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# NCHS Protocol Determination Request Form

The purpose of this form is to guide investigators through a series of questions to help determine the required level of review for submissions according to the HHS Policy for Protection of Human Subjects regulation (45 CFR 46) and the NCHS Practices and Procedures for the Protection of Human Subjects. In some instances, the investigator will be asked to provide additional information to justify his/her response. Ultimately, this information will be used to determine if the proposed activity is exempt research, non-exempt human subjects research, is not considered research, not considered research involving identifiable human subjects (e.g., surveillance), or is non-exempt human subject research in which NCHS is not engaged (e.g., an NCHS investigator with solely an advisory role to a non-NCHS research project).

Which projects need to use this form?

- New Data Collection Projects involving NCHS investigators
- Amended Data Collection Projects involving NCHS investigators
- Non-NCHS Data Collection Projects involving NCHS investigators (Non-NCHS data collections in which NCHS investigators solely serve in an advisory role)

## Protocol Title: National Survey of Family Growth (2022-2029) (or should we start in 2021?)

## NCHS Primary Contacts

| | Name and degrees (First name Last name, Degrees) | User ID | CITI Expiration Date | Telephone# | NCHS Division/Branch |
|---|---|---|---|---|---|
| Primary Contact | Anjani Chandra, Ph.D. | ayc3 | 5/23/2024 | 301-458-4138 | DVS/RSB |

Principal Investigator/
Project Advisors Same as above

## Section 1: Activity Classification

| Yes | No | |
|---|---|---|
| X | | 1. Does the activity involve obtaining information about living individuals? (If no, go to Section 4 to provide a project summary and justification for your response. The activity does not involve human subjects; however, it is subject to review by the Human Subjects Contact.) |
| | X | 2. Is the activity for administrative purposes only? (If yes, go to Section 4 to provide a project summary and justification for your response. The activity does not involve human subjects; however, it is subject to review by the Human Subjects Contact.) |

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Yes No

[x] [ ] 3. Is the activity conducted, supported, requested, ordered, required, or authorized by NCHS? (If no, go to Section 4 to provide a project summary and justification for your response.)

[ ] [x] 4. Is the activity limited to the collection or study of data, documents, records, or biospecimens that were collected for some other primary or initial activity? (If yes, this is solely a secondary data collection; skip to Section 3 Question #1. If no, this activity includes primary data collection; go to Section 2 Question #1. Projects with both primary and secondary collection should respond with "no" and proceed to Section 2 Question #1.)

## Section 2: Primary Data Collection

Yes No

[X] [ ] 1. Does the activity involve intervention or interaction with the individual about whom the data are collected, or with their legally authorized representative? (If yes, skip to Section 2 Question #4.)

[ ] 2. Is the information individually identifiable and can the identity be readily ascertained by the investigator or associated with the information? (If no, go to Section 4 to provide a project summary and justification for your response. The activity does not involve human subjects; however, it is subject to review by the Human Subjects Contact.)

[ ] [ ] 3. Is the information private? Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record). (If no, go to Section 4 to provide a project summary and justification for your response. The activity does not involve human subjects; however, it is subject to review by the Human Subjects Contact.)

[X] [ ] 4. Is the activity considered to be public health surveillance? As defined by §46.102: Public health surveillance activities [include] the collection and testing of information or biospecimens [and are] conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or

crisis that threatens public health (including natural or man-made disasters. (If yes, go to Section 4 to provide a project summary and justification for your response that addresses the NCHS' role in the activity. The activity is excluded from the Common Rule. The NCHS Practices and Procedures apply and NCHS ERB review is required.)

Yes No

☐ ☐ 5. Is the activity a systematic investigation (an activity that is planned in advance and that uses data collection and analysis to answer a question) designed to develop or contribute to generalizable knowledge? (If no, go to Section 4 to provide a project summary and justification for your response. The activity is excluded from the Common Rule. The NCHS Practices and Procedures apply and NCHS ERB review is required.

