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DETERMINING THE CONSENTING CAPACITY OF MINORS BEARING CHILDREN:

A PRACTICAL MODEL

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A PRACTICAL MODEL

INTERNSHIP PRACTICUM REPORT

Presented to the Graduate Council of the

Graduate School of Biomedical Sciences

University of North Texas

Health Science Center at Fort Worth

In Partial Fulfillment of the Requirements

For the Degree of

MASTER OF SCIENCE

By

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Fort Worth, Texas

May 2013

ACKNOWLEDGMENTS

I would like to thank Dr. John Fling, Vicki Cannon, Kathryn Adams and Andrea Torres. Together they tackle a variety of investigational vaccine studies. These studies have trial populations which range from pediatric to geriatric. While working with a wide range of patients, I have become acquainted with the differences between working with the youth and the elderly.

Finally, I would like to thank Dr. Patricia A. Gwirtz, Dr. Robert Mallet and Dr. Michael W. Oglesby for reviewing and editing this internship practicum report.

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INTRODUCTION

Implementing informed consent process for subjects who are minors is a complicated issue. The standard procedure for attaining voluntary permission from minors is documenting assent; however, particular situations and conditions grant minors additional responsibilities. As defined in the context of clinical research, assent serves as balance between two forms of reasoning concerning the consenting capacity of minors. The prior form of reasoning regards minors as incapable of providing a thoughtful examination of the inherit risk in the proposed clinical trial; furthermore, such examination is believed to be paramount to properties originally reserved for an adult who provides consent either on behalf of the minor or on behalf of themselves (Grodin et al 1988). A paradigm shift in literature describing the empirical cognitive abilities of minors refuted the prior hypothesis in primarily two aspects (Santelli et al 2003). One of the two notions is readily accepted. The first notion suggests minors, who are as young 7 years old, present an emerging capacity to understand some level of risk associated with clinical research (Susman et al 1992). On the other hand, the latter notion is still being debated amongst scholars. The second notion builds on the first and suggests minors who are as young as 14 years of age possess similar cognitive abilities as that of an adult; therefore, minors who are as young as 14 years of age could provide consent on behalf of themselves (Weithorn and Campbell 1982). Bioethics and legal scholars compromised between the two forms of thought

by promulgating a reasonable attempt of obtaining assent from capable minors participating in clinical research studies in addition to obtaining parental permission from the minor's parent or legal guardian.

Obtaining assent from minors and parental permission from adults describes ideal investigator practice of the legal framework governing informed consent practices for minors. Moreover, the general framework, which is federally regulated, does not usually allow minors to independently consent to participating in clinical research. However, the federal framework governing informed consent procedures for minors provides exemptions to the standard informed consent procedures based on certain federal exemptions and State regulations (Santelli et al 2003). Minor who bear or have borne children are one of many exceptions to the general framework. Thus, for investigators studying minor who are pregnant or who are parents there is some ambiguity regarding the capacity of minors with children, or the parents of minors with children, to give informed consent.

Problem- The question regarding the ability of minors to provide their own consent to research is complicated, and there is inconsistent guidance concerning the consenting of children when the parent consenting on behalf of the child is a minor.

1) In the most basic of forms, the consenting capacity of minors with children or parents of minors with children, is ambiguous because:
    a. Investigators must comply with Code of Federal Regulations (CFR) Title 21 Food and Drugs Part 50 "Protection of Human Subjects" and Code of Federal Regulations Title 45 Public Welfare Department of Health and Human Services Part 46 "Protection of Human Subjects".

b. The CFR lacks a clear definition of the phrase informed consent and individual States must define criteria; however, States are variable in their regulations, and some States defer to federal regulations in the same instance that federal regulations defer to States (Gandhi 2005).

Aims- The specific aim of this proposal was to develop a practical decision tree to assist investigators and Institutional Review Board (IRB) members as they assess the capacity of a minor with a child to provide informed consent on behalf of the child.

