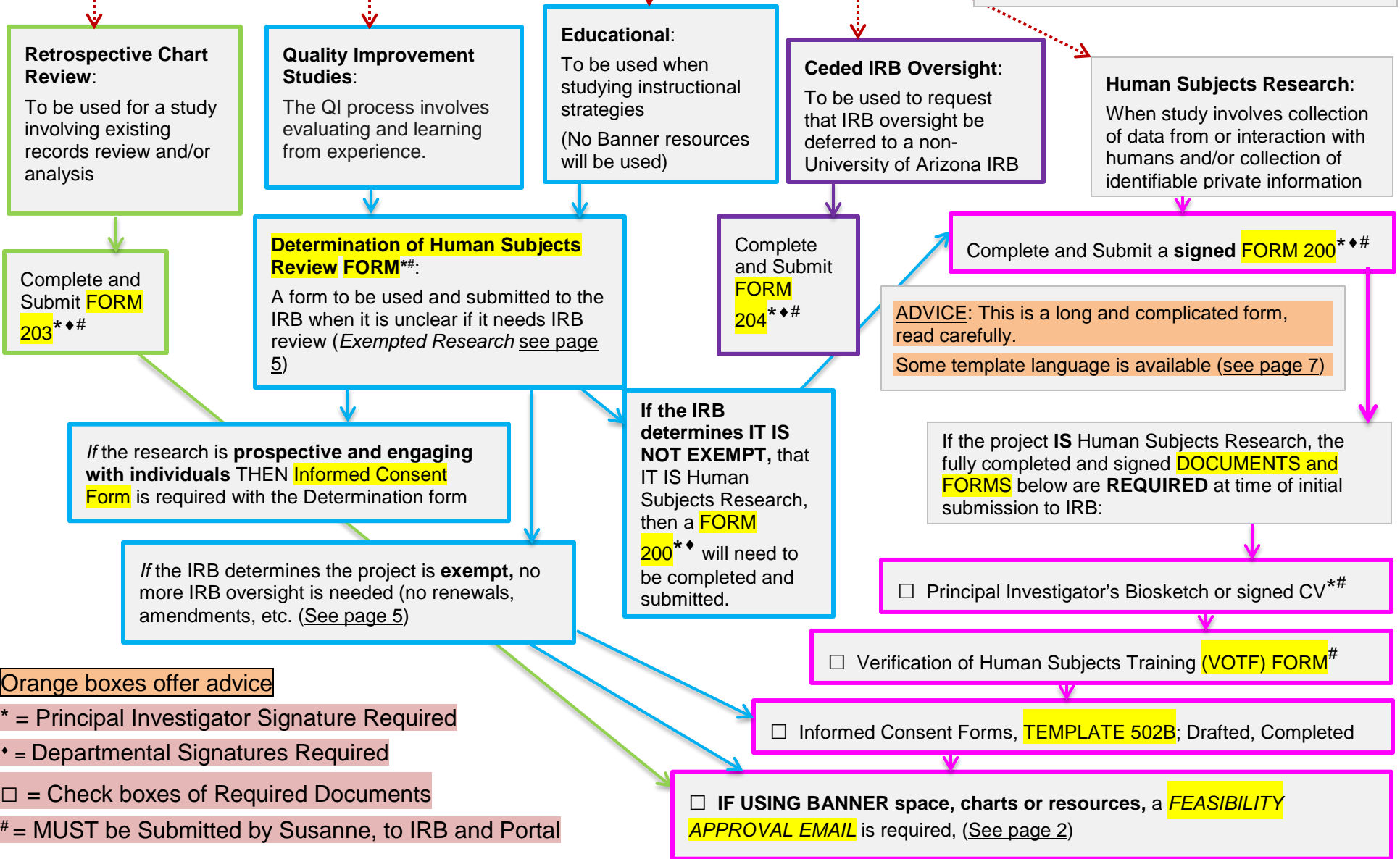


Type of Research Project or Study? These are the first forms to be considered and they determine what further documents are required. **This STEP 1.**

Research is the systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.



