When Researchers also Serve as a Participant in Their own Studies

It is possible for you as the lead researcher and/or you as a research team member to serve as a participant in your own research project. However, there are special considerations and stipulations. Please read through this guidance to understand IRB considerations regarding when researchers should serve as their own participants, and what ethical and regulatory information needs to be considered and communicated to the IRB.

Though investigator self-experimentation may not always raise the conventional ethical concerns outlined in the Belmont Report, all research projects involving human subjects should undergo ethical and regulatory review to assure the safety of people involved and the integrity of the research at the university.

While researchers may be aware of the risks of self-experimentation, they may also be more willing to accept risks that are ill-advised. Application for review with the IRB office allows a neutral third party to raise concerns and/or propose measures to promote the welfare of lead researchers and research team members.

NC State regards investigator self-experimentation as research with human participants, and requires the same review and approval as research that recruits other people as subjects. The IRB reviews self-experimentation research for the following reasons:

1. Protecting lead researchers and research team members from unwarranted risks
2. Allowing a neutral third party to raise concerns, if any, regarding the credibility of resulting data
3. Ensuring that the protocol is in compliance with the federal regulations that govern the IRB

Ethical Issues to Consider

- Coercion, Perceived Coercion, and Voluntariness of Research Team Members as participants
  - If lead researchers want members of their research team to also be participants, the lead researchers will need to consider issues of power dynamics among themselves and those on their team. As the lead researcher,
    - You will need to think about how the power dynamics of your relationship affects the voluntariness of participation.
    - This relationship will need to be examined and any risks related to coercion will need to be minimized. These elements must be articulated in the IRB application.
  - Examine issues related to voluntariness. Is it really voluntary for you and your team to be in this study? Can research team members really say no without letting you down? Without feeling like they harmed your career or hurt theirs? If they don’t participate, will something bad happen to them?
  - Is funding or employment relying on this study being completed, and as a result, you all want to be participants to ensure that you and your team have enough data to complete the study? This is an example of coercion and non-voluntariness.

- Conflict of Interest and Perceived Conflict of Interest
  - No matter what, people will look twice at research where the researcher serves as the participant. This will create, at minimum, the appearance of a conflict of interest.
  - All researchers must be very transparent about their role and about each step taken throughout the process to ensure clarity and transparency of research activities.
  - Depending on your role in the study (as lead researcher or research team member), your funding, and your other endeavors, you may have a regulatory defined conflict of interest and this will need to be addressed with the NC State COI & NOI office as well as the IRB office: [https://research.ncsu.edu/sparcs/compliance/coi-and-noi/](https://research.ncsu.edu/sparcs/compliance/coi-and-noi/)

- Study Continuity, Duality of Roles, and Data Integrity
  - Researchers cannot participate in the research if their participation will skew the data – even if this would be inadvertent. The IRB will consider whether your participation could unduly affect the data, or if you as the lead researcher or research team member would have information that would skew results.
• Purposefully or inadvertently skewing data through self-recruitment in your study will result in an investigation of IRB non-compliance, and you may be referred to the Institutional Official for possible research misconduct.

• As the lead researcher, you will need to address issues of generalizability and transferability of your data if you are the only participant, or are one of few participants. As research is designed to contribute to generalizable knowledge, this is an important criterion to address.

• Researchers cannot be compensated for serving as a participant in their own research. This is unethical, illegal (under NC General Statutes 14-234), and non-compliant with the IRB regulations, NC State Policy, and accounting standards.

