Using Colleagues as Subjects

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The CP Study

- The CP study is designed to assess the effects of high level allergens in subjects with allergic asthma.

- Study procedures include EKG, allergy skin testing, several blood draws, and bronchoprovocation.
Bronchoprovocation

- Bronchoprovocation involves the controlled administration of a stimulus to induce airway constriction.

- Subjects in the CP study receive provocation with allergen, methacholine, and cold dry air.
Research bronchoprovocation

- Allergen bronchoprovocation is a well recognized research technique.
- It allows investigators to study the activation of peripheral blood basophils.
Safety Guidelines for Bronchoprovocation

- Monitor pulmonary function.
- Stop the procedure when a subject has a moderate drop in airflow (≥ 20% drop in FEV1).
- A 20% drop in airflow is mild and typically does not cause wheezing.
Risks

- Bronchoprovocation can cause asthma attacks and, rarely, severe allergic reactions.

- Some subjects experience more substantial drops in airflow (>35% drop in FEV1).

- These subjects experience wheezing and chest tightness.
The study endpoint (basophil activation) is difficult to measure.

Therefore, enrolling subjects with a high \textit{in vitro} basophil response increases the value of the data.
B.F.

“B.F.” is a 29 y.o. white female with an M.S. in biology.

She has worked in the lab for 6 years, and currently is supervised by the principal investigator of the CP study.
B.F.’s Basophils

- B.F. has an unusually high *in vitro* basophil response, making her an excellent candidate for the CP study.

- BF asked whether she could participate in the CP study.
Consult Request

The principal investigator is concerned about the appropriateness of enrolling a colleague in the CP study, and calls a bioethics consult.
The bioethics team meets with B.F., independent of the research team. B.F. states that she wants to participate, will withdrawal if she changes her mind, and understands the risks.
The P.I.

- The P.I. feels confident that B.F. would say “no” if she did not want to participate in the CP study.

- He reports that she has been comfortable refusing blood draws requested of her in the past.
The bioethics consultants conclude B.F. understands the study well, and is not being pressured to participate.

However, they point out that maintaining confidentiality in the lab may be difficult, and participation might adversely affect B.F.’s relationship with the team.
Given these concerns, the bioethics consultants recommend that the PI solicit input from the C.C. Ethics Committee.

The PI presents the case to the Clinical Center Ethics Committee.
Reasons to include B.F.

- Increases the quality of the data.
- Saves time in finding quality subjects.
- B.F. understands the study’s risks and requirements extremely well.
- B.F., a co-author on any resulting publications, could validate her own scientific observations.
The Cons of B.F.’s Participation

- B.F. may be feeling pressure at some level to participate.
- It might *appear* that B.F. was pressured.
- Her participation might lead to “role confusion.”
- Her participation might adversely affect relationships in the lab.
Ethics Committee Resolution

- “There are no clear regulatory, legal or ethical prohibitions against enrolling B.F.”

- Since B.F. is in a vulnerable position, her participation calls for additional protections, especially independent consent and participation monitors.