

**Section 1: IRB Protocol Title**

*Access to the Data in the N3C Data Enclave for [xxx]*

**Section 2: Project Personnel**

**a. Principal Investigator**

Contact Name: *Click or tap here to enter text.*  
 email: *Click or tap here to enter text.*  
 Phone: *Click or tap here to enter text.*  
 BlazerID: *Click or tap here to enter text.*

**b. Contact (Person who can answer questions about this submission)**

**(Note, unless this person is listed as a delegate receiving communications in IRAP, they will not receive any notifications about this submission)**  
 Contact Name: *Click or tap here to enter text.*  
 email: *Click or tap here to enter text.*  
 Phone: *Click or tap here to enter text.*

**c. UAB (and affiliates) Protocol Personnel:** Complete the IRB PERSONNEL eFORM to list all key personnel (each individual involved in the design and conduct of this protocol). Include personnel at UAB affiliated organizations (e.g., Lakeshore, Children’s of Alabama).

**d. Non-UAB Personnel** – List personnel from other institutions that may be directly involved in your project. If you are requesting that the UAB IRB serve as the IRB of record for anyone not affiliated with UAB and not affiliated with another IRB, list these individuals below.

Name and Degree	From Institution with or without own IRB?	Protocol Responsibilities and Qualifications
Name: <i>Click or tap here to enter text.</i> Degree: <i>Click or tap here to enter text.</i> Institution: <i>Click or tap here to enter text.</i> Email: <i>Click or tap here to enter text.</i>	<input type="checkbox"/> Has own IRB (submit copy of Exempt designation from site IRB) -OR- <input type="checkbox"/> Does not have own IRB and needs to rely on UAB IRB (submit a copy of the investigator’s training with the application).	Qualifications: <i>Click or tap here to enter text.</i> Roles & Responsibilities: <i>Click or tap here to enter text.</i>  <b>NOTE: Non-UAB investigators may not have access to the direct medical record (e.g., EMR)</b>
Name: <i>Click or tap here to enter text.</i> Degree: <i>Click or tap here to enter text.</i> Institution: <i>Click or tap here to enter text.</i> Email: <i>Click or tap here to enter text.</i>	<input type="checkbox"/> Has own IRB (submit copy of Exempt designation from site IRB) -OR- <input type="checkbox"/> Does not have own IRB and needs to rely on UAB IRB (submit a copy of the investigator’s training with the application).	Qualifications: <i>Click or tap here to enter text.</i> Roles & Responsibilities: <i>Click or tap here to enter text.</i>  <b>NOTE: Non-UAB investigators may not have access to the direct medical record (e.g., EMR)</b>

**e. Is the principal investigator a student, fellow, or resident?**

- NO - Continue with Item 2.f.
- YES - Complete the following

<b>Supervisor's Name</b>	<i>Click or tap here to enter text.</i>
<b>Title</b>	<i>Click or tap here to enter text.</i>
<b>Phone</b>	<i>Click or tap here to enter text.</i>
<b>email</b>	<i>Click or tap here to enter text.</i>
<b>Signature</b>	

**f. Are any investigators listed above, except the PI, using this research for their thesis or dissertation?**

- NO - Continue with Item 3.
- YES, another investigator is the student - Complete the following

<b>Student Name</b>	<b>Thesis/Dissertation Title</b>
<i>Click or tap here to enter text.</i>	<i>Click or tap here to enter text.</i>

### Section 3: Funding

**a. Is the project funded?**

- NO - Specify which department will cover the costs of the research (e.g., PI's time and effort) or that the PI will cover these costs personally, then continue with Item 4. *Click or tap here to enter text.*
- YES - Continue with Item 3.b.

**b. Sponsor/Funding route:**

<b>Title of Grant, Contract, or agreement</b>	<i>Click or tap here to enter text.</i>
<b>PI of Grant, Contract, or Agreement</b>	<i>Click or tap here to enter text.</i>
<b>OSP Assigned Number</b>	
<b>Sponsor/Funding Route</b>	<p><i>(Check and describe all that apply)</i>  <i>(If subaward, list both the funding source and the institution receiving the direct award)</i></p> <ul style="list-style-type: none"> <li><input type="checkbox"/> Gov't Agency or Agencies—Agency name(s): <i>Click or tap here to enter text.</i> <ul style="list-style-type: none"> <li><input type="checkbox"/> Department of Defense (DoD): Identify DoD component: <i>Click or tap here to enter text.</i></li> <li><input type="checkbox"/> Department of Energy (DOE)</li> <li><input type="checkbox"/> Department of Justice (DOJ)</li> <li><input type="checkbox"/> Department of Education</li> </ul> </li> <li><input type="checkbox"/> NIH Cooperative Group Trial - Group name: <i>Click or tap here to enter text.</i></li> <li><input type="checkbox"/> Private Nonprofit (e.g., Foundation) - Name <i>Click or tap here to enter text.:</i></li> <li><input type="checkbox"/> Industry, investigator-initiated - Name: <i>Click or tap here to enter text.</i>  Describe the funding arrangement (e.g., investigator initiated): <i>Click or tap here to enter text.</i>  <i>NOTE: The UAB IRB typically only reviews industry-sponsored protocols that are investigator initiated or when the protocol qualifies for expedited review or involves gene therapy.</i></li> <li><input type="checkbox"/> Veterans Affairs Funding—Specify: <i>Click or tap here to enter text.</i></li> </ul>