☐ ☐ 6. Does the research involve only survey procedures, interview procedures, and/or benign behavioral interventions? (If no, skip to Section 2 Question 8.)

☐ ☐ 7. Does the research involve children? (If no, go to Section 4 to provide a project summary and justification for your response. The activity is research involving human subjects, but it is eligible for exemption from the Common Rule. Complete and submit both the 1255x and 1379 forms in support of an exemption request. The NCHS Practices and Procedures do apply and NCHS ERB review is required.)

☐ ☐ 8. Is the research eligible for exemption under any other provisions of 45 CFR 46.104? (Exemption categories are noted on page 9. If yes, go to Section 4 to provide a project summary and justification for your response. The activity is research involving human subjects but is eligible for exemption from the Common Rule. Complete and submit both the 1255x and 1379 forms in support of an exemption request. The NCHS Practices and Procedures do apply and NCHS ERB review is required. If no, the activity is research involving human subjects, and the research is not eligible for exemption from the Common Rule, go to Section 4 to provide a project summary and justification for your response. The research involves human subjects and requires IRB review consistent with the HHS Policy for Protection of Human Subjects. Complete and submit both the 1255 and 1379 forms in support of an IRB Review. If this is a subsequent request for change, rather than an initial review, use a 1257 form instead of the 1255.)

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## Section 3: Secondary Use Activity

Yes No

☐ ☐ 1. Are the data, documents, records, or biospecimens individually identifiable and can the identity be readily ascertained by the investigator or associated with the information? (If no, go to Section 4 to provide a project summary and justification for your response. The activity does not involve human subjects; however, it is subject to review by the Human Subjects Contact.)

☐ ☐ 2. Is the information private or does the activity involve identifiable biospecimens? Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (*e.g.,* a medical record). (If no, go to Section 4 to provide a project summary and justification for your response. The activity does not involve human subjects; however, it is subject to review by the Human Subjects Contact.)

☐ ☐ 3. Is the activity considered to be public health surveillance? As defined by §46.102: Public health surveillance activities [include] the collection and testing of information or biospecimens [and are] conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters). (If yes, go to Section 4 to provide a project summary and justification for your response. The activity is excluded from the Common Rule. The NCHS Practices and Procedures apply and NCHS ERB review is required.)

☐ ☐ 4. Is the activity a systematic investigation designed to develop or contribute to generalizable knowledge? (If no, go to Section 4 to provide a project summary and justification for your response. The activity is excluded from the Common Rule. The NCHS Practices and Procedures apply and NCHS ERB review is required.

☐ ☐ 5. Does the research involve identifiable private information (not identifiable biospecimens) that was generated or collected by the Federal government, and was the information originally obtained for non-research activities (e.g., for public health surveillance or administrative purposes)? (If yes, the activity is research involving human subjects, but is eligible for exemption from the Common Rule. Go to Section 4 to provide a project summary and justification for your response. Also, complete and submit both the 1255x and 1379 forms in support of an exemption request.)

Yes No

☐ ☐ 6. Does the research involve the use of identifiable biospecimens, and was regulatory broad consent obtained for the storage, maintenance, and secondary research use of the biospecimens? (If yes, the activity is research involving human subjects, but is eligible for exemption from the Common Rule. Go to Section 4 to provide a project summary and justification for your response. Also, complete and submit both the 1255x and 1379 forms in support of an exemption request.)

☐ ☐ 7. Is the research eligible for exemption under any other provisions of 45 CFR 46.104? (Exemption categories are noted on page 9. If yes, go to Section 4 to provide a project summary and justification for your response. Also, complete and submit both the 1255x and 1379 forms in support of an exemption request. If no, the activity is research involving human subjects, and the research is not eligible for exemption from the Common Rule. Go to Section 4 to provide a project summary and justification for your response. Also, complete and submit both the 1255 and 1379 forms in support of an IRB Review. If this is a subsequent request for change, rather than an initial review, use a 1257 form instead of the 1255.)

