Research or Non-Research Decision Tree for IRB Submission

**Retrospective** (patient files)
- Identifiers* available?
  - YES: Complete IRB Form B* prior to start of project
  - NO: Data manipulation
    - YES: Complete IRB Form A* prior to start of project
    - NO: Single case study or case series or multi chart review reporting patient condition, treatment, outcome, or presentation
      - YES: Submit Form E (Guidance for Case Studies)
      - NO: Check with IRB

**Prospective** (current or continuing patient)
- Experimental Intervention (“n of One”)?
  - YES: Complete IRB Form B* prior to start of project
  - NO: Identifiers* available?
    - YES: Complete IRB Form B* prior to start of project
    - NO: Special Population*?
      - YES: Complete IRB Form B* prior to start of project
      - NO: Incentives offered (e.g. compensation, free treatments or diagnostic work)
        - YES: Complete IRB Form B* prior to start of project, may qualify for expedited review
        - NO: Added interventions to enhance case study (additional treatments, diagnostic work or questionnaires)
          - YES: Complete IRB Form B* prior to start of project may qualify for expedited review
          - NO: Submit FormX (Guidance for Case Studies)

*See Appendix I for details
Appendix I

* From “Research or Non-Research Decision Tree for IRB Submission”

IRB Form A: NUHS IRB New Project Application, “Claim of Exemption”

IRB Form B: NUHS IRB New Project Application for projects requiring full or expedited IRB review, “Application to the IRB for Approval of a Research Project”

Special populations:
- Pregnant women, human fetuses and neonates [45 CFR 46 Subpart B]
- Prisoners [45 CFR 46 Subpart C]
- Minor children [45 CFR 46 Subpart D]

Patient medical identifiers: De-identified dataset cannot contain any of the identifiers listed below. 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, 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
Appendix II

Additional Information

1. Case study:
   a. Definition: A case study is by definition not research. However, it is not always clear what is or is not a case study. More often defined is research, which requires both a) a systematic investigation and b) the intent to contribute to generalizable knowledge [read as “publish”]. (Bankert, Amdur, p103) The case study is taken to mean the organization of patient notes and the medical file for a given patient such that the case can be shared with others for educational purposes. This may be retrospective or prospective and both are addressed below. This organization of the medical file is not interpreted to mean the “systematic investigation” referred to in the definition of research.
   a. IRB: At NUHS IRB consideration is required even for the case study.
      i. Rationale: IRB approval is required because
         1. The project will be classified as exempt from review. While annual consideration will be necessary for projects not completed, the process is not a burden.
         2. The definition for the case study is not always clear and there are numerous potentially confounding factors. The practitioner can come to us (including a designee) and we will tell you whether IRB approval is needed or whether the project is exempt
         3. A brief discussion with IRB now may help to alert you to potential problems along the way
         4. IRB clearance at NUHS is not a hindrance or burden to the publication process. Clinicians can expect readily accessible consultations, easily available forms, quick turnaround time, minimal paperwork, etc.
         5. Approval authority may be delegated to a representative of the IRB, e.g. a faculty member who reports to the IRB annually, or more often as needed.
         6. Due to the ready availability of IRB review at NUHS, the occasional field practice of simply stating that the intervention conforms to the Helsinki Accord and other standards is not appropriate.
   b. Informed consent
      i. Retrospective vs. prospective case studies
         1. For retrospective case studies
            a. Informed consent is strongly recommended when the report is intended for publication. While IC is not required for case studies at some institutions, that is not the situation at NUHS.
            b. IRB reserves the right to require IC for retrospective studies if the need arises
2. For prospective case studies
   a. Informed consent is required
   b. IC for publication must be obtained at the beginning and confirmed at the end of care, prior to publication. There may be changes in perception from the initiation of care to the time of publication. Informed consent for care is differentiated from IC for publication. The latter must be confirmed following treatment whenever possible.

ii. Special populations
   1. Informed consent is required for protected populations
   2. As a minor comes of age, it is assumed he/she can give consent to his/her previous records
   3. An exception can be made if it can be demonstrated that every effort was made to gain the informed consent but the patient or representative could not be found after diligent search

iii. Informed consent is required without exception if any element of the 18 categories of PMI is to be used, or if a photo or some other clear identification of the patient will be used.

c. Coercion:
   i. Definition: There is no clear definition; the meaning is contextual. Coercion is taken to be a stronger term than “incentive” and both are included in this discussion. Unlike the research project, the case study is a review of that intervention that is entirely dictated by standard clinical reasoning for the situation. There is no manipulation of the intervention to test a hypothesis other than the usual and customary. An offer of an incentive of any sort out of the usual and customary practices for a given practitioner removes the encounter from the bounds of case study.

ii. Compensation: in research compensation is appropriate for time and trouble. Even care at no cost to the participant is an accepted incentive (there are deeper discussions for the research context which will not be addressed here). For the case study, compensation does not fall within the range of usual and customary, and is therefore inappropriate. Care at no charge is appropriate only if the provider would conceivably provide care at no charge for another patient under similar circumstances even if no publication or case review were intended.

d. Intervention
   i. The entire intervention must be based entirely and solely on medical reasoning appropriate to the moment. Here the provider intending to publish must be vigilant and self-reflective. There is great risk to slightly modify an intervention to make it more interesting, or more acceptable to publication, or to include an intervention that is not quite standard for the sake of creating an
interesting and useful teaching/educational moment. Any of these removes the encounter from the realm of case study.

i. Additional documentation (e.g. an otherwise uncalled for visual analog scale, etc.) for the purposes of enhancing the case study are not appropriate to the case study.

ii. Additional laboratory studies for the purposes of enhancing the case study are not appropriate to the case study, even if no charge is accrued to the patient.

iv. Experimental care
   1. Therapy for a case study, even if not previously tried by that practitioner must be based entirely upon what that therapist would be inclined to do medically regardless of intent to publish.
   2. Any care considered experimental removes the relationship from the realm of case study.
   3. Published conventions or other literature may aid in the definition of experimental status for a particular intervention.

2. Case series
   a. Case series relationship to research
      i. Simple numbers of cases studied does not create a research scenario.
   b. Some levels of data manipulations from case series are considered to fall within the definition of “systematic investigation” including “…use of statistical method such as subgroup comparisons and test for prognostic factors.” (Bankurt, Amdur, p 103)
   c. Once a study is presented to the IRB as retrospective and exempt status is assigned, then no additional cases may be added to that case series. Those new cases would be prospective and may not be added to the retrospective project.

3. N of One
   Insofar as the N of One calls for a trial modification of the intervention, IRB is required