	<input type="checkbox"/> UAB Departmental/Division Funds—Specify: <i>Click or tap here to enter text.</i>
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### Section 4: Locations

**a. Indicate which sites will provide space, services, facilities, or serve as a source of recruitment or study conduct.**

- UAB Hospital
- UAB Hospital - Highlands
- The Kirklin Clinic of UAB Hospital
- The Kirklin Clinic at Acton Road
- UAB Callahan Eye Hospital
- UAB Clinical Research Unit
- Children's of Alabama
- Birmingham Veterans Affairs Medical Center (research may only be conducted by investigators who have a VA appointment)
- Jefferson County Department of Health
  - If YES -describe the involvement of JCDH and list the JCDH clinics being used: *Click or tap here to enter text.*
  - Also, submit the JCDH Research Review Panel approval, if applicable.
- Other UAB Site (Describe):*Click or tap here to enter text.*
- Non-UAB Site (Describe **each** site by name and role in the research):***Data will be accessed on the NIH data enclave***
- None

### Section 5: Clinical Trial

**a. Does this protocol meet the following definition of a clinical trial\*?**

*\*A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes. For more information, see the full definition of clinical trial [here](#).*

- NO
- YES - If YES -ensure that all key personnel have current Good Clinical Practices (GCP) training. For information on this requirement, visit the IRB website [here](#).  
If YES -register the project on ClinicalTrials.gov and Provide the National Clinical Trial (NCT) number: *Click or tap here to enter text.*

### Section 6: Purpose and Background Do not describe any methodology or procedures in this section.

**a. Describe the purpose of your research. Ensure that the purpose describes a research endeavor. If you are conducting Quality Improvement only or some other non-research activity, you will likely need to submit a different application (e.g., NHR) to the OIRB.**

**We will access limited data sets on COVID-19 patients available on the NIH National COVID Collaboratory Cohort (N3C) Data Enclave. Data will be analyzed on the NIH system. Only summary, de-identified data will be downloaded. No detailed research subject data will be downloaded.**

**Note that all data in the enclave have been provided by the source institutions under appropriate IRB exemptions and HIPAA Waivers.**

The purpose of the study is [xxx]

b. Provide any needed background information to address why the research is being done or the issue being addressed.

*The N3C Data Enclave has been created from data submitted by US health care organizations. Note that all data in the enclave have been provided by the source institutions under appropriate IRB exemptions and HIPAA Waivers. UAB is a contributor (under IRB-300005342). The enclave is intended to support national efforts to study and understand the COVID-19 pandemic, in order to develop effective preventive and therapeutic measures. This exemption request is for one such study.*

c. Will the data resulting from this research ever be submitted to the FDA?

- YES – This project is not eligible for exemption. Your project should be submitted to the OIRB using the HSP.
- NO
- Not Applicable

## Section 7: Participants

a. Describe each group of participants to be included in your research, including those who will only be represented through collection of secondary data (copy and repeat rows for each participant group type).

Participant Description: Patients who meet study criteria for COVID-19 positivity

Age Range of This Participant Group: All ages

Number of Participants in this Group: 300,000

Participant Description: Patients who meet study criteria for COVID-19 negativity

Age Range of This Participant Group: All ages

Number of Participants in this Group: 300,000

b. Indicate which, if any, of the special populations listed below will be involved in the protocol. Special Populations Review Forms (SPRF) should not be submitted for Exempt research. Individual exemption categories below also ask information about populations where there is category-specific applicability. Ensure you are consistent in your description of populations to be included in the project.

- Pregnant Women
- Neonates/Nonviable Neonates
- Minors less than 18 years old (NOTE: For VA research, the age of consent is 19 years and older)
- Employees or students at institution where research conducted – if checked, include appropriate voluntary participation language in the consent document.
- Non-English Speakers – if checked, provide a copy of all translated documents and the identity and credentials of the person translating them with your submission to the OIRB).
- Prisoners – if checked, continue with Item 7.b.i.
- None of the above – if checked, continue with 7.c.