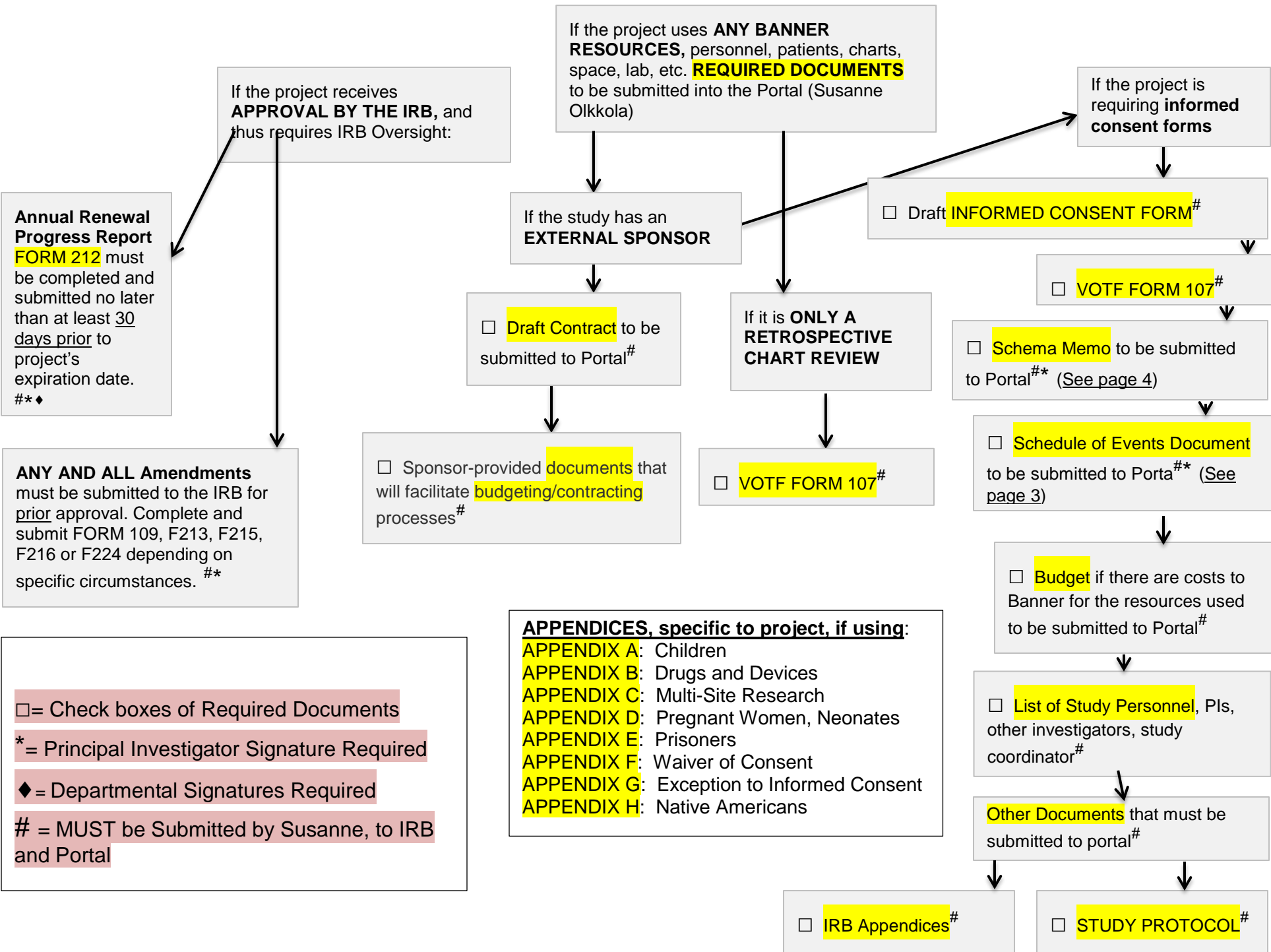
Orange boxes offer advice

* = Principal Investigator Signature Required

♦ = Departmental Signatures Required

[] = Check boxes of Required Documents

= MUST be Submitted by Susanne, to IRB and Portal



EXAMPLE OF SCHEDULE OF EVENTS, you should cut/paste this example below. Then complete, sign and submit to Susanne Olkkola

Project Title: XXX
Principal Investigator: XXX
Planned Enrollment Number: XXX
Study Period: one year XXX
Sponsor, if any: XXX

THE RED CIRCLE, OR OTHER INDICATION, IS REQUIRED TO INDICATE STUDY (not standard care) PROCEDURES

SCHEMA

1. Screen for eligibility / Recruit and Consent:

Enrolled patients will be identified by the Banner – University Medical Center Tucson (BUMCT) and Banner – University Medical Center South (BUMCS) within the Emergency Departments

Enrolled patients will be of one type:

1. Patients 18 years old and older who present to the BUMCT or BUMCS with complaint of acute dental pain and found to have symptoms and physical findings consistent with diagnosis of pulpitis/dental apical abscess and are not excluded by exclusion criteria.

Informed Consent:

Potential participants will be given information on the study, its goals and objectives, and the benefits and risk involved. Informed consent will be obtained in the participant's primary language. Informed consent will be obtained by research investigators, documented, and signed by participant. No monetary benefits will be offered for participation. Potential participants will have the right to refuse enrollment without recompense and maintain the right to withdraw from the study at any time without consequence.

Patient will be identified. Patient will be consented by member of Study Team. Patient will be assigned SPN. Patient will be treated at discretion of ED physician. Patient will be dosed with study drug that is pre-assigned to Study Patient Number (SPN). Patient will be discharged and will provide pain score at time of discharge. Patient will be contacted at time interval and asked to provide pain score.

