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ABET Addendum

1. List two to four **Desired Needs** of your project that led to your final design objectives. The need to monitor early immune activation via minimally invasive T-cell tracking and the desire to study the effect of disease progression or treatment response in T-cells.

2. List the major **Constraints** on your design/project

a) Safety/Regulatory Affairs

Ideally, the T-cells should retain function after their labeling to not harm the host. IACUC was an initial constraint regarding time, but should not be since filing the proper forms.

b) Risks

The T-cells have limited endocytosis and it is likely that the nanoparticles will instead be taken up by the mononuclear phagocytic system.

c) Global Impact

It would be difficult to spread this to areas where the beads are not easily accessible.

d) Manufacturability

The SPIONs in question are commercially available and easy to access.

e) Quality Control/Marketability

The in vivo labeling is what is being marketed, so the best we can do in terms of quality control is recommend a manufacturer and share the best possible method and hope it is widely adopted.

3. List the major **Engineering Standards** on your design/project

ISO 10993-2:2022 “Biological evaluation of medical devices Part 2: Animal welfare requirements.”

ISO/TS 19807-1:2019 “Nanotechnologies — Magnetic nanomaterials Part 1: Specification of characteristics and measurements for magnetic nanosuspensions”

ISO 10993-5:2009 “Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity”

4. Explain **Ethical, Environmental, and Societal concerns** for practical applications of your project. Please address each of these areas.

There are few concerns on the ethical and societal fronts as this is merely an attempt to update a long existing technique, but there could be issues in exposing nanoparticles to the human body, which would then expel these particles as waste down the line. It is a nearly negligible amount, but it could add up over time.

5. Describe **Active Teamwork and Leadership** in your design group

The team collaborated in meetings that happened twice a week in the earlier part of the project then once a week when it was more established. It was difficult to decide on the overall design, but when it happened many goals and deadlines were put in place. Our mentors were an invaluable tool in this process and they encouraged our working together in the lab.

6. What were the most significant motivating factors that led you to

I knew the least about the subject, so I was more determined to look through related articles. I didn't want my teammates to be working alone so I became more involved, and I didn't see setbacks as permanent.