary research use of identifiable private information or identifiable biospecimens?

Options:
1. Yes (Goes to Question 33)
2. No (Goes to Question 36)

33. Publicly Available — Type: Multiple Choice

Notification Variable: [QUESTION:194]

Are these sources publicly available?

Options:
1. Yes (Goes to Question 62)
2. No (Goes to Question 35)

34. HIPAA Data Type: Multiple Choice

Notification Variable: [QUESTION:195]

Is all the study data and use covered by HIPAA?

Options:
1. Yes (Goes to Question 62)
2. No (Goes to Question 35)

35. Identifiers Type: Multiple Choice

Notification Variable: [QUESTION:196]

Will information be recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects?

Options:
1. Yes (Goes to Question 62)
2. No (Goes to Question 36)

36. Fed Dept/Agency Type: Multiple Choice

Notification Variable: [QUESTION:197]

Is the data from a federal department or agency and was the data collected for non-research purposes?

Options:
1. Yes (Goes to Question 62)
2. No (Goes to Question 50)

37. Federal Projects Type: Multiple Choice

Notification Variable: [QUESTION:198]

Is the research conducted or supported by a federal department or agency, or otherwise subject to the approval of federal department or agency heads (or the heads of bureaus or subordinate agencies that have been delegated authority to conduct the research and demonstration projects)?

Options:
1. Yes (Goes to Question 38)
2. No (Goes to Question 50)

38. Intent Type: Multiple Choice

Notification Variable: [QUESTION:199]

Is the study designed to evaluate, improve, or otherwise examine public benefits or service programs, including procedures for obtaining benefits or services under those program, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs?

Options:
1. Yes (Goes to Question 63)
2. No (Goes to Question 50)

39. Wholesome Foods Type: Multiple Choice

Notification Variable: [QUESTION:200]

Does the research involve only wholesome foods without additives?

Options:
1. Yes (Goes to Question 41)
2. No (Goes to Question 40)

40. Additives Type: Multiple Choice

Notification Variable: [QUESTION:201]

Does the food contain ingredients at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Options:
1. Yes (Goes to Question 41)
2. No (Goes to Question 50)

41. Alcohol/Supplements Type: Multiple Choice

Notification Variable: [QUESTION:202]

Does the study involve alcohol, vitamins or supplements?

Options:
1. Yes (Goes to Question 50)
2. No (Goes to Question 64)

42. Repository Type: Multiple Choice

Notification Variable: [QUESTION:203]

Does this project involve the storage or maintenance of a repository for data and/or tissue samples?

Options:
1. Yes (Goes to Question 43)
2. No (Goes to Question 50)

43. Broad Consent Type: Multiple Choice

Notification Variable: [QUESTION:204]

Does the consent form contain the required elements for broad consent?

45CFR46.116(d) *Elements of broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens*. Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs (b) and (c) of this section. If the subject or the legally authorized representative is asked to provide broad consent, the following shall be provided to each subject or the subject's legally authorized representative:

(1) The information required in paragraphs (b)(2), (b)(3), (b)(5), and (b)(8) and, when appropriate, (c)(7) and (9) of this section:

(b)(2) A description of any reasonably foreseeable risks or discomforts to the subject;
(b)(3) A description of any benefits to the subject or to others that may reasonably be expected from the research;
(b)(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
(b)(8) A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled;

And when appropriate:

(c)(7) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit;
(c)(9) For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

(2) A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted;

(3) A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens;

(4) A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite);

(5) Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies;

(6) Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject; and

(7) An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

Options:
1. Yes (Goes to Question 44)
2. No (Goes to Question 50)

44. Exemption 7 Limited Type: Multiple Choice

Notification Variable: [QUESTION:205]

Your protocol may be eligible for exemption (#7) with limited IRB review to ensure that adequate measures to protect subject privacy and the confidentiality of the data are in place.

