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| Logo for the Office of Quality Compliance, University of Utah |

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| Determining Eligibility & Enrollment  Eligibility criteria are the specific requirements that potential participants must meet prior to enrollment into a research study. Eligibility is based on inclusion/exclusion criteria and is required to be followed when determining eligibility. Research teams should review the following questions PRIOR to enrollment/randomization to help ensure the safety of research participants.  |

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| * Is the most current IRB approved protocol version being used to determine eligibility?
* Have each of the IRB approved eligibility criteria been reviewed and signed off by the Principal Investigator (PI) or Sub-Investigator (Sub-I)?
* Is any eligibility criterion pending? (e.g. labs, diagnosis, etc.)
* Are screening labs and/or imaging and diagnostic reports documented as reviewed by the PI/Sub-I or a medically qualified designee?
* Has the PI/Sub-I answered "yes" to any exclusion criterion?
* Is source documentation for all eligibility criteria filed within the participant chart? (e.g. specific labs, assessments etc. must be provided as evidence for validation)
* Were screening procedures completed within the protocol required timeline?
* Is there documentation confirming eligibility status that has been signed and dated by the PI/Sub-I?
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