Note that all patients in the EHR who meet eligibility requirements will be included. No particular attention if made for specific special populations that may incidentally be included.

i. Are prisoners intentionally recruited for this project?

- YES -prisoners are intentionally recruited for this project – **This project is not eligible for exemption. Your project should be submitted to the OIRB using the HSP.**
- NO -this project is aimed at involving a broader subject population that may only incidentally include prisoners.

c. If your project involves any interaction (e.g., emails, surveys, interviews, focus groups, phone calls), observations, or interventions (e.g., training, instruction, benign behavioral intervention), describe all methods used to **recruit and screen** (if applicable) participants for your research. In your description, include how and when recruitment will occur, who will recruit these participants, and any measures taken to minimize coercion, if applicable. *This question is seeking information regarding recruitment and screening only. You will be asked about the rest of your project in later questions.*

- NO interaction
- YES interaction – If checked, continue with 7.c.i

**i. How will you recruit potential participants and screen them for eligibility?**

*Patients whose data in the EHR satisfy eligibility criteria.*

d. Explain how you are allowed access to the participant information needed to recruit your participants you wish to enroll or the data or specimens you wish to utilize in this project. Do not rewrite your recruitment plans; instead, choose from the list below

- These are my patients, patients in my department’s care, or patients from a staff member listed in the IRB PERSONNEL eFORM [list staff name(s)]: Click or tap here to enter text.
- These are my students or students from a staff member listed in the IRB PERSONNEL eFORM [list staff name(s)]: Click or tap here to enter text.
- My participants are coming from a previous study of mine (cite study title, IRB Protocol #): Click or tap here to enter text.
- My participants are coming from a previous study conducted by someone outside the study staff (cite study title, IRB Protocol #, and PI and attach a letter of permission to use): Click or tap here to enter text.
- Other (describe): Patient data are obtained from the national data enclave

## Section 8: Exemption Categories

The full text of each exemption category, along with examples, is provided in the [IRB Guidebook for Investigators – Chapter 9](#). Investigators need only complete the sections below that apply to their research. However, be sure to complete sections 9-11 for all projects.

- Category 1: Research conducted in established or commonly accepted educational settings involving normal educational practices.
- Category 2: Research involving educational tests, survey procedures, interview procedures, or observation of public behavior.
- Category 3: Research involving benign behavioral interventions.
- Category 4: Secondary research uses of identifiable private information or identifiable biospecimens.
- Category 5: Research and demonstration projects that are conducted, supported by, or otherwise subject to the approval of a Federal department or agency on public benefit or service programs.
- Category 6: Taste and food quality evaluation and consumer acceptance studies.

- Categories 7 & 8: These categories are not represented in this application as the UAB IRB is not adopting them at this time.

**1.  EXEMPT CATEGORY 1 [§46.104(d)(1)]:** Research conducted in established or commonly accepted educational settings that specifically involves normal educational practices that are not likely to adversely impact students’ opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies and research on the effectiveness or the comparison among instructional techniques, curricula, or classroom management methods.

**a. What is the common educational setting for your project (e.g., Chelsea High School, UAB School of Nursing BSN program, adult care class at Brookview Retirement Home, etc.).**

*Click or tap here to enter text.*

**b. What is the educational practice to be evaluated (e.g., team-based learning, diabetes education, implementation of new accreditation standards into course, etc.) and provide justification that it is a normal educational practice that reasonably occurs within the setting described in Item 8.1.a above.**

*Click or tap here to enter text.*

**c. Indicate whether the normal education practice to be evaluated is being implemented as part of the research or is separate from your research.**

The research involves the implementation of a normal educational practice for research purposes only; only those who agree to participate in the research will be part of the educational practice to be evaluated (i.e., participants will be recruited *into* the practice). If checked, include a copy of all curriculum materials with your submission to the OIRB.

The research involves the evaluation of a normal educational practice that has already been or will be implemented as part of the regular curriculum separate from the research (i.e., participants will be recruited *from* those involved in the normal educational practice).

**d. Will your research involve obtaining and analyzing data from secondary sources including, but not limited to, online educational sources; student records; local, state, or federal datasets?**

NO - Skip to Item 8.1.e

YES - Continue to 8.1.d.i

If YES -include documentation of permission to use the data from the source, when applicable. If this documentation does not indicate the data to be received, or if you will be collecting the data from the source yourself, provide a full list of variables to be obtained or a data collection form for each data set.