Problem/Hypothesis

Bioethicists and researchers collectively developed the ethical foundation of the informed consent process in 1947, beginning with the Nuremberg Code. Through that document a voluntary consent clause was developed and essentially stated that participation must be voluntary for research to be considered ethically conducted. After the Nuremberg Code laid this ethical foundation, the Belmont Report molded the voluntary consent clause to the modern concept of autonomy; subsequently, the modern ethical concept of autonomy was translated into the modern framework that currently governs clinical research. When researchers act in compliance with this framework when obtaining informed consent, the research is presumed to be ethically compliant. Therefore, in order to obtain informed consent, researchers must proficiently interpret federal and state regulations pertaining to the informed consent process.

This practicum project concerns clinical research involving minors because in this population numerous practical problems surrounding Informed Consent often confront

researchers. A particular problem that is not well resolved involves the obtaining of informed consent for research with children when the parent of the child is in fact a minor (Santelli et al 2003). This thesis proposal will review the literature surrounding this difficulty and then propose an approach to the appropriate handling of such issues.

Researchers are burdened by interpreting two different sets of federal clinical research regulations, and investigators must act in compliance with the correct regulation to be complaint with federal law. The Department of Health and Human Services (HHS), and its subdivisions the Food and Drug Administration (FDA), have developed different sets of regulations that govern the informed consent process in the United States investigators. Pending the funding or nature of the study, researchers accordingly comply with HHS, FDA or both regulations and their definition of informed consent. These differences can have a significant impact, particularly with regard to the conduct of pediatric researchers.

In addition to this "appropriate agency" problem, neither set of clinical research regulations provides a clear definition of the phrase "informed consent." Moreover, while most investigators and clinicians understand the concept of informed consent, the definitive capacity to accept consent provided by minors with children, or parents of minors with children, is not well defined in the Code of Federal Regulations (CFR). In particular, instead of the CFR providing explicit definition of those capacities, parts of the regulations defer to State laws to provide more insight into the ability of minors to consent their children to research (Santelli et al 2003). State laws determine the capacities of minors with children to provide consent by weighing the minor's age, the condition of living, and the type of research to be conducted, all of which can be interpreted differently by rational people (Gandhi 2005, Chanaud 2007).

In summary, developing informed consent procedures for clinical trials involving the children of minors is particularly difficult. First, when investigators develop or comply with informed consent procedures for federally funded trials, investigators must comply with two distinct federal codes. Second, both sets of code lack a clear definition of when a minor with a child can provide informed consent for themselves or their child.

The Office for Human Research and Protection Agency (OHRP) has developed decision trees to aide investigators and IRB members, but the OHRP has not developed a tree that focuses on minors with children. Indeed, few studies have provided practical guidelines for assisting investigators to study the minors with children population (Santelli et al 2003). With the proper tools to develop informed consent procedures, investigators could save valuable time. This practicum project proposes a systematic review of varying scenarios of minors with children and developing a practical decision tree that will help investigators study this unique population (Chanaud 2007).

Significance

Participation by specific populations in research is critical for the advancement of medical services; however, due to the uncertainty about the legal status of minor's involvement in research, minors are frequently excluded from research. Excluding minors from clinical research precludes minors from participating in numerous research initiatives needed to improve minors healthcare and to inform health policy. Specific requirements for broader inclusion of minors have coincided with a declining population of minors who bear children or minors who are parents. The Center for Disease and Control (CDC) estimation of teenage

pregnancy and teenage birth rate for the United States serves as an important warning for investigators to develop accurate consenting procedures for minors bearing children. The CDC found U.S. teenage pregnancy and birth rates reached a record low in 2008 (Ventura et al 2012, Martin et al 2010). To be precise, the CDC found that in women aged 15–19 a pregnancy rate of 69.8 per 1,000 women and a birth rate of 40.2 per 1,000 women (Ventura et al 2012, Martin et al 2010). These historically low rates are true even in the sub-grouped ages of 10-14, 15-17 and 18-19 (Ventura et al 2012, Martin et al 2010). Also, the historically low rates are held across the various racial and ethnic groups although race and Hispanic origin does correlate with varying teenage pregnancy and birth rates (Ventura et al 2012, Martin et al 2010). For instance, the rate of Non-Hispanic black and Hispanic teenage pregnancy is two to three times higher than that of Non-Hispanic white teenagers, and the birth rates follow a similar trend with Non-Hispanic black and Hispanic birth rates three to four times higher than that of Non-Hispanic white teenagers (Ventura et al 2012, Martin et al 2010). (Non-Hispanic white pregnancy rate is 21.6 per 1,000 women and birth rate is 11.6 per 1000 women, the Non-Hispanic black pregnancy rate is 72.8 per 1000 women and the birth rate is 33.6 per 1000 and Hispanic pregnancy rate is 72.8 per 1000 women and the birth rate is 42.2 per 1000. (Ventura et al 2012, Martin et al 2010).