Options:
1. Proceed with exemption and limited IRB review (Goes to The End)
2. Proceed to expedited review categories (Goes to Question 50)
3. End survey (Goes to Question 65)

45. Identifiable Data Type: Multiple Choice

Notification Variable: [QUESTION:206]

Does the research involve the use of identifiable private information or identifiable biospecimens for secondary research?

Options:
1. Yes (Goes to Question 46)
2. No (Goes to Question 48)

46. Consent or Waiver Type: Multiple Choice

Notification Variable: [QUESTION:207]

Were the data and/or specimens obtained either:

Options:
1. ...under rules of broad consent with appropriate documentation of consent. (Goes to Question 47)
2. ...under a waiver of informed consent (Goes to Question 47)
3. None of the above (Goes to Question 48)

47. Returning Results Type: Multiple Choice

Notification Variable: [QUESTION:208]

Does the study include returning results to subjects?

Options:
1. Yes (Goes to Question 48)
2. No (Goes to Question 49)

48. Exempt or Expedited8 Type: Multiple Choice

Notification Variable: [QUESTION:209]

Sorry, based on your answers, your study does not meet the definition of exemption for secondary research under broad consent. You may proceed to:

Options:
1. Review the expedited review categories (Goes to Question 50)
2. End survey (Goes to Question 65)

49. Exemption 8 Limited Type: Multiple Choice

Notification Variable: [QUESTION:210]

Your protocol may be eligible for exemption (#8) with limited IRB review to ensure that adequate measures to protect subject privacy and the confidentiality of the data are in place.

Options:
1. Proceed with exemption and limited IRB review (Goes to The End)
2. Proceed to expedited review categories (Goes to Question 50)
3. End survey (don't continue to protocol submission) (Goes to Question 65)

50. Expedited Type: Multiple Choice

Notification Variable: [QUESTION:211]

Based on your responses, the project is not exempt from IRB review. The IRB chair will confirm this finding. Your project may be eligible for expedited review (that is, the IRB can approve your project without a full meeting).

Does the research present no more than minimal risk to human subjects and does the research involve only procedures including in the following categories?

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
   b. Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
   b. from other adults and children 2, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:
   a. hair and nail clippings in a nondisfiguring manner;
   b. deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;
   c. permanent teeth if routine patient care indicates a need for extraction;
   d. excreta and external secretions (including sweat);
   e. uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue;
   f. placenta removed at delivery;
   g. amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;
   h. supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (
   i. mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
   j. sputum collected after saline mist nebulization.

4. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
   a. physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject=s privacy;
   b. weighing or testing sensory acuity;
   c. magnetic resonance imaging;
   d. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
   e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

6. Collection of data from voice, video, digital, or image recordings made for research purposes.

7. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

Options:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met. (Goes to Question 51)
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows... (Goes to Question 52)
3. Prospective collection of biological specimens for research purposes by noninvasive means. (Goes to Question 53)
4. Collection of data through noninvasive procedures. (Goes to Question 54)
5. Research involving materials (data, documents, records, or specimens)... (Goes to Question 55)
6. Collection of data from voice, video, digital, or image recordings made for research purposes. (Goes to Question 56)
7. Research on individual or group characteristics or behavior... (Goes to Question 57)
8. No - my research does not fit any of these categories or is more than minimal risk. (Goes to Question 58)

51. Expedited 1 Type: Multiple Choice

Notification Variable: [QUESTION:212]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

52. Expedited 2 Type: Multiple Choice

Notification Variable: [QUESTION:213]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission. (Goes to The End)
2. End survey (don't proceed to protocol submission) (Goes to Question 65)

53. Expedited 3 Type: Multiple Choice

Notification Variable: [QUESTION:214]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

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54. Expedited 4 Type: Multiple Choice

Notification Variable: [QUESTION:215]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission. (Goes to The End)
2. End survey (don't proceed to protocol submission) (Goes to Question 65)

55. Expedited 5 Type: Multiple Choice

Notification Variable: [QUESTION:216]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

56. Expedited 6 Type: Multiple Choice

Notification Variable: [QUESTION:217]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission. (Goes to The End)
2. End survey (don't proceed to protocol submission) (Goes to Question 65)

57. Expedited 7 Type: Multiple Choice

Notification Variable: [QUESTION:218]

Your project may be eligible for expedited review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

58. Full Board — Type: Multiple Choice

Notification Variable: [QUESTION:219]

Your project requires full IRB board review. The IRB chair will review your project and make a determination.

