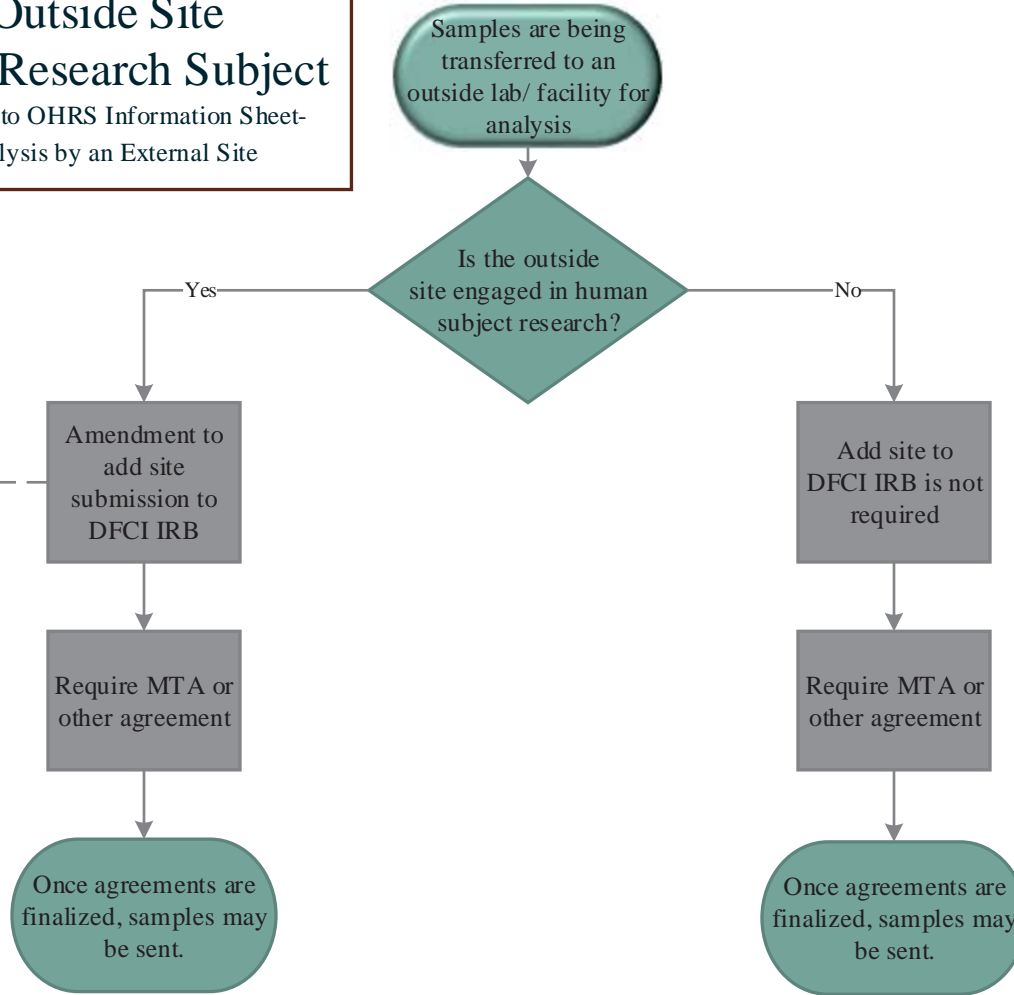


# Determination of Outside Site Engagement in Human Research Subject

For more in-depth guidance please refer to OHRS Information Sheet- Research Acquired and/or Data Analysis by an External Site

Non-clinical facilities that are being added to a trial to only perform sample analysis do not require a site PI. Samples that are sent to the Broad require a Broad Case Manager.



## Engaged in Human Subject Research

Is when the external site has the ability to have access to identifiable information that would enable them to readily ascertain the identify of the individual to whom the private data and/or specimen pertain. Samples that are coded are still identifiable if the investigator conducting the research has access to the key that would allow them to enable linkage of the identifying information to the private data or specimen.

For example, coded samples are sent to the Broad where the research is being conducted by an investigator who is also a DFCI co-investigator on that trial.

If samples are being analyzed under a project that has received Federal funding, IRB approval is required.

## Not Engaged in Human Subject Research

Is when identifiable information is not attainable by the external site and/or the site is providing commercial or other services that do not merit professional recognition and or publication privileges.

For example, an outside lab is fee for service for analysis that they would routinely perform.