**Office of Human Research Ethics Training Tips**

**Use of Consultants by the IRB**

**UNC SOP: 4.7 Consultants**

**OHRP 45 CFR 46.107(f) & FDA 21 CFR 56.107(f)**

The UNC-Chapel Hill IRB may, at the discretion of the Chair or its members, invite individuals with competence in special areas and no conflict of interest with the study to assist in the review of issues that require expertise beyond or in addition to that available on the IRB.

**Consultants Are:**

* Consultants are selected because they have expertise in specialized areas needed
* The IRB Chair and/or primary reviewer identifies the proposed consultant and contact the prospective consultant to request the needed assistance.
* Consultants may be drawn from another IRB or faculty from the UNC-Chapel Hill campus, or from outside the University.
* Consultants are asked to disclose any relevant conflicts of interest and once the consultant has agreed to assist and has signed a confidentiality agreement, the IRB staff will send the necessary materials for review.
* Consultants may provide their comments in writing to the IRB or present their comments in person at the relevant meeting.
* Consultants will be excluded from discussion except to provide information requested by the IRB and will leave the meeting room for the discussion and may not vote with the IRB.

**IRB Meeting Minutes**

* Consultants are not included in determining or establishing a quorum at the meetings.
* Review by a consultant is noted in the committee minutes.

***REMINDER: The IRB is still responsible for determining if the protocol meets the 111 Criteria for approval. The consultant only provides the Board with additional information upon which to reach a determination.***