Options:
1. Proceed to protocol submission. (Goes to The End)
2. End survey (don't proceed to protocol submission) (Goes to Question 65)

59. Exemption 1 — Type: Multiple Choice

Notification Variable: [QUESTION:220]

Based on your responses, your project may be exempt from IRB review (exemption #1). The IRB chair will confirm this finding after reviewing your protocol.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

60. Exemption 2 — Type: Multiple Choice

Notification Variable: [QUESTION:221]

Based on your responses, your project may be exempt from IRB review (exemption #2). The IRB chair will confirm this finding after reviewing your protocol.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

61. Exemption 3 — Type: Multiple Choice

Notification Variable: [QUESTION:222]

Based on your responses, your project may be exempt from IRB review (exemption #3). The IRB chair will confirm this finding after reviewing your protocol.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

62. Exemption 4 — Type: Multiple Choice

Notification Variable: [QUESTION:223]

Based on your responses, your project may be exempt from IRB review (exemption #4). The IRB chair will confirm this finding after reviewing your protocol.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

63. Exemption 5 — Type: Multiple Choice

Notification Variable: [QUESTION:224]

Based on your responses, your project may be exempt from IRB review (exemption #5). The IRB chair will confirm this finding after reviewing your protocol.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

64. Exemption 6 — Type: Multiple Choice

Notification Variable: [QUESTION:225]

Based on your responses, your project may be exempt from IRB review (exemption #6). The IRB chair will confirm this finding after reviewing your protocol.

Options:
1. Proceed to protocol submission (Goes to The End)
2. End survey (don't continue to protocol submission) (Goes to Question 65)

65. Thanks — Type: Multiple Choice

Notification Variable: [QUESTION:226]

Thanks for taking our diagnostic survey. We hope it was helpful.

Options:
1. Thanks!

II. Draft your answers to the Application Forms

All protocols require Form 1: Application, Form 2: Consent, Form 3: Data Storage and Security, Form 4: Personnel.

Expedited review protocols also require Supplemental form: Expedited Review. Full review protocols require Supplemental form: Full Review.

Form 1: Application

1. Affiliation	Type: Multiple Choice	Required

What is your affiliation with Bryn Mawr College:

Options:
- BMC Faculty
- BMC Staff
- BMC Student
- Haverford Student
- Swarthmore Student
- Other

2. UndergradFunding	Type: Multiple Select	Required

If you are an undergraduate, check any of the following that apply to this research:

Options:
- Senior Thesis
- Mellon Mays
- Hanna Holborn Gray
- Pollak
- Dean's Research Fund
- Career and Civic Engagement Center or Other Internship
- Faculty Funding
- Other
- Not Applicable

3. Purpose	Type: Short answer	Required

What is the purpose of the proposed study?

4. Procedures	Type: Long answer	Required

Briefly describe all research procedures (e.g., experiments, surveys of any kind, open-ended interviews, participant observation, etc.) that will apply to human subjects. Approximately how much time is each participant expected to devote to the research? Will all of the data be collected at one time, or will data collection be spread out over time?

5. Participants	Type: Short answer	Required

Describe the pool of participants that will be involved in the proposed research, including their expected age range.

