Case Studies

IRB Guidance Document
University of Texas at El Paso

The University of Texas at El Paso (UTEP) requires that all research involving human subjects conducted by faculty, staff, and/or students affiliated with the university, be reviewed and approved by the Institutional Review Board (IRB) prior to initiation, regardless of the source of funding and regardless of its federal status as an exempt, an expedited, or a full board review protocol. Investigators may not solicit subject participation or begin data collection until they have received written approval from the IRB.

Research is defined by federal regulation as a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge [45 CFR46.102(d)].

A ***Case Study*** is understood to mean the collection and presentation of detailed information about a particular participant or small group, frequently including the accounts of subjects themselves. A form of qualitative descriptive research, the case study looks intensely at an individual or small participant pool, drawing conclusions only about that participant or group and only in that specific context. It may involve collecting data about participants using participant and direct observations, interviews, protocols, tests, examinations of records, and collections of writing samples. Case studies may also involve either retrospective or prospective study. A *retrospective case study* looks backwards and examines the incidence of certain factors in relation to an established outcome. A *prospective case study* looks forward and examines a particular individual or case for a particular outcome that may be associated with the presence/absence of relevant factors.

IRB Review of Case Studies: Case studies generally fail to meet the federal definition of research because there is no intent to test a hypothesis via systematic analysis. As a result, case studies generally qualify for exempt review by the IRB provided that the study (a) does not involve a sensitive topic, (b) is conducted in a manner that protects subjects' identity, and (c) does not involve at-risk or special populations. A listing of privacy issues and special populations are provided below.

> ***Subject private and/or medical identifiers:*** Exempt studies may not include any of the following identifiers (see Privacy Rule [45 CFR46.514(B)(2)]).
>
> - Names
> - All elements of dates (except year) for dates related to an individual, including birth date, admission date, discharge date, or date of death
> - All geographic subdivisions smaller than a State, including street address, city, county, precinct, zip code, and their equivalent geocodes
> - Telephone numbers
> - Fax Numbers
> - Electronic mail addresses
> - Social security number
> - Medical record numbers
> - Health plan beneficiary numbers

- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers, including license plate number
- Device identifiers and serial numbers
- Web Universal Resource Locators (URLs)
- Internet Protocol (IP) address numbers
- Biometric identifiers, including finger and voice prints
- Full face photographic images and any comparable images
- Any other unique identifying number, characteristic or code

Special populations: Exempt studies may not include participants from any of the following protected groups:

- Pregnant women, human fetuses, and neonates [45 CFR 46 Subpart B]
- Prisoners [45 CFR 46 Subpart C]
- Children [45 CFR 46 Subpart D]

IRB Review of "N of one" Studies and Case Series with Data Manipulation: It is noted, however, that an "N of one" trial that uses an experimental treatment on a single subject, or a case series that incorporates levels of data manipulation (statistics) to allow possible extrapolation of the results to a larger population, would satisfy the federal definition of research. As such, these studies must be submitted to the IRB for expedited for full board review.

A flow chart and checklist are provided below to assist researchers in determining whether a given project meets the criteria for exempt vs. expedited/full board review by the IRB. UTEP's IRB staff is available to answer any questions related to submission of your protocol via email to irb.orsp@utep.edu or telephone to 915-747-8841.

Procedures for Submitting Exempt vs. Expedited or Full Board Protocols:

All protocols submitted to the IRB for review should be submitted at least 21 days before the next scheduled IRB meeting. Each submission requires ***at minimum*** a proposal and informed consent.

Each study is case specific and other documents necessary to properly conduct the study should be submitted as required. All approved IRB templates (i.e. proposal, consent forms, assents, checklists and guidelines are available for download from IRBNet forms and reference library).