**i. Describe each data set below, including the source of the data and how you have access. Provide specific information, including an IRB protocol number if using secondary research data at UAB.**

*Click or tap here to enter text.*

**e. Will your research involve any interaction (e.g., e-mails, surveys, interviews, focus groups, phone calls), observations, or interventions (e.g., training, instruction)?**

NO -Skip to Item 8.1.f

YES -Continue to Item 8.1.e.i

**i. DESCRIBE YOUR RESEARCH – NOTE: THIS IS WHERE YOU TELL US EVERYTHING YOU ARE DOING**

**Points to consider in your description (this is not intended to be a comprehensive list nor is it intended to be presented in this order):**

- Describe in chronological order the participant’s full experience.
- Include a description of all data to be collected directly from the participant (what specific data, how).
- Describe all interactions (emails, surveys, focus groups, etc.), observations, or interventions (e.g., training, instruction – if part of your research).
- Describe any data requested from the participant that they have created themselves (e.g., lesson plans, diaries, journals, IEPs, homework assignments, online entries).
- Describe how surveys will be delivered (online survey host vs. pen/paper) and returned.

- Describe whether or not interviews or focus groups will be audio/video recorded and, if so, who will transcribe them.
- Ensure clarity of difference between confidentially collected data and anonymously collected data.
- Include a copy of all data collection instruments or observation forms with your submission to the OIRB.

*Click or tap here to enter text.*

**f. Family Educational Rights and Privacy Act (FERPA):** Does data to be collected or obtained in Items 8.1.d or 8.1.e include any identifiable student records (e.g., grades, test scores, class assignments, class evaluations) beyond standard [directory](#) type data?

NO

YES - Indicate which of the following you will do to ensure FERPA regulations are followed:

Obtain documented permission to use this information from the adult (18 and older) student or their parent/guardian, which can be obtained through the consent process described in Item 10.

**-OR-**

Obtain and submit a copy of a documented FERPA exception from the educational site's registrar. For records obtained at UAB, request this document from the UAB registrar, email [ferpa@uab.edu](mailto:ferpa@uab.edu).

**g. Provide justification that your project will not adversely impact any student's ability to learn.**

*Click or tap here to enter text.*

**h. Provide justification that your research will not adversely impact the assessment of educators who provide instruction.**

*Click or tap here to enter text.*

**2.  EXEMPT CATEGORY 2 [§46.104(d)(2)]:** Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording), and at least one of the following criteria is met:

- The information obtained 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;
- Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

Note that there are restrictions of Category 2 when research will involve children.

**a. Does the research involve children younger than 18 for UAB and affiliates except VA, which is under 19?**

NO – Skip to 8.2.b.

YES - If YES - does research with children involve any of the following:

- Survey procedures
- Interview procedures
- Observation of public behavior when the investigator(s) will participate in the activities being observed

NO – proceed to 8.2.b.

YES – **Exemption 8.2 does not apply** to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using the HSP.

**b. Does the research include any intervention [i.e., physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes and are intended to change the participant’s behavior, thoughts, perceptions, or knowledge level]?**

No

Yes - **Exemption 2 does not apply** to your project. Consider whether other exemptions apply (specifically Category 3) or if your project should be submitted to the OIRB using the HSP.

**c. Exemption category 2 does not allow linkage of other data sources to the information collected through the educational tests, survey procedures, interview procedures, or observations of public behavior. Will your project involve linkage of any other data sources?**

NO

YES - **Exemption 2 does not apply** to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using the HSP.

**d. DESCRIBE YOUR RESEARCH – NOTE: THIS IS WHERE YOU TELL US EVERYTHING YOU ARE DOING**

**Points to consider in your description (this is not intended to be a comprehensive list nor is it intended to be presented in this order):**

- Describe in chronological order the participant’s full experience.
- Include a description of all data to be collected directly from the participant (what specific data, how).
- Describe all interactions (emails, surveys, focus groups, etc.) and observations.
- If using an online survey hosting service, cite host and address whether you will have access to identifiers such as URLs, IP addresses, or emails of participants
- Describe how pen/paper surveys will be administered and returned to the PI
- Describe whether or not interviews or focus groups will be audio/video recorded and, if so, who will transcribe them
- Ensure clarity of difference between confidentially collected data and anonymously collected data.
- Include a copy of all data collection instruments with your submission to the OIRB.

*Click or tap here to enter text.*

**3.  EXEMPT CATEGORY 3 [§46.104(d)(3)]:** 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, and at least one of the following criteria is met:

- (i) The information obtained 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;
- (ii) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or
- (iii) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and an IRB conducts a limited IRB review to make the determination required by §46.111(a)(7).

