UMASS GLOBAL
A nonprofit affiliate of the University of Massachusetts

UMASS GLOBAL INSTITUTIONAL REVIEW BOARD

Full Committee Review Criteria

Full BUIRB review is required for all research involving greater than minimal risk to subjects. This responsibility cannot be delegated. Full review is required for research involving any protected subject population. If research protocols involve any of the following, it will most like require full BUIRB review.

- Pregnant women/Neonates
- Human in vitro fertilization
- Fetuses
- Infants or Children younger than seven years of age
- Minors ages seven through seventeen
- Inmates or Prisoners
- Elderly/Aged Persons
- Non-English Speaking Persons
- Economically or socially disadvantaged
- Adults with physical or mental disabilities
- Patients
- Psychiatric patients
- Groups vulnerable to coercion or undue influence
- Impaired capacity to make decisions
- Dietary assessment/manipulation or any medical/clinical assessment of patients or volunteers
- Cognitively impaired people
- Drug use, sexuality, AIDS
- Experimental deception likely to result in emotional or psychological distress
- Other special populations targeted in the study protocol

If there are any questions concerning whether or not a proposed study protocol must be submitted for full BUIRB review contact the Chair of the IRB.

Regulations and References

- DHHS 45 CFR 46.110
- DHHS 45 CFR 46.111(a)(1-2)
- FDA 21 CFR 56.110
- FDA 21 CFR 56.111(a)(1-2)

OHRP IRB Guidebook, Chapter 3: Basic IRB Review, Section A, Risk/Benefit Analysis