Nevertheless, for all ethnic groups both rates are in a continual decline and have reached record lows. While the United States national adolescent birth rate continually declines, the United States remains at the top of the industrialized world in the rate of adolescents births (Elders 2012). The US has held this unfortunate distinction for the past 10 years (Elders 2012). For investigators and coordinators studying minors bearing children, this

description highlights the importance of continued efforts to research these unique populations and the importance of more refined methods to recruit and retain young research participants.

With respect to obtaining informed consent for children from their minor parents, conducting a systemic review of varying scenarios and developing a practical decision tree will help investigators and IRBs by alleviating confusion.

CHAPTER I

DETERMINING THE CONSENTING CAPACITY OF MINORS BEARING CHILDREN: A PRACTICAL MODEL

Overview of Federal Regulations

Institutional Review Board members and investigators use the CFR to assess the capacity of minors with children, or parents of minors with children, to provide informed consent; therefore, a brief analysis of pertinent HHS and FDA regulations will be crafted to provide the initial building blocks of the practical decision tree. In other words, HHS and FDA regulations define several basic elements of the informed consent document, and they also help define individuals who are able to provide informed consent. Although the two sets of regulation have common elements, unfortunately, they also have some differences that are significant for this issue. In 1973, the Department of Health & Human Services (HHS) developed Subpart A of CFR Title 45 Part 46 "Protection of Human Subjects," which is also called the "Common Rule" (Santelli et al 2003). The Common Rule provides some of the basic regulations for research such as requiring minimization of subject risk, reasonable benefits for subjects, and mandatory informed consent for subjects. Title 45 provides regulation that gives HHS jurisdiction for federally funded clinical trials, and numerous federal agencies and federally

funded organizations follow HHS code of regulations when conducting clinical trials (Chanaud 2007). Furthermore, HHS regulations promulgate that any study involving humans should make a reasonable attempt to comply with the Common Rule in the spirit of benefiting human subjects.

The Food and Drugs Administration (FDA) is part of the HHS, but the FDA enforces a different section of the Code of Federal Regulation (Field and Berman 2004). FDA officials enforce "Title 21 Department of Food and Drugs Part 50 Protection of Human Subjects" (Chanaud 2007). This set of regulations provides oversight to studies being conducted with an Investigational New Drug (IND) or Investigational Device Exemption (IDE). Whether federally or privately funded, "Title 21" possesses jurisdiction over numerous institutions that conduct IND or IDE clinical trials in either adults or children (Chanaud 2007).

FDA and HHS regulations contain fourteen common elements of informed consent (Chanaud 2007). Of the fourteen, eight are generally found in most informed consent documents, and the remaining six are case specific elements that can also be required in the informed consent document if the IRB deems necessary (Chanaud 2007). The eight general regulations common to both FDA and HHS are that the study disclose: 1) the study involves research; 2) foreseeable risks; 3) a summary of benefits to subjects and others; 4) alternative procedures that may be available; 5) a statement of confidentiality of records; 6) a list of compensations and medical treatments in case of injury; 7) a person to contact in case of injury; and 8) that participation is voluntary (Chanaud 2007). Certain types of studies require additional elements. Dpending the type of study, the HHS and FDA may require six additional statements to protect subjects, consisting of: 1) risk to fetus; 2) investigator discretion to

terminate participation; 3) cost to participants; 4) consequences of the decision to withdraw; 5) disclosure of pertinent new information; and 6) approximate number of patients (Chanaud 2007).