**a. Does your research involve one or more benign behavioral interventions? (Item 8.3.c. below provides assistance on determining whether an intervention meets the definition of a benign behavioral intervention.)**

YES

NO – Exempt Category 3 does not apply to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using a different application (e.g., NHSR or HSP).

**b. Are all research participants adults (aged 18 and older for UAB and affiliates except VA, which is 19 and older)?**

YES



NO – Exempt Category 3 does not apply. You will need to submit your project to the OIRB using the HSP.

**c. DESCRIBE YOUR RESEARCH – NOTE: THIS IS WHERE YOU TELL US EVERYTHING YOU ARE DOING**

**Points to consider in your description (this is not intended to be a comprehensive list nor is it intended to be presented in this order):**

- Describe in chronological order the participant’s full experience.
- Include a description of all data to be collected directly from the participant (what specific data, how).
- Describe all interactions (emails, surveys, focus groups, etc.) and observations.
- Fully describe the intervention (uploading materials, as needed)
- If using an online survey hosting service, cite host and address whether you will have access to identifiers such as URLs, IP addresses, or emails of participants
- Describe how pen/paper surveys will be administered and returned to the PI
- Describe whether or not interviews or focus groups will be audio/video recorded and, if so, who will transcribe them
- Describe specifically how data are to be collected as Exempt Category 3 only allows for data to be collected are through verbal or written responses (e.g., surveys or interviews, test responses, data entry), observation, or audiovisual recordings. Data cannot be collected via physical procedures such as blood pressure monitoring, EEG, activity trackers (e.g., Fitbit), or blood draws.
- Ensure clarity of difference between confidentially collected data and anonymously collected data.
- Include a copy of all data collection instruments with your submission to the OIRB.

*Click or tap here to enter text.*

i. What is the maximum amount of time the intervention(s) could take for any single participant? *To qualify for exempt Category 3, the intervention(s) must be brief in duration, which the UAB IRB has defined as taking “NO more than a five (5) hours in a single day.”*

*Click or tap here to enter text.*

ii. Is the intervention(s) harmless?

YES

NO - Exempt Category 3 does not apply. You will need to submit your project to the OIRB using the HSP.

iii. Is the intervention(s) painless?

YES

NO - Exempt Category 3 does not apply. You will need to submit your project to the OIRB using the HSP.

iv. Is the intervention(s) physically invasive?

YES - Exempt Category 3 does not apply. You will need to submit your project to the OIRB using the HSP.

NO

v. Is the intervention(s) likely to have a significant adverse lasting impact on the subjects?

YES - Exempt Category 3 does not apply. You will need to submit your project to the OIRB using the HSP.

NO

vi. Does the investigator have any reason to think the subjects will find the intervention(s) offensive or embarrassing?

YES - Exempt Category 3 does not apply. You will need to submit your project to the OIRB using the HSP.

NO

**d. Does the research involve deception or partial disclosure of the purpose or activities involved in the research, including not disclosing the research title?**

YES - to be eligible for Exempt Category 3, participants must prospectively agree to the deception through an agreement in which they are informed that they will be unaware of or misled regarding the nature or purposes of the research. Describe how you will obtain participants' agreement to the deception in Item 10.

NO

**e. Is information from subjects recorded through verbal or written responses (including data entry) or audiovisual recording only? (NOTE: data collection via physical procedures such as blood pressure monitoring, activity trackers, eye trackers are not allowed in Exempt Category 3).**

YES

NO - **Exempt Category 3 does not apply.** You will need to submit your project to the OIRB using the HSP.

**4.  EXEMPT CATEGORY 4 [§46.104(d)(4)]:** Secondary research for which consent is not required: Secondary research uses of identifiable private information or identifiable biospecimens, if at least one of the following criteria is met:

- (i) The identifiable private information or identifiable biospecimens are publicly available;
- (ii) 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;
- (iii) 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); or
- (iv) 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. [§46.104(d)(4)]