6. Recruitment	Type: Short answer	Required

How will subjects be recruited and selected? Include copies of all recruitment scripts, flyers, e-mail notices, etc. that you will be using with your protocol (in Word (.doc or .docx) or RTF format). If the research will be carried out in an institutional setting (i.e., at a school, social service agency, hospital, etc.), include an email or letter from an appropriate administrator at that institution, indicating that he/she knows about the research and what the institution is expected to do or provide.

7. Compensation	Type: Long answer	Required

If subjects will receive payment or compensation (i.e., gift card, entry into lottery, etc.) for their time and inconvenience, describe in detail the amount or value of this compensation, when and how it will be delivered, and how the researcher will pro-rate compensation for subjects who withdraw early. These details should also be explained to participants in any consent and/or assent forms used.

8. Coercion	Type: Short answer	Required
Describe any relationships between the researcher(s) and subjects, such as: teacher-student, friend-friend, employer-employee, etc. If such a relationships exists, what procedures will you use to ensure that participants are free to decline participation without penalty and that no coercion to participate exists?		

9. Instruments	Type: Short answer	Required
List all research instruments (web surveys, other surveys, standardized and non-standardized tests or measures, demographic forms, interview scripts, focus group guides, etc.) that will be used. Attach copies of all instruments to your submission (next question). Note: if data is collected online, the instruments must include a web survey security statement.		

10. Instrument Upload	Type: File Upload
If you have instrument documentation and data collection forms, please upload them here	

11. Upload Permission	Type: File Upload
Please upload your site permission(s).	

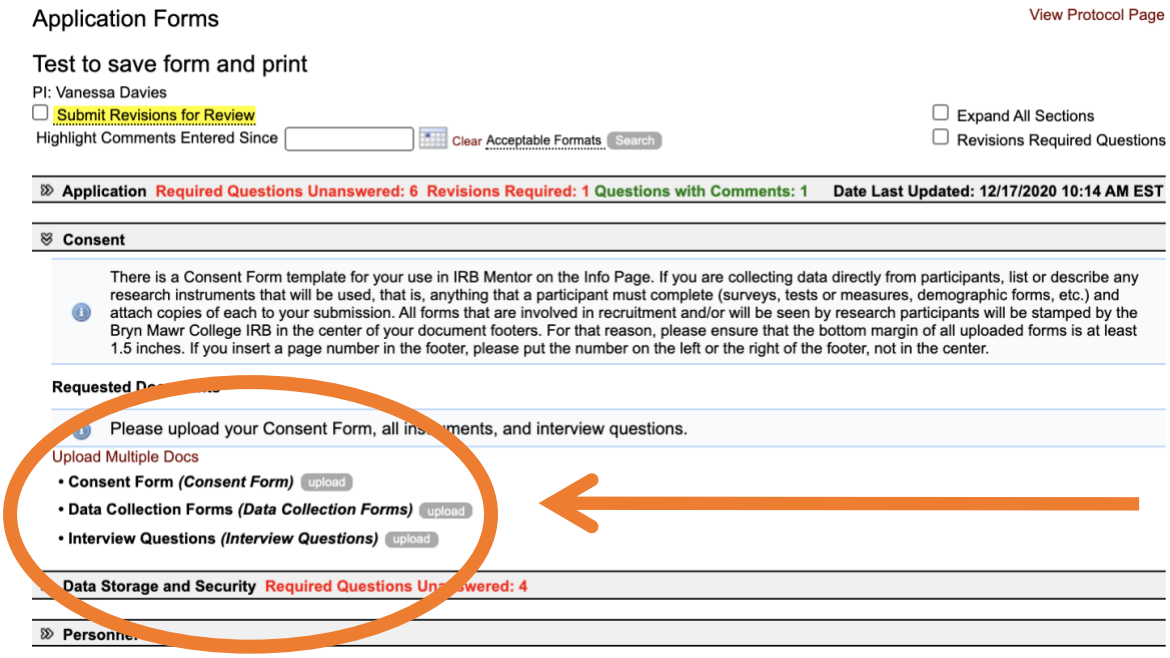
12. Upload flyers	Type: File Upload
Please upload your flyers, recruitment stuff, etc.	