2. **Study Protocol/Procedure – procedure # 1:** Patient will be assigned SPN
3. **Study Protocol/Procedure – procedure # 2:** Patient will be dosed with study drug that is pre-assigned to Study Patient Number (SPN)
4. **Study Protocol/Procedure – procedure #3:** Patient will be discharged and will provide pain score at time of discharge
5. **Study Protocol/Procedure – procedure #4:** Patient will be contacted at time interval and asked to provide pain score
6. **Procedures that are considered Standard of Care:** Any other care the patient receives is standard of care

Signed (date): _____

Signature of PI

NAME OF PI

EXAMPLE OF SCHEMA MEMO. This is the actual memo (below) to be used, so cut/paste, complete, sign and submit to Susanne Olkkola

IDENTIFICATION OF SERVICES PROVIDED TO CLINICAL TRIAL PARTICIPANTS

PI:

Sponsor:

Study Title:

Using the clinical trial protocol schema, please indicate the clinical encounters, tests and/or procedures that are considered research-related and should be paid for by the study/sponsor (please circle all research-related charges on the protocol events/schema). In making your assessment, consider the following:

- A) The encounters, tests, and/or procedures are required for research purposes only as part of this clinical trial and are not part of routine care for patients with this medical condition.
- B) The sponsor of the trial is providing compensation for a service and, therefore, it is not considered billable to a subject and/or their third party.

The University of Arizona Health Sciences requires source documentation that shows the detail for all required study procedures and a determination of who is paying upfront and before the trial starts. The basis for this requirement is to complete a Payer Coverage Analysis and use the designation of procedures to ensure that the informed consent, external budget, internal budget, billing grid, and the clinical care expenses related to an active study all coincide to this process.

Per the CMS National Coverage Decision (Sept. 2000), only services considered routine costs of qualifying clinical trials are ‘billable’ to Medicare. All coverage rules and payment requirements (i.e. local coverage decisions) must still be met. To be ‘billable’ to the subject and/or their third party, all services considered routine/conventional care must meet the following criteria:

- The services are considered safe and effective based on authoritative evidence as generally accepted by the medical community.
- The services are considered medically necessary.
- The services are not unproven or experimental in nature.
- Supported by past billing practices.

Other Budget-Related Items (please answer all questions):

1. How many subjects do you plan to enroll? _____
2. Will the Banner Investigational Pharmacy be used? Yes No NA
3. Will Banner Radiology Imaging Services be used? Yes No NA
4. Labs will be processed: Locally Sponsor’s central lab
5. Do you plan to provide subject compensation? Yes No
If so, what is the total amount per study subject for the duration of the study? \$ _____
6. Will the study interactions occur: INPATIENT OUTPATIENT BOTH

Your signature below will serve as your attestation that, following your review of the clinical trial protocol, all clinical services you expect to perform have been identified and labeled as either clinical trial/research-related or routine care.

PI Signature: _____ **Date** _____

Epic Charge Validator Name (if no charges will be in Epic, study coordinator can sign):

_____ (print name)

Signature: _____ **Date:** _____

EXEMPT RESEARCH

Federal regulations designate certain types of research involving Human Subjects as being exempt from further IRB oversight. A designation of 'exempt' means the project IS human research, but it is very low risk and not subject to further requirements in the federal regulations. Determination of whether a project is exempt from further IRB oversight requires a determination by a designated IRB member. Investigators cannot make determinations whether Human Research projects meet the regulatory criteria for exemption.

The regulations allow for **six (6) categories** of research that qualify for exempt status.

- (1) Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as
 - (i) Research on regular and special education instructional strategies, or
 - (ii) Research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
- (2) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless:
 - (i) Information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and
 - (ii) Any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- (3) Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph [\(b\)\(2\)](#) of this section, if:
 - (i) The human subjects are elected or appointed public officials or candidates for public office; or
 - (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
- (4) Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.
- (5) Research and demonstration projects which are conducted by or subject to the approval of department or agency heads, and which are designed to study, evaluate, or otherwise examine:
 - (i) Public benefit or service programs;
 - (ii) Procedures for obtaining benefits or services under those programs;
 - (iii) Possible changes in or alternatives to those programs or procedures; or
 - (iv) Possible changes in methods or levels of payment for benefits or services under those programs.
- (6) Taste and food quality evaluation and consumer acceptance studies:
 - (i) If wholesome foods without additives are consumed; or
 - (ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

In addition to the exemptions in the federal regulations, **the UA HSPP has created two additional exempt categories** for projects that are not federally funded, supported, or for an agency that has adopted the federal rules.

a) **Exempt 7:** Projects that do not conform to a specific exempt category under 45 CFR 46.

Examples include:

- Online surveys, in-person focus groups, and/or interviews involving minors as long as the information collected does not place the individual at greater than minimal risk
- Behavioral games
- Studies of traits of non-public, non-elected officials
- Studies requiring performance of tasks that incur no risk
- Studies involving focus groups, oral histories, ethnographies, or studies utilizing eye-tracking

b) **Exempt category 8** may still require a HIPAA waiver. Studies that typically fall under expedited category 5 (involving analysis only of already collected data/documents/records) may now qualify for exempt category 8.

Exempt category 8 may still require a HIPAA waiver. Studies that typically fall under expedited category 5 (involving analysis only of already collected data/documents/records) may now qualify for exempt category 8.

IRB Submission requirements

Submission of:

- “Determination of Human Research”

If the research is **prospective and engaging with individuals**, a consent document that contains just the required elements on the C100 is required.

- Informed Consent form

TEMPLATED LANGUAGE

TO BE COMPLETED