**a. Are the data and/or biospecimens to be evaluated considered private and identifiable?**

- YES – The proposed study involves the collection of identifiable, private information from materials that were collected and maintained subject to HIPAA regulations (e.g., electronic medical record, another study). NOTE: this subsection is for the use of data only; obtaining and/or analyzing biospecimens is not allowed, although *information* about biospecimens may be collected)
- YES – Research members of this project have access to identifiers (data only; biospecimens are not allowed in this exemption subsection) through primary material collection (e.g., they are research members on the source study, they were involved in the collection and maintenance of QI data) and as such, have access to identifying information; however, no identifiers will be recorded for this proposed research study.
- YES – The identifiable private information or identifiable biospecimens contain identifiers (e.g., zip codes) and are publically available – Cite Source (e.g., URL, web address): **Click or tap here to enter text.**
- YES – The proposed study involves the collection of identifiable, private information that was collected by or on behalf of the federal government using government-generated or collected information obtained for non-research activities.
- YES – Other (i.e., the data contain identifiers, do not qualify for any of the above criteria, but the PI can justify why they are not readily identifiable, either directly or indirectly). Justify your choice: Proposals that involve contributing clinical data to an externally created and maintained registry can be considered under EXEMPT category #4 (e.g., collaborative, multi-site registries, created and maintained by another site).

- YES – The proposed study involves the collection of identifiable, private information but does not fit any of the above criteria. **Exemption 4 does not apply** to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using a different application (e.g., HSP).
- NO - The data contain no identifying information and cannot be indirectly identified. No one listed in Item 2 of this application or on the IRB PERSONNEL eForm have access to identifying information in the source data. **Exemption 4 does not apply** to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using a different application (e.g., NHSR).

**b. Does your research ONLY involve the evaluation of secondary (retrospective or prospective) information or biospecimens for which consent is not required?**

- NO - some or all of the information or biospecimens will be collected directly from the participant by me or by someone else specifically for my research. **Exemption 4 does not apply** to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using a different application (e.g., NHSR or HSP).
- YES

**c. Does your research involve *establishing* a data registry or a biospecimen repository for future studies?**

- NO (Item 6.a must provide a focused research purpose)
- YES - **Exemption 4 does not apply**. You will need to submit your project to the OIRB using the HSP.

**d. DESCRIBE YOUR RESEARCH – NOTE: THIS IS WHERE YOU TELL US EVERYTHING YOU ARE DOING**

Points to consider in your description (this is not intended to be a comprehensive list nor is it intended to be presented in this order):

- Fully describe what you plan to do.
- Fully describe the materials (data, specimens) to be utilized.
- Describe the source of any data/specimens.
- Whether any dataset/biospecimen will be linked to another set of data
- Whether any data/biospecimens will be sent to another entity (regardless of identifiers)
- Whether any other entities are involved and how (e.g., analysis, coordinating center, receipt of data)
- Either provide a list of the variables to be obtained (not just used in your analysis) below or attach data collection forms in your application to the OIRB (datacollection.yymmdd).

***In this project, we will analyze data from the N3C Data Enclave. Data will consist entirely of data collected during the normal course of patient care at institutions across the US. Sufficient identifying information has been removed to render a "limited data set". We will only access the data on the host system and will only download summary (de-identified) data. No detailed subject data will be downloaded from the host system.***

**Data will include:**

- **Demographics: Gender, Race, Ethnicity, Date of Birth, Zip Code**
- **A hashed identifier to support future linkage with imaging, viral RNA, or other major national data resources with a shared hash identifier (below).**
- **Laboratory tests and results, including dates**
- **Medications, including start and where available stop dates**
- **Vital signs, with dates**
- **Diagnoses, with dates**
- **Procedures, with dates**
- **Admission, Discharge, Transfer information with dates**
- **Including death with dates**

**The information will be retrospective for one year or longer, at the contributing sites discretion, prior to the query start date (1/1/2020), and through the present with serial data updates for a given patient.**

**Note that all data in the enclave have been provided by the source institutions under appropriate IRB exemptions and HIPAA Waivers.**

**Data will be used [xxx]**

5.  **EXEMPT CATEGORY 5 [§46.104(d)(5)]:** Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, 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. Such projects include, but are not limited to, internal studies by Federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

- (i) Each Federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible Federal Web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the Federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects. as collected subject to the Paperwork Reduction Act of 1995, 44 U.S.C. 3501 et seq. [§46.104(d)(4)]

**a. Does your research ONLY involve research on a public benefit program (e.g., Social Security) conducted by or subject to the approval of the federal government?**

- NO -Exemption 5 does not apply to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using a different application (e.g., NHSR or HSP).
- YES -Provide the publicly accessible Federal website on which this project is listed: *Click or tap here to enter text.*

6.  **EXEMPT CATEGORY 6 [§46.104(d)(6)]:** Taste and food quality evaluation and consumer acceptance studies:

- (i) If wholesome foods without additives are consumed, or
- (ii) If a food is consumed that contains a food ingredient 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.