13. Additional Docs	Type: File Upload
If you have any additional documentation to supply to the IRB Committee for review of your protocol, please upload it here.	

Form 2: Consent

Here, upload the Consent Form, Data Collection Forms, and Interview Questions. There are no questions in this form.

There are templates for the Consent Form and Waiver of Consent Form in IRB Mentor on the Info Page.



Form 3: Data Storage and Security

1. Recording data	Type: Long answer	Required
How will data be recorded (e.g., on paper, electronically, etc.)? Explain if data will involve other items, such as photography, video recordings, or audio recordings.		

2. Data storage	Type: Long answer	Required
How are your data stored and secured? Include discussion of plans for storing data and recordings (both temporary strategies and permanent storage), how long they will be stored, and how they will be disposed of or destroyed at the conclusion of the research. These details should also be explained to participants in any consent and/or assent forms used.		

3. Confidentiality	Type: Long answer	Required
How will you protect the privacy of the research subjects and confidentiality of their data? Include discussion of steps to conceal the identity of specific subjects and when/how those measures will be taken. These details should also be explained to participants in any consent and/or assent forms used.		

4. Risk	Type: Long answer	Required
If the research involves the collection or recording of behavior that, if known outside the research could reasonably (a) place the subjects at risk of criminal or civil liability, or (b) be damaging to the subject's financial standing, employability, or reputation, or (c) involve the collection of information regarding sensitive aspects of the participants' behavior (e.g., drug or alcohol use, illegal conduct, sexual behavior), indicate clearly why the collection or recording of such behavior is scientifically necessary.		

Form 4: Personnel

1. External Personnel	Type: Long answer
If this protocol includes personnel who do not autopopulate above, please enter here their name, institutional affiliation, email address, and role (PI, co-PI, Research Assistant).	

2. Human Subjects Cert	Type: File Upload
Upload any current human subjects training certificates, if not autopopulated.	

Supplemental form: Expedited Review

1. Informed consent	Type: Long answer	Required
How will you obtain informed consent or, in the case of minors, assent from the minor participants (if applicable) and consent from a parent or legal guardian? Upload copies of all materials used to obtain informed consent and/or assent. (See informed consent template in the Documentation section of IRB Mentor.)		

2. Deception	Type: Long answer	Required
If deception is to be employed, provide a scientific justification for it and describe debriefing procedures. Upload a copy of your debriefing script. **Reminder:** If debriefing is not possible, the project requires full IRB review.		

Supplemental form: Full Review

1. Vulnerable Pop.	Type: Long answer	Required
If your research involves participants who are children, prisoners, individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons, explain why their participation is scientifically necessary.		

2. Risk	Type: Long answer	Required
If the research presents more than minimal risk to the subject (i.e., the probability and magnitude of harm or discomfort anticipated in the proposed research is greater than that ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests):		

3. Consent	Type: Long answer	Required
Describe methods for obtaining informed consent or, in the case of minors, assent from the minor participants (if applicable) and consent from a parent or legal guardian. Upload copies of all materials used to obtain informed consent and/or assent. (See informed consent template in the Documentation section of IRB Mentor.)		

4. Deception	Type: Long answer	Required
If deception is to be employed, provide a scientific justification for it and describe debriefing procedures. Upload a copy of your debriefing script. **Reminder:** If debriefing is not possible, the project requires full IRB review.		

5. Relationships	Type: Long answer	Required
Describe any relationship between researcher and subjects, such as: teacher-student, friend-friend, employer-employee, etc. If such a relationship exists, how will it affect the subject's ability to participate voluntarily and how will the principal investigator handle it?		

6. Benefits	Type: Long answer	Required
What direct benefits are expected to accrue to subjects as a result of their participation in the research? If there are none, please state that.		