Registry (Subject Pool) Best Practices:

When is IRB approval needed?

If the plan is to develop a list or database of participants and to grant access to that list of potential participants to multiple PIs and/or multiple projects, that is what the IRB refers to as a registry and some schools or departments refer to as a subject pool. For the purposes of this document, a registry and a subject pool are the same. However, please note in your protocol registries that are students only and those who may include members of the public as well as students.

A registry is an independent project that needs to be submitted to the IRB for review and approval. Because potential participants are specifically recruited to a registry with the expectation of being eligible for certain kinds of research and because obtaining names and contact information from a registry for the purpose of recruitment is a step in the research process, oversight of the registry is within the scope and of the mission of the IRB. IRB approval is needed in accordance with the Federal guidelines and with regard to the Belmont principles around the protection of private identifiable information as it relates to voluntary participation and the right to be treated with dignity and respect.

A project needs to be submitted in the eIRB+ and a protocol that describes a subject registry will include the following:

A. Introduction to the Registry should include:

1. The purpose of the registry.
2. Who is eligible to be recruited into the registry.
3. What is the information that is kept in the registry about each participant and/or participant family unit if recruiting parents and children. Attach to the protocol a copy of a blank data entry record or a codebook that describes the fields if they go beyond name, address, email and phone number. Note: Typically there would be no research data, no medical or diagnostic information kept in a registry unless there is a compelling reason.
4. How are the actual names entered into the registry (is it automatic from an online form or put in by hand or both?).
5. What is the process for opting for inclusion to the registry and for opting out of the registry if someone changes his or her mind.
6. For those registries that include children or vulnerable populations, please indicate how you will document assent if it is appropriate. Include how you will consent minors who turn 18.

B. Description of Access and Data Security for the registry should include:

1. Where and how for the physical storage of the registry; i.e., on a computer or on a server. Include if password protected or encrypted or both.
2. Access to the registry: describe how the information in the registry accessed and by whom In addition explain how access will be monitored and/or verified. Include who will manage access and how access will be managed with specific details with regard to role on the registry project, where passwords are kept, and how frequently passwords are changed.
3. Specific information as to who is responsible for training and supervising students who may access the registry.

4. Upload a blank copy of the letter of agreement that will be in place between the PI managing the registry and the PI of projects which are requesting access to the registry. The letter should also include who from the lab is the designated person responsible for serving as administrator for their lab.

C. <u>Description for maintaining the registry information</u> should include:

1. A plan for how information in the registry will be accessed (directly or remotely) and what security is in place for maintaining real time recording of which participants are being contacted, when, how and by whom. What is the agreement about who 'owns' the participant contact information once participants come into one or more labs or studies? How will the registry monitor who is contacting whom if multiple projects are contacting the same individuals or families?

2. A training plan for all individuals who will access the registry regarding the registry rules, polices and/or procedures for requesting access, obtaining access, and how to actually access the information. If there will be multiple RAs accessing the registry, a manual may be more appropriate. Among other things, this training plan or manual should include a specific script that is standard language to be used by all projects when recruiting to and <u>from</u> the registry. Recruitment from the registry is different from recruitment to the registry and needs to be delineated that way.

D. <u>Recruitment to the registry</u>:

1. Include specific recruitment strategies that will be used to recruit participants <u>to</u> the registry. This could be traditional use of flyers, web site, ads online and so forth. If it is a student subject pool and all students enrolled in certain a class, program, or other academic entity are automatically included in the registry, include how they are informed and what options they have if they want to opt out.

2. The text for recruitment material must include a brief description of the purpose of the registry, include the name of the registry and the STU#. As part of any of the recruitment there must be a statement to the effect that if participants agree to inclusion to the registry this means they could potentially be contacted by different researchers for different studies at NU.

E. <u>Consent to the registry</u>:

1. Include a description of how participants will be consented <u>to</u> the registry. This could be by registering through a web site using an online form that contains both recruitment and the consent information, it could be in person, by regular mail, email or it could by phone. Regardless of the method used, there must be an approved consent that is completed to document a valid consent process. Consent to the registry is not done on the fly as someone is walking out the door. The participant must be able to have access to some sort of consent document that they can print, that they are handed, or receive by email. This consent document must include what they are agreeing to, who to contact if they have questions, contact information as well as information about how to stop being a part of the registry if they want to withdraw.

2. Consent records: a field should be added to the registry to indicate that a participant has been duly consented to the registry, by whom, in what manner, and if appropriate, by what project so that if audited, it can be easily established which consents are in physical format and which are electronic.

<u>Other documents</u>:

In addition to the protocol, the submission to IRB should include the following documents:

1. Copy of the agreement between the registry and the PI or lab requesting access.
2. Training plan for individual projects that will access the registry including how to use the registry, policies re; confidentiality and security of the registry.
3. Sample copies of recruitment materials to recruit to the registry.
4. Consent document language that will be used by anyone consenting participants to the registry.

9-29-2018 kem