**a. Which of the following applies to your project?**

- Wholesome foods without additives  
Describe the foods: *Click or tap here to enter text.*
- Food that contains a food ingredient, agricultural chemical, or environmental contaminant found to be safe.  
Describe the food(s), food ingredient(s), agricultural chemical(s), and/or environmental contaminant(s):  
*Click or tap here to enter text.*  
Provide information from the Food and Drug Administration, the Environmental Protection Agency, and/or the Food Safety and Inspection Service of the U.S. Department of Agriculture regarding the safety of the items noted above:  
*Click or tap here to enter text.*
- None of the above - Exemption 6 does not apply to your project. Consider whether other exemptions apply, or if your project should be submitted to the OIRB using a different application (e.g., NHSR or HSP).

**Section 9: HIPAA**

**a. Does your project *obtain, review, or make other use of* participant’s “protected health information” (i.e., information, whether oral or recorded in any form or medium that (a) is created or received by a health care provider and (b) relates to past, present, or future physical or mental health or condition of an individual; or provision of health care; or payment for provision of health care)?**

- NO – Skip to Section 10
- YES

**b. Is the principal investigator requesting that the UAB IRB waive patient HIPAA authorization from another institution or entity (e.g., insurance company, collaborating institution)?**

- NO
- YES -If YES -attach copies of the privacy notices from each entity and a letter from that institution requesting that the UAB IRB serve as the HIPAA Privacy Board, and provide the name of each institution/entity: [\*Click or tap here to enter text.\*](#)

**c. Indicate below which of the entities would be a source for this information, will be the site of active recruitment, and/or will be the site of storage/maintenance of data/biospecimens.**

- UAB Hospital or UAB Hospital - Highlands
- The Kirklin Clinic of UAB Hospital or Acton Road (and/or associated clinics)
- UAB Callahan Eye Hospital
- Children's of Alabama
- Jefferson County Department of Health
- School of Dentistry
- School of Health Professions
- School of Medicine
- School of Nursing
- School of Optometry
- University of Alabama Health Services Foundation
- UAB Health Centers
- Viva Health
- Ophthalmology Services Foundation
- Valley Foundation
- Medical West - UAB Health System Affiliate
- The VA (for research conducted at the VA, use the VA HIPAA authorization form)
- The Lakeshore Foundation
- None – if NONE, skip to Item 10

**d. Indicate any *information systems* (e.g., electronic medical record) that will be the source(s) of information used for the protocol.**

- A system maintained centrally by UAB Health System  
[e.g., HealthQuest for registration, billing, and patient administration; PowerInsight (clinical data warehouse); Cerner IMPACT for PowerNotes for meds, Lab, Radiology, UED, Surgery].

NOTE: If a researcher needs information in a specified format or a specified time, the researcher must confirm with the unit who can supply the information/service that the request can be met before writing the information/service into the research protocol. In addition, the researcher must be aware that these services may have a cost attached that should be considered in the research budget.

- Another information system on a UAB server or an information system used at one of UAB’s affiliates (e.g., Children’s of Alabama, Callahan, VA). Describe: [Click or tap here to enter text.](#)
- No information system is being utilized for this project.

**e. Indicate which of the listed identifiers will be accessed, associated and/or linked with the protected health information (PHI) used for this protocol.**

- Names
  - Geographic subdivisions smaller than a state
  - Elements of dates (except year) related to an individual
  - Telephone numbers
  - Fax numbers
  - Email addresses
  - Social security numbers
  - Medical record numbers
  - Health plan beneficiary numbers
  - Account numbers
  - Certificate/license numbers
  - Vehicle identifiers and serial numbers
  - Device identifiers and serial numbers
  - Biometric identifiers (e.g., fingerprint, voiceprint, etc.)
  - Web universal resource locators (URLs)
  - Internet protocol address numbers
  - Full-face photographic images
  - Any other unique identifying number – Describe the number and how derived: [Click or tap here to enter text.](#)
- NOTE: Codes are not identifying as long as the researcher cannot link the data to an individual*
- None - If None, skip to Item 10

**f. Choose one plan to describe your use of the personal health information:**

- The data collected or obtained meet the specifications for a “limited data set” (LDS)  
If the LDS will leave the covered entity or will be received from another covered entity you will need a [Data Use Agreement](#)
- Research staff will obtain authorization from each participant to use the information
- PI requests to waive authorization to use the information.  
Attach a [Waiver of HIPAA Authorization](#) form.