In addition to the shared Common rule informed consent elements, Title 21 of the FDA requires an additional four measures (Chanaud 2007). These measures include explaining: 1) the purpose of the trial; 2) the procedures entailed in the study; 3) which aspects of the study are experimental in nature; and 4) the subject's anticipated duration of participation in the study (Chanaud 2007). A highly debated difference between the regulations is Sec. 406.408 subsection (c) of Subpart D in CRF 45 Part 46. Under HHS regulations, the Sec. 406.408 subsection (c) informed consent for parents can be waived in certain situations (Santelli et al 2003). Section 406.408 subsection (c) has not been adopted by the FDA despite being pointedly challenged by the National Human Subjects Protections Advisory Committee which is a federal advisory committee to the Office of Human Research Protections (OHRP). This would seemingly imply that parental consent cannot be waived for minors with children when using an IND or IDE (Santelli et al 2003).

Special Protections for Pregnant Women

Subpart B of CRF 45 Part 46 affords special protection to pregnant women and fetuses. Currently, there is not a direct equivalent of Subpart B in FDA regulations, so a brief description of only the related HHS regulations is provided (Bonnie M. Lee 2000). According to HHS guidelines Section 46.201, fetuses are described as the product of conception from implantation to delivery, and pregnancy encompasses this period until delivery or a negative

pregnancy test. The special protections of Subpart B define the consenting capacity of parents similar to Subpart D because the consenting capacity depends on a categorical hierarchy. The categorical hierarchy is based on the prospect of risk and benefits for a pregnant woman or her fetus. Section 46.204 (d) explicitly designates the consenting capacity to the mother when the prospect of benefit is designed to help her or there is no more than minimal risk for the child. The subsequent Section 46.204 (e) describes when research presents a potential benefit for the fetus. The prospect of potential benefit for only the fetus needs consent of both the expectant mother and father. The following represents the two categories and clauses of Section 46.204 (d) and Section 46.204 (e):

(1) Potential benefit for the mother or mother and fetus, or no potential benefit for the mother but there is no greater than minimal risk for the fetus;

(d) Expectant mother provided consent in accordance with Subpart A.

(2) Potential benefit for only the fetus

(e) Both expectant mother and father consent is required in accordance with Subpart A.

If the expectant teenage mother is not considered a child according to the stipulation in Subpart D, then the investigators should follow the stipulations outlined in Subpart's A and B when obtaining informed consent.

On the other hand, when pregnant teenagers are considered children, investigators are presumed to follow regulations in accordance with Subparts B and D. For example, if a pregnant teenager is considered a child and the research pertains to benefiting the teenager, the teenagers' parent should generally provide permission for the teenager. In this instance, also

required is the teenager's assent. The teenager's assent is obtained with the stipulations outlined in Subpart A. In absence of the teenager's assent, the investigation cannot proceed unless the IRB determines the direct benefits of the study outweigh the teenager's dissent which is similar to stipulations outlined in Section 46.116 of Subpart A.

Subpart D Special Protections for Children

In 1983, the HHS developed Subpart D of 45 CFR 46. Subpart D section 46.401-409 provides specific protection for children participating in research. The FDA has largely adopted Subpart D as part of the Children's Health Act of 2000 with the exclusion of Sec. 46.408 subsection (c) (Field and Berman 2004). Subpart D Section 46.401-2 details when the special protections should apply. For instance, Section 46.402 defines individuals who are considered children. Subpart D Section 46.404-407 and FDA counterpart describes a risk and benefits hierarchy. The following represents the four categories of the hierarchy of risks and benefits:

(1) involves no more than minimal risk;

(2) involves more than minimal risk, but there is a potential for direct benefit to individual research subjects;

(3) involves a minor increase over minimal risk without direct benefit, but research is likely to yield generalizable knowledge about the subject's disorder or condition; and

(4) not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Section 46.408 subsections (a-b) outlines the eligibility requirements for a child's assent and parental permission from one or both parents pending the IRB's classification of the study and characteristic of study population (Field and Berman 2004). The following represents the eligibility requirements in subsection (a-b) of Section 46.408:

(a) Solicit assent of children when children are deemed reasonably capable by the IRB.

(i) Exceptions to the rule: the study holds out a prospect of direct benefit to the child and is available only in the context of the research; or assent may be waived in accordance with Section 46.116 of Subpart A.