**Section 4: Protocol Summary and supporting justification** (Please provide a summary of the project below and attach copies of the complete protocol. Proposed surveillance projects should include text with justifications that are consistent with the definition of public health surveillance. Likewise, data collection efforts submitted as not meeting the definition of human subjects research should provide text that would support that position. And finally, projects claiming eligibility for exemption should document the basis for that conclusion.)

If NCHS staffers have a limited role in the activities captured in the attached protocol (for example, only serving in an advisory capacity or only analyzing the data), please be sure to document those distinctions both within this summary and the actual protocol.

This is a new protocol submission to conduct the National Survey of Family Growth (NSFG) over its next 8 years of data collection, from January 2022 through December 2029 as a surveillance project. As defined by §46.102: Public health surveillance activities [include] the collection and testing of information or biospecimens [and are] conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or

investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products).

Since 1973, NSFG has been conducted by the National Center for Health Statistics (NCHS), part of the Centers for Disease Control and Prevention (CDC), with the collaboration and support of several other groups within the Department of Health and Human Services (DHHS). NCHS, under its duties specified in 42 U.S.C. 242k, Section 306(a and b)(1)(h) of the Public Health Service Act, conducts the NSFG to collect and disseminate "statistics on family formation, growth, and dissolution." The NSFG supplements and complements the data from birth and fetal death certificates on factors (such as sexual activity, contraception, marriage and cohabitation, and infertility) that affect birth and pregnancy rates. In addition, the NSFG serves a variety of data needs in public health programs and agencies in DHHS that sponsor and depend on it. The data are used to track key indicators over time as well to conduct generalizable research based on the U.S. household population. Throughout its history, NSFG has been administered in person, in English and Spanish, with a self-administered portion added in more recent survey periods. Under the plan laid out in this protocol, NSFG builds on its past survey design and procedures and incorporates online administration into a multi-phase, multi-mode design. About 5,000 people aged 15-49 are to be surveyed each year.

**Section 5: Signatures**

As the Principal Investigator, I hereby accept responsibility for conducting this project in an ethical manner, consistent with the NCHS Practices and Procedures for the Protection of Human Subjects and to abide by the principles outlined in federal policies for the protection of human subjects according to 45 CFR 46.

Principal Investigator's Signature: Anjani Chandra -S Digitally signed by Anjani Chandra -S Date: 2021.08.10 15:37:27 -04'00'

Date: / /

Remarks: _____

As the supervisor of the Principal Investigator, I hereby accept responsibility for conducting this project in an ethical manner, consistent with the NCHS Practices and Procedures for the Protection of Human Subjects and

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to abide by the principles outlined in federal policies for the protection of human subjects according to 45 CFR 46.

Branch Chief's Signature: Isabelle L. Horon -S Digitally signed by Isabelle L. Horon -S Date: 2021.08.11 07:15:14 -04'00'

Date: / /

Remarks: _____

As the supervisor of the Principal Investigator, I hereby accept responsibility for conducting this project in an ethical manner, consistent with the NCHS Practices and Procedures for the Protection of Human Subjects and to abide by the principles outlined in federal policies for the protection of human subjects according to 45 CFR 46.

Division Director's Signature: Steven Schwartz Digitally signed by Steven Schwartz Date: 2021.08.10 17:36:27 -04'00'

Date: / /

Remarks: _____

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## Section 6: Supplemental Questions to be Completed by the HSC/ERB Chair

Yes No

☐ ☒ 1. Does the activity involve only the use of identifiable private information that was shared (or will be shared) with NCHS by another government agency? (If no, skip to Section 6 Question 3.)

☐ ☐ 2. Will the government-generated or government-collected information be linked to other NCHS-generated or NCHS-collected data using direct identifiers?