**Section10: [Consent](#)**

**a. If there are interactions with participants, there should be a consent process that will disclose the information below. Review the [Consent in Exempt Research](#) section of the Guidebook for Investigators and refer to the Sample Exempt Information Sheet on the IRB website.**

- Title of Study
- Purpose of the research and procedures of the research
- Approximate duration of participation
- A statement that the activities involve research

- A statement that participation is voluntary
- Description of confidentiality of the responses and/or anonymity of the process
- Risks, costs, and payment (if applicable)
- Alternatives, if needed (e.g., students not participating may be doing something else while others complete the study)
- Employee or student voluntary participation language modeled after language in the UAB IRB’s Sample Consent, if applicable. NOTE: you may be using students and employees from another site, so this section may need to be adjusted.
- Contact information for the Principal Investigator, including phone number
- Contact information for the UAB IRB, as follows: If you have questions about your rights as a research participant, or concerns or complaints about the research, you may contact the UAB Office of the IRB (OIRB) at (205) 934-3789 or toll free at 1-855-860-3789. Regular hours for the OIRB are 8:00 a.m. to 5:00 p.m. CT, Monday through Friday.

**b. Will the project involve any interaction (including any written communication) with participants?**

NO – A consent process is not required for the project.

YES – Describe your consent process and attach a copy of the document with your submission to the OIRB (do not use this space to provide the content of your consent) -OR- explain why a consent process is not warranted or feasible. Note that projects reviewed under Exempt Category 3 must include participants’ prospective agreement to both the intervention and information collection.

*Click or tap here to enter text.*

**c. Will the project involve any deception, including incomplete disclosure to participants regarding the nature or purposes of the research?**

NO - The project will not involve any deception or incomplete disclosure.

YES - Describe the deception or incomplete disclosure, including any plans for debriefing participants or if not, why a debriefing process is not warranted or feasible.

*Click or tap here to enter text.*

Note that projects that involve deceiving participants regarding the nature or purposes of the research are only allowed under Exempt Category 3 if participants authorize the deception through a prospective agreement to participate that informs participants they will be unaware of or misled regarding the nature or purposes of the research.

**Section 11: Privacy and Confidentiality**

**a. Describe how you will protect the privacy interest of the participants. Include how you will make sure others cannot overhear your conversation with potential participants and that individuals will not be publicly identified or embarrassed.**

*There will be no contact with potential participants or participants. Individuals will not be discussed by program staff.*

**b. Describe how you will store research data to maintain confidentiality (both paper records and electronic data). Points to consider in your description (this is not intended to be a comprehensive list nor is it intended to be presented in this order):**

- Storage of paper data (where specifically stored, who has access and how limited, how long stored)

- Storage of electronic data (whether stored on UAB servers, personal devices, or other; who has access and how limited, whether those devices are encrypted or password-protected, etc.)
- Whether any portable devices are utilized at any point of the study (e.g., laptops, jump drives, cameras, cell phones, etc.) and how data will be secured and managed.
- If identifiable data is retained, describe whether the data will be coded with links to identifiers stored separately or whether the data will be stored with identifiers). Describe all locations.
- Specific confidentiality information pertaining to any data that is collected in a less secure manner such as use of WiFi-connected devices, online sites or apps, or data emailed to/from another person.

*Only deidentified, summary data will be downloaded from the secure NIH enclave system.*

**c. Does your research involve audio or video recording or photographs?**

- NO
- YES – Describe plans for disposal of these materials or justify why they will not be destroyed. If a transcription service is to receive private, identifiable recordings, identify the service and describe the confidentiality agreement in place. *Click or tap here to enter text.*

**d. Will investigators have any way of ascertaining the identity of the subjects, directly or through identifiers linked to the subjects, at any point during the course of the study?**

- Data to be collected and evaluated are completely anonymous (i.e., no one on the study staff knows who participated in the study).
- Investigators will know or may be able to ascertain the identity of participants
- Investigators will have access to identifiers, but these identifiers do not allow participant identities to be readily ascertained. Provide a description of the identifiers and a thorough justification: Dates and zip codes

**e. Could disclosure of the human subjects' responses outside the research reasonably place the subjects at any risk of harm? That is, could the information in the study place participants at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation? **NOTE: potential loss of disease or condition status should be considered as a potential risk of harm.****

- No – the information in the study, if disclosed outside the study, would not place subjects at any risk of harm.
- YES – the information in the study could place subjects at risk of harm if disclosed outside the study.

**f. Will any individual data or biospecimens be shared with anyone outside the research team at UAB?**

- NO
- YES – But any data or biospecimens shared will be completely **stripped of all identifiers** including dates or identifiers created using potentially identifiable pieces of information (e.g., initials).
- YES – **Individually identifiable** data and/or biospecimens will be shared.

If YES to above, describe who will receive the data and or biospecimens, what specifically will be shared, and whether they will be coded or otherwise labeled. *Click or tap here to enter text.*