(b) Parental permission is to be obtained in compliance with Subpart A

(i) One parent's permission is sufficient when the IRB considers research a category I or II study.

(ii) Both parents must be reasonably given the opportunity to provide permission for research considered category III or IV.

(iii) Exceptions to the rule: one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child.

Section 46.408 subsections (a-b) describe the minor's consenting capacity in the informed consent process when a minor is considered a child. Because it is presumed that children lack the intellectual capacity to understand concepts related to research, in the context of Subpart D assent is only agreement from a child and is distinctly different from traditional presumed

understanding gathered in the consenting process (Santelli et al 2003). Assent from a child may be waived in circumstances when the IRB concludes that the nature of the study falls within Section 46.404 and Section 46.405 (category 1 or 2) or when the subject is not cognitively capable of providing consent. Regardless, when assent is necessary, parental permission is also required for minors in most cases. Parental permission must be conducted in compliance with Subpart A of 45 CFR 46 and the FDA counterpart Title 21 Part 50 so that parents gain the presumed understanding that children lack (Santelli et al 2003).

Overview of Waiving Parental Permission

Parental permission attempts to ensure the protection of children, and researchers are supposed to attain parental permission to normally comply with FDA and HHS guidelines (Santelli et al 2003). The Common Rule or the FDA equivalent is explicitly referenced as specific federal guidelines to inform parents. Parental permission explicitly differs from informed consent because the parent is not the subject. The National Commission for the Protection of Human Subjects in 1977, which provided the basis of the Belmont report, recognized the importance of protecting vulnerable children and recognized that parental permission is not always a reasonable requirement to protect a child. Section 46.408 (c) has two conditions that allows parental permission to be waived.

The first condition that would allow waiving parental permission occurs in situations similar to 45 CFR 46 Subpart A Section 46.116. Under stipulations in Section 46.116, an IRB may waive informed consent for adults when it is not plausible, would not adversely affect the potential research participant, involves no more than minimal risk, and when appropriate the

participant is informed afterwards. Section 46.408 (c) allows parental permission to be waived for a child when in accordance with Section 46.116 an adult's consent is not reasonably required (Santelli et al 2003). For example, it may not be practical to gather informed consent or parental permission for retrospective research involving the medical records of deceased subjects.

Additionally, Section 46.408 subsection (c) allows parental consent to be waived under certain circumstances for minors when the research involves less than minimal risk but would normally require informed consent or parental permission (Santelli et al 2003). When applying this section, IRBs or investigators need to designate additional appropriate protective procedures such as adding a patient advocate. Types of advocates may vary from an independent research monitor to a grandparent so long as the advocate can verify that the minor understands the research concepts, the minor is voluntarily participating, and that the minor can document the rationale for waiving parental permission.

While Subpart D outlines some necessary regulations, Subpart D of both FDA and HHS defers to State laws for the definition of who is a child. According to Section 46.402, children are persons who have not attained the legal age for consent to treatment or procedures, under the applicable law of the jurisdiction in which the research will be conducted. In general, most States define children as individuals under the age of 18 years; however, some States have certain provisions that allow certain minors to have the ability to consent to treatment like an adult.

Overview of Definitions of Minor

Department of Health and Human Services regulations and FDA regulations defer to State laws to define the "age of majority," which is the term defining when States view an individual as an adult (Field and Berman 2004). In most States the age of majority is 18 years; however, three States recognize the age of majority to be a different age: Nebraska and Alabama recognize the age of majority as 19 years, and Mississippi recognizes the age of majority as 21 years (Field and Berman 2004). This issue can cause confusion in multi-center trials that includes different states, but the age of majority does serve as an easily visible bright line-test for investigators to determine legal status.

Minors have expanded rights under two complex legal categories. Although the amount of overlap between the two descriptions has increased over the years, the two statutes are not identical (Field and Berman 2004). The term emancipated minor describes adolescents meeting certain criteria. The conditions defining an emancipated minor are based on State laws and vary, but generally adolescents become emancipated minors though an act of marriage, military service or court order. If an adolescent becomes an emancipated minor, then the State expands the minor's rights to adult status (Field and Berman 2004).

