Blood Draws
Information to include in your IRB Application and Supporting Documentation

Inclusion/exclusion criteria for participation

• In order for your study to be approved at the mid-level review which is the “expedited” level articulated in the federal regulations require that participants must be 18 years old or older, healthy, weigh at least 110 pounds, and not pregnant.
  
  o Those above criteria (in addition to any other inclusion/exclusion criteria you may have) must be articulated in all of your recruitment and consent materials and accounted for in your procedural processes in the step-by-step procedures narrative response
  
  o If you are including or excluding individuals due to age or because of a particular diagnosis/condition/health behavior (e.g. smoker, cancer, anemia, HIV+), those also need to be stated in the IRB application and in all recruitment and consent materials.

• If you need to include people under 18 years of age, it is okay to do so, but you must scientifically justify why it is needed for your project.

For each group of participants in your study, provide a step-by-step description of what they will experience from beginning to end of the study activities.

When you write this description in your procedures tab, you need to include the following information about blood draws:

• Who the blood is being collected from and how you’re determining these criteria.

• Who will draw the blood and what training they’re given to do it both effectively and safely. For example, is it participant self-administered or drawn by a licensed phlebotomist, nurse, physician, physician’s assistant, etc. Unless they have an additional license specific to collecting blood in humans, veterinarians cannot collect blood from humans for research.

• Where will the blood be drawn on the body (i.e. physical location).

• What the sanitary practices are in the location/room where the blood is drawn, any tools used to procure the blood, and all individuals in the space where the blood is drawn.

• How the blood will be drawn (finger stick, heel stick, ear stick, venipuncture, etc.).

• How much blood is collected at each drawing and how much blood in total for research purposes.

• How often is the blood collected during the study (once? twice a week for 6 weeks?).

• Describe your plan
  
  o For humans if there is an emergency (i.e. a participant passes out, a researcher is accidentally stuck by a participant’s used needle)
  
  o For the biological materials you must work with the NC State IBC and complete all of their requirements, which likely include:
    ▪ This will require that you complete the Biosafety Orientation Training in Reporter, a Biological Use Authorization (BUA) form, create and implement a biological materials safety plan, exposure control plan, and a biowaste plan. Post approval,

Revised 10.25.2019
you will need to comply with the following regulations: Laboratory Biosafety Manual, BSL-2 Checklist, and the CDC Guidelines for Laboratory Biosafety competency.

- In your IRB application you do not need to detail the plans approved by the IBC instead you can state that you have worked with the IBC and completed all necessary requirements and trainings and that you will follow them as described.

**Discuss identifying information, links, and destruction of samples throughout your application**

- Discuss the identifiers on the blood sample itself and the identifiers collected as part of the associated blood draw processes.
- Discuss what identifying information your analysis will reveal and how your access, expertise, use of technology, and ability to compare samples and data – can or cannot identify an individual or third parties.
- Whether or not you’re retaining the blood for future research purposes, we need you to articulate all links there are between the blood and a participant’s unique identity.
- We want you to talk about when, or if, you’ll remove identifying links and at what stage in the research process (e.g. during data collection, at beginning of data analysis, at end of data analysis, after the study has ended but before the data is published etc.).
- Describe how data will be reported (aggregate, individual responses, use of direct quotes) and describe how identities will be protected in study reports. In addition to discussing the smallest N that you’ll report, you’ll also need to discuss the nature of the data set (de-identified, re-identifiable) and biospecimens that you will share with journals and/or other researchers.

**Risks and benefits in your application**

- Discuss physical risks of blood draw itself and discuss how you are mitigating them
  - You can use and adapt the following example language and fill-in-the-blanks to discuss the physical risks due to blood draw: The risks of taking blood include pain, a bruise at the point where the blood is taken, redness and swelling of the vein and infection, and a rare risk of fainting. The likelihood of these risks occurring are <discuss likelihood> because <give reasons why the likelihood, due to things like participant exclusion, study design or procedures etc.>. Refer also to aspects of your emergency plan that mitigate the physical risks of blood draws.
  - Discuss risks to the participant (primary and third party) as a result of the analysis you are running. This is particularly important if you are retaining blood samples for future use or publishing your full data set with participant names redacted because that’s your field’s journal publication standard.
    - Some mitigation techniques include limiting analysis of sample to only the unique markers you’re looking for and not analyzing everything in the blood because you can, securely destroying the blood samples immediately after using them, and having a thorough recruitment and consent process that informs participants of the risks of sharing their genetic data for research that might in the future be used for purposes that they may not agree with.
    - Disclosure whether or not you will be getting information about other individuals via the blood sample, so discuss if and how there is a risk to third parties, the level of that risk, and how you will protect the third parties from that risk. A glucose reading where the blood sample is securely destroyed after the reading is much less risk to third party participants than a blood sample that is sequenced and kept for future research purposes.
    - If using the samples and data for future research, discuss how future research, scientific discoveries, and technological advances could impact your participants and third parties via your data set.
Supporting Documentation Information and Verbiage

