**How to decide whether a study is a NIH Clinical Trial**

HSD recommends using these resources for deciding whether your research project is a NIH Clinical Trial.

1. **NIH Decision Tree** <https://grants.nih.gov/policy/clinical-trials/definition.htm>

This 4-question decision tree lays out the criteria NIH uses. **HSD advice about using the decision tree**:

* The definition is not based on whether the human subjects are healthy or are patients.
* NIH has made it clear that it defines “intervention” very broadly.
* The very broad NIH interpretation of this criterion is the most controversial and is the most likely to be evaluated incorrectly by PIs: Is the study designed to evaluate the effect of the intervention on the participants?
* NIH considers almost all human subjects research it funds to be “health-related”.
* Clinical trials may be looking at efficacy, effectiveness, safety, or mechanisms, and may be exploratory/pilot/feasibility studies.
* It is not a requirement to have multiple groups to be considered “prospectively assigned”. NIH does consider single-arm trials to be clinical trials.
* Risk is not part of the definition.
* The number of subjects is irrelevant. NIH states that there can be clinical trials with a N=1.
* Studies need not include a comparison group to be considered a clinical trial.



1. **NIH FAQs about Clinical Trials** <https://grants.nih.gov/grants/policy/faq_clinical_trial_definition.htm>
2. **NIH Case Studies** <https://grants.nih.gov/policy/clinical-trials/case-studies.htm> (scroll down the page to see them)

This is a series of short 1-paragraph descriptions of about 3 dozen hypothetical studies, written to illustrate the difference between clinical trials and studies that are not clinical trials. **This is probably the single most useful resource**, because PIs are likely to find at least one case study whose approach/design matches what they are considering. They are extremely revealing of NIH’s broad definition of “clinical trial”.

Example: Case Study #14. The study involves the recruitment of healthy volunteers for a respiratory challenge study; participants are randomized to receive different combinations of allergens. The study will evaluate the severity and mechanism of the immune response to different combinations of allergens introduced via inhalation. ***NIH considers this to be a clinical trial.*** The case study is analyzed in terms of the 4 criteria, to explain why.

1. **NIH staff**. If you are still not sure after using the above resources, we suggest contacting one of the NIH staff named in the Funding Opportunity Announcement you are considering. *They will expect you to have used the above resources first.*