On the other hand, States find that under certain conditions a dependent adolescent has enough maturity to choose only certain decisions that are context specific (Field and Berman 2004). The term "mature minor" describes adolescents who have the legal right to consent for certain treatments. For example, in Texas, pregnant adolescents have the legal right to choose from a limited number of medical treatments that are only related to pregnancy. In this example, the condition is pregnancy, and the limitations of the adolescent's consenting

ability are confined to prenatal care. This term may also be applied to dependent minors that seek confidentially sensitive treatment such as for sexually transmitted disease (Santelli et al 2003). Because several States and HHS regulations are not clearly explicit on the regulations for mature minors, IRBs and investigators are left to determine if a minor is mature enough to provide consent (Field and Berman 2004).

Research Design and Methodology

The study design for this practicum project is a literature review of concepts related to obtaining informed consent from to pregnant minors. After the concepts are gathered, they will be used to make a practical decision tree much like some provided by the FDA (Figure 1). The information will pertain mainly to federal and state laws, and the information will not focus on international guidelines.

Results

Section 46.402 of Subpart D describes children as persons who have not attained the legal age to provide consent to all medical treatments or procedures involved in the study's applicable law of jurisdiction. In nearly all States, the legal age or age of majority to provide consent is 18 years except in AL, MS and NB (Campbell 2003). This concept is the most direct to determine the consenting capacity of the potential teenage research participant, and is the first question investigators should ask.

Next, a solution is presented to help clarify how State laws affect the consenting capacity of minors. A review of the literature describes considerable variability in State laws; thus, an exhaustive list of each State's laws and practices would be impractical (Campbell 2003).

Based on the findings of Campbell et al, three of the most common instances a minor can become an emancipated or mature minor are through an act of marriage, military commitment or court order (Campbell 2003). The three most common conditions as well as statutes granting minors with children or pregnant minors the additional responsibilities to consent to medical treatment will be used to define who is considered a minor or an adult in the practical decision tree. These conditions are listed as specific categories in the decision tree's chart with the applicable State abbreviations (Appendix A). These conditions of mature minors are consistent with the findings of Campbell et al, but have since been updated and itemized as discrete categories.

Finally, to determine which portions of the federal guidelines are not applicable, a discussion of the appropriate solution is presented. Chaunda et al (2007) described a solution to the appropriate agency dilemma by providing a practical tool to assist investigators solve the appropriate agency dilemma. The solution essentially revolves around determining if the institution receives funding from NIH grants and/or if the nature of the study requires an IND/IDE application with the FDA. If the institution receives NIH grants and has FWA with the ORHP, then the institution should follow HHS regulations. Moreover, if the study requires an IND/IDE application, then the investigator should also follow FDA guidance. Lastly, in the absence of NIH funding and if an IND/IDE is used, then the investigator should follow FDA guidance. The solution to the appropriate governing agency dilemma is important for two

reasons. Firstly, in trials following FDA guidance parental consent cannot be waived via Section 46.408(c). Lastly, FDA guidance does not provide a direct equivalent to Subpart B special protections for pregnant women. The two distinctions are color coded in the decision tree to signify HHS specific regulations. The following hypothetical case examples correspond with outlined diagrams to demonstrate some of possible utility of the practical decision tree (Figures 2-4).

Hypothetical Cases

Case Report 1

An established Center of Family and Adolescent Research Institute in the State of Arizona, which is sponsored by NIH grants, proposes a pediatric study to test the effects of an FDA approved medication on learning (Janet L. Brody et al 2005). That is, will an asthma medication make learning harder? The trial population will consist of preschool aged children who attend community daycares. The study participation will consist of three weekends of preschool-like participation over a month of required evaluation. The required procedures will include random assignment of an FDA approved medication, allergy skin testing and psychological examination. The IRB deems that the proposed study will be of minimal risk, and a reasonable attempt to attain parental permission is required. A dilemma will occur when the mother of a potential subject has not reached the age of majority (eighteen) in Arizona. The investigator will have questions concerning consenting the mother.