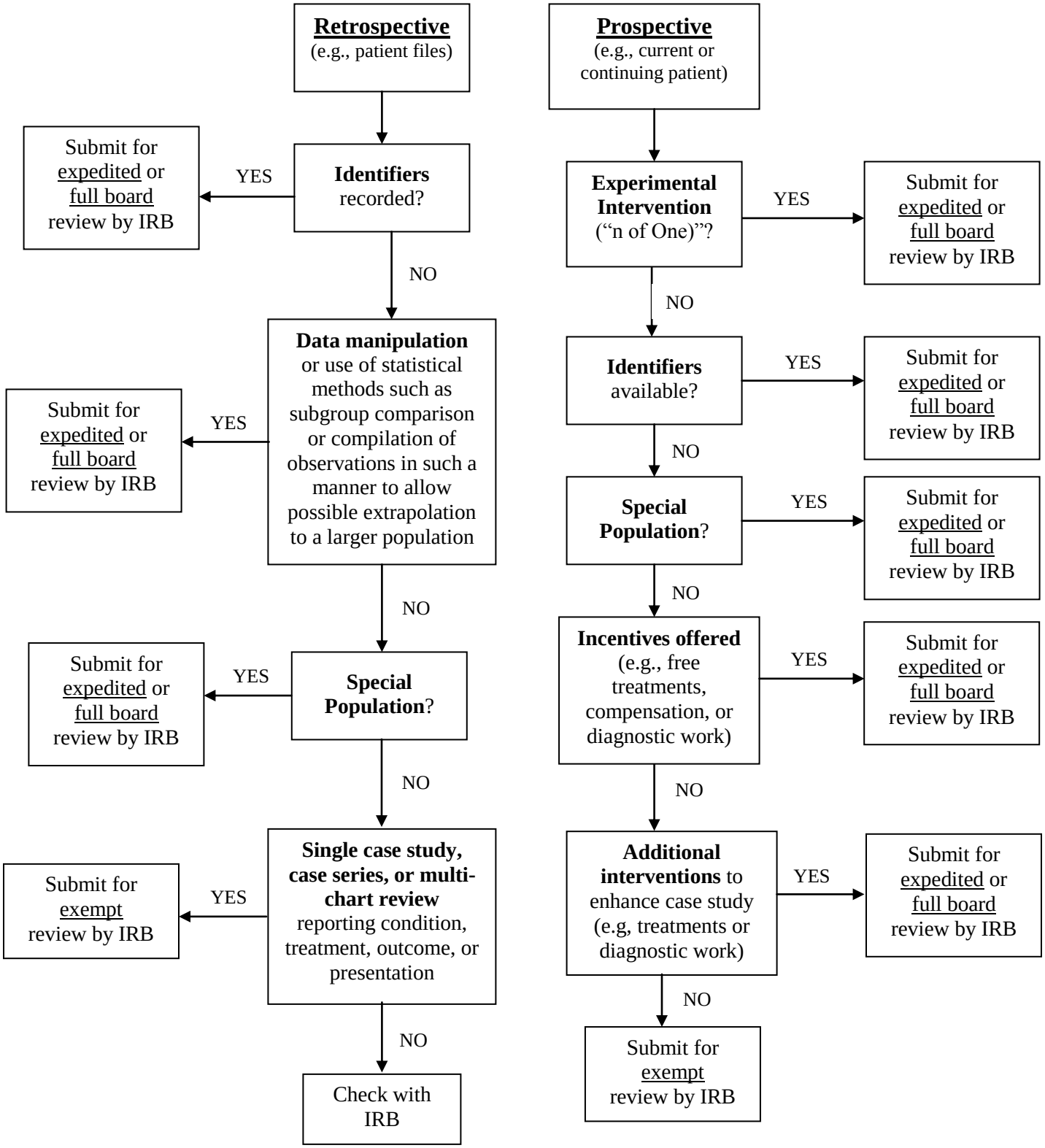
***Exemptions*:** Studies in certain very low risk categories are exempt from full committee review. You must submit the Protocol to the IRB for this determination including your completed exemption request document.

Expedited Review: Studies submitted and considered minimal risk will be assigned to an expedited review (not necessarily considered expedient). Expedited review is defined as being assigned to one or more qualified reviewers as designated by the IRB chairperson thus not requiring Full Board review.

Full Board Review: Submitted studies found to be more than minimal risk by the IRB (i.e. sensitive topics, vulnerable populations, identifiers) will be referred to the next Full Board scheduled meeting.

Case Study/Case Series

Research or Non-Research Decision Tree for IRB Submission



Case Study/Case Series Checklist

This document is intended to assist researchers in assessing whether case studies or case series review may be exempted from review by the UTEP Institutional Review Board (IRB). All items below must be satisfied for case studies to be reviewed as exempt. For questions relating to such projects, please contact irb.orsp@utep.edu or 915-747-8841.

[ ] The project does not involve sensitive topics, confidential information, or identifiers that could place a participant at risk if disclosed.

[ ] The project does not involve persons from vulnerable populations.

[ ] The project does not include data manipulation to include use of statistical methods such as subgroup comparison or compilation of observations in such a manner that might allow for generalization to a larger population.

[ ] The project is a single case study, case series, or multi chart review reporting patient condition, treatment, outcome, or presentation that draws conclusions only about that participant or group and only in that specific context.

[ ] The project is not an experimental intervention ("n of one").

[ ] The project does not offer incentives to participants (e.g., compensation, free treatments, or diagnostic work).

[ ] The project does not include any added interventions to enhance the case study (additional treatments, diagnostic work, etc.).

[ ] The faculty PI or advisor is fully aware of all aspects of the research project and will take responsibility for overseeing the project and assuring that ethical principles are adhered to in the conduct of those activities.