Compliance Issues to Consider and Communicate to the IRB

• Scientific Rationale for Researchers as Participants
  • A scientific rationale for participating in your own research is a rationale that justifies why you as the researchers should be the target population.
    • Maybe you are researching your team’s research process and team collaborations and as a result you need to be both researchers and participants.
    • Maybe you are in a niche role and your experiences would be beneficial to the scientific community, or you and your research team have specific training that could be considered a participant protection.
    • Perhaps, there is something rare and special about your physical body that should be researched, and you serve as an expert in the field.
    • It may be possible that you and your team are uniquely qualified to assess the risks involved in a particular study procedure, so that your participation in the study would reduce overall risks to the participants you recruit for your study.
  • In some qualitative inquiries, the researcher is expected to be the participant, and the the best literature on these methods provides guidance on how to accomplish this scientifically. This could be in the area of narrative inquiry, participant/observation, or case study.
  • You may be doing basic testing of equipment to see if the equipment works properly and records data as expected. As you test the equipment, you adjust the equipment or study procedures, but you are also recording data to report out this process. Your participation is required due to your expertise and the data collected is not influenced by your participation.

• Researcher Participation as a Participant Protection
  • Serving as a participant in your own research CAN BE a participant protection.
    • For example, if you are researching something that takes special expertise or handling, and you have that expertise. This research may pose some risks to people when recruited from a general population, but, for you, your expertise may mitigate risks.
    • For example, you have expertise and training in handling certain chemical, viruses, equipment, or insects and that expertise and training serves to protect you and mitigate some risks because of your history and training.
    • “Not enough participants enrolled” is not justification for your participation in the research.
    • “Because I can easily access myself and our research team” is not a justification for your team to participate in the research.

• Consent Process
  • For all researchers who intend to participate in their own research, they will need to develop a consent process and consent form for all researchers to sign.
  • This consent process should be done with the following in mind:
    • If enrolling research team members, the person running the consent process cannot have undue influence over the researcher-participant.
    • The consent form will contain language that explicitly discusses voluntariness and rationale for research-participants.
    • Use the NC State IRB Consent Form Template.
    • Example: “I am an investigator or key personnel on the above-referenced research study and intend to conduct the following procedures described in the IRB protocol on myself:”
- Example: “RISKS: The potential risks to myself from these research procedures are: _____ and I am mitigating the risks to myself by ____.”
- Example: “BENEFITS: I do not expect to benefit personally from any of these procedures performed and hope the results will provide the basis for further refinement of the research technique before further tests are performed in other human subjects.”
- Example: A statement “I am aware that the procedures are considered to constitute research on human subjects. I am performing these procedures on myself voluntarily.”

- Recruitment Process
  - If you are the only person in the study, there is not a recruitment process.
  - If you are a lead researcher enrolling your research team members, you will need to provide talking points or actual recruitment material (such as emails) to the IRB that explains what is discussed during recruitment process and how the above possible ethical issues are addressed.

- Disclosures, Laws, Appropriate Regulations
  - Your research will still be subject to the Federal regulations governing human subjects research (45 CFR 46).
  - Make sure you are familiar with any NC laws that may govern your research; you must comply with them.
  - Make sure you properly disclose all needed information regarding your role in the research and anything else that is needed for proper consideration of your study. Do this in any IRB application and in your reporting of your results.

- Piloting and Refining Study Design.
  - These are additional reasons that you may serve as a researcher and participant. You will need to communicate these reasons when completing the IRB application if this applies to you.
  - Using your experiences to refine your methods.
    - For example, maybe you want to know exactly where to don sensors, or you want to make sure that your software is running properly and you want to use the information from that experience to shape your methods.
  - Using your experiences to understand what a participant would experience and want and need to know before being in your study.
    - This could be things like skin irritation, psychological consequences, clarity of directions, refining your processes and procedures.

- Targeting your Friends and Family as Participants
  - Occasionally you may want to target your friends, family (including partners, children, dependents, siblings, and/or other extended family) to be participants in your research. This is okay to do, but it must be justified in your IRB application by addressing the scientific rationale and/or participant protection rationale for inclusion.
    - An example of a scientific rationale for inclusion would be something like your friends and family are few of the people who speak a certain language.
    - An example of a scientific rationale for inclusion would be something like your friends and family are few of the people who have experienced a specific environment, culture, or phenomenon.
  - Please keep in mind issues noted above regarding power dynamics, real and perceived coercion, and voluntariness. You will need to address how these issues will be managed.