**Adult consent template**
Include the following sample language and complete the fill-in-the-blanks as part of your procedural description:

- **Adult consent:** You will have <insert amount> of blood taken <number of times drawn and frequency of the blood draws>. The blood will be taken from <location of blood draw on the participant’s body, i.e., arm> by <specify who is taking the blood>. The total amount of blood taken for the whole study will be __ml <amount in teaspoons or tablespoons>.

Include the following sample language and edit if your protocol has fasting blood draws:

- The risks of having blood drawn from your body include some pain when the needle goes in and a small risk of bruising and/or infection at that site. Some people get lightheaded, nauseous, or faint. You are less likely to have these problems if you drink at least 2 glasses of water and have a snack before the blood draw. The American Red Cross recommends that you do not donate more than 1 pint (32 tablespoons) of blood within a 2 month period. Tell the study team if you have recently had your blood drawn for any reason.
- The risks to the information generated from the analysis of your blood draw includes: <insert this could be – could it affect insurability, medical decisions, third parties, etc>.

Include the following sample language and complete the fill-in-the-blanks:

- Your samples will be used for <insert what they will be used for, including future research>.
- Your samples will be destroyed <how they will be destroyed and when they will be destroyed>.
- Though your samples will be destroyed, the data from those samples will be <describe what will be done with data in raw and de-identified/re-identifiable formats>.

**Parental permission template**
Include the following sample language and complete the fill-in-the-blanks as part of your procedural description:

- **Your child will have** <insert amount> of blood taken <number of times drawn and frequency of the blood draws>. The blood will be taken from <location of blood draw on the child’s body, i.e., arm> by <specify who is taking the blood>. The total amount of blood taken for the whole study from your child will be __ml <amount in teaspoons or tablespoons>.

Include the following sample language and edit if your protocol has fasting blood draws:

- The risks of having blood drawn from your child’s body include some pain when the needle goes in and a small risk of bruising and/or infection at that site. Some kids get lightheaded, nauseous, or faint. Your child is less likely to have these problems if they drink at least 2 glasses of water and have a snack before the blood draw. Tell the study team if your child has recently had their blood drawn for any reason.
- The risks to the information generated from the analysis of your child’s blood draw includes: <insert this could be – could it affect insurability, medical decisions, third parties, etc>.

Include the following sample language and complete the fill-in-the-blanks:

- **Your child’s samples will be used for** <insert what they will be used for, including future research>.
- **Your child’s samples will be destroyed** <how they will be destroyed and when they will be destroyed>.
- **Though your child’s samples will be destroyed**, the data from those samples will be <describe what will be done with data in raw and de-identified/re-identifiable formats>.

**7-10 years old assent template**
Talk about how they will have their blood drawn by someone else, that it might hurt, and tell them that it’s okay if they don’t want to participate in the study.
11-13 years old assent template
Explain that if the decide to participate in the study that their blood will be drawn, from what part of their body, how it will be drawn (finger/heel/ear stick or venipuncture), and how many times it will be drawn over the course of the study.

Language you can use: There is some pain when the needle goes into your body. Some kids get a small bruise or infection where the needle went in or don’t feel well after getting their blood drawn. To try to make sure this doesn’t happen to you, I/we will <insert ways that you will try to mitigate these possible outcomes in simple, age appropriate language>.

14-17 years old assent template
Explain that if the decide to participate in the study that their blood will be drawn, from what part of their body, how it will be drawn (finger/heel/ear stick or venipuncture), and how many times it will be drawn over the course of the study.

Language you can use: Some teens get a small bruise or infection where the needle went in or don’t feel well after getting their blood drawn. To try to make sure this doesn’t happen to you, I/we will <insert ways that you will try to mitigate these possible outcomes in simple, age appropriate language>.

Language you can use: At no point right now will we or anyone else be able to identify you from your blood. But as science and technology develops, identifying you could be a possibility even though we will not attempt to. Your genetic/genomic information that you give us now could be used in the future for research or purposes you don’t agree with. Therefore, it’s important that you decide whether you are comfortable taking that risk.