☐ ☒ 3. Does NCHS currently have custody of the identifiable private information? (If yes, the ERB will determine if the secondary use is within the scope of consent or data sharing agreement. If no, the ERB will determine if the information to be provided to the data custodian is consistent with NCHS Practices and Procedures for secondary use activities.)

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**Human Subject Contact Office Use Only**

☐ Proposed activity does NOT involve human subjects (No institutional Review Needed.)

Date:_____ HSC Signature: _____

Remarks:_____

_____

☒ Proposed activity DOES involve human subjects but is EXCLUDED from the purview of 45 CFR 46, 2018 requirements (e.g., public health surveillance, per 46.102)

Date: 08/11/2021 HSC Signature: Verita C. Buie -S Digitally signed by Verita C. Buie -S Date: 2021.08.11 13:22:59 -04'00'

Remarks: The activities captured in this submission meet the definition for public health surveillance.

_____

☐ Proposed activity is human subjects research that is NOT EXCLUDED* from the purview of 45 CFR 46, 2018 requirements

Date:_____ HSC Signature:_____

Remarks:_____

_____

* This proposed activity needs to be referred to the NCHS ERB for further determination and processing

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**NCHS ERB Chair Use Only**

## NCHS' Ethics Review Board Chair Determination

| | |
|---|---|
| ☐ Yes ☐ No | NCHS' Ethics Review Board Chair has determined that this proposed activity is EXEMPT from the full extent of 45 CFR 46, 2018 requirements.<br>(This proposed activity is subject to NCHS ERB review per internal Practices and Procedures for the Protection of Human Subjects. This proposed activity may need certification from the Confidentiality Officer and be subject to Limited Review under 45 CFR 46 and HRPO registration and processing.)<br>Please check one or more applicable exempt categories under 45 CFR 46, below (see 46.104(D) for full descriptions and additional, necessary criteria involving these): |
| | ☐ Research conducted in educational settings that specifically involves normal educational practices<br>☐ Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behavior<br>☐ Research involving 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 if the subject prospectively agrees to the intervention and information collection<br>Secondary research uses of identifiable private information or identifiable biospecimens<br>☐ The identifiable private information or identifiable biospecimens are publicly available<br>☐ Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects<br>☐ The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of "health care operations" or "research" as those terms are defined at 45 CFR 164.501 or for "public health activities and purposes" as described under 45 CFR 164.512(b)<br>☐ The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for nonresearch activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, 44 U.S.C. 3501 note, if all of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. 552a, and, if applicable, the information used in the research was collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 *et seq.*<br>☐ Research and demonstration projects that are conducted or supported by a Federal department or agency that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants.<br>☐ Taste and food quality evaluation and consumer acceptance studies<br>☐ Storage or maintenance for secondary research for which broad consent is required<br>☐ Research involving the use of identifiable private information or identifiable biospecimens for secondary research use for which broad consent is required |

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## If the proposed activity is classified as EXEMPT research above, please indicate:

| | |
|---|---|
| ☐ Yes ☐ No | This exempt research requires that NCHS' ERB refer the package to HRPO's Lead Administrator for IRB review under the provisions of Limited Review per 46.104(d) and 46.111(a)(7) or 46.111(a)(8). |

## Check below if the proposed activity is research (i.e., NOT EXCLUDED) and NOT EXEMPT:

| | |
|---|---|
| ☐ Yes ☐ No | This research requires that NCHS' ERB refer the package to HRPO's Lead Administrator for IRB review under the full provisions of 45 CFR 46. |

## Check below if the proposed activity does not meet the definition of human subjects research or is excluded from 45 CFR 46, 2018 requirements (for example, surveillance projects):

| | |
|---|---|
| ☐ Yes ☐ No | This activity has been reviewed and approved by the NCHS' ERB to be in compliance with NCHS Practices and Procedures. |

Date:_____ ERB Chair Signature: _____

Remarks:_____