A practical way for investigators to solve the appropriate agency issue is to consider the funding of the institution and the nature of the potential clinical trial. In this situation, the

institution will receive NIH funds and would not necessarily apply for an IND or IDE application; therefore, unless suggested otherwise by the institutional IRB, investigators are expected to comply with the HHS regulation (Chaund 2007). HHS regulations stipulate that because the potential subject is a preschool aged child, investigators must comply with the additional special protections Subpart D provides.

According to Subpart D minimal risk or category I studies, approval of only one parent is necessary regardless of age unless in conflict with State law. A conflict in State law will not occur. If the parent is indeed the biological parent, then under federal guidance the underage individual will be responsible for providing permission for the preschool-aged child in clinical research participation. Consequently, the clinical research staff and institutional IRB will be responsible for verifying that the individual is capable of providing acceptable informed consent on behalf of the preschooler. In other words, does the individual possess the capacity to make informed decisions?

Additional measures and appropriate safeguards could be used to verify the appropriateness of the minor's ability to consent. For example, in order to validate the consenting ability of the adolescent, the investigator could use a questionnaire or survey instrument. An effective questionnaire could assist investigators in determining if the minor has the decisional capacity to consent to research (Joffe et al 2001, Dunn 2006). So long as a young parent can demonstrate capable consenting capacities, the young parent could reasonably provide adequate parental permission. Figure 2 shows how an investigator might use the decision tree to solve the described dilemmas.

Case Report 2

A well-known academic center in the State of Ohio plans to implement a longitudinal community-based mental health intervention for adolescent mothers. The study group will consist of teenage mothers who are between the ages of thirteen and eighteen years. The intervention will screen potential participants four to six weeks post-partum, and enrolled participants will be in the study for approximately six months. The purpose of the study will be to assess the effects of implementing a mental health intervention program on depression. The intervention will consist of eleven phone calls each lasting 15-20 minutes during the first six weeks, less than one phone call a week for the remainder of the study, and data will be collected during normal school hours (Melissa Pinto-Foltz et al 2011).

IRB members will approve the study provided a reasonable attempt of parental permission is attained, and will deem the study to be of minimal risk. Researchers will attain parental permission for a majority of participants; however, researchers wish to avoid high attrition rates by waiving parental permission in some instances. How does State law affect the legal definition of children? How would researchers go about waiving parental consent? What conditions will need to be in place after waiving parental consent?

In some states, individuals under the States' age of majority can independently solicit mental health treatment. In such states, via an interpretation of Section 46.402, adolescent mothers could independently consent to participate in clinical research. In this hypothetical example, Ohio State law will not stipulate a specific State statute which conflicts with the

State's age of majority; therefore, in Ohio, individuals under the age of majority receiving mental health services are considered children.

In the absence of a conflicting Ohio law, researchers studying populations considered children could explore waiving parental permission under Section 46.408(c). Implementing a procedure to waive parental permission via Section 46.408(c) can be burdensome. The burden stems from the additional safeguards HHS regulations require to use the exemption, but Fisher et al clearly demonstrate that it is quite possible to ethically study sensitive adolescents' behavior without involving parents (Angela Holder 2008 and Pinto-Foltz et al. 2011). Fisher et al detailed several Community-Based Participatory Research (CBPR) safeguards for targeting youth populations such as situating the research in a community context, ensuring a youth friendly process and appropriately valuing participation (Fisher et al 2008). CBPR programs are recognized as an effective strategy for addressing complex health disparities, and united with the additional regulatory requirements; therefore, CBPR could be a venue for researchers to study adolescent medicine without parental permission and with sensitivity and accountability (Holder 2008). Figure 3 shows how an investigator might use the decision tree to solve the described dilemmas.

Case Report 3

A group of researchers in the State of Wisconsin propose to conduct an observational study of child-bearing adolescents to evaluate the adolescents' levels of cortisol and nitric oxide (Brody et al 2007). Participants will be recruited from a local organization promoting healthy teenage pregnancies. The study participants will be placed in hospital observation for thirty-six

hours, and will participate in the following procedures: twenty-four hours of urine collection, one spirometry test, three peak flow measures and nitric oxide levels measured every four hours.

IRB members will approve the study and deem it to be of minimal risk. At issue will be the current practice of requiring parental permission of the teenager because IRB members cannot reach a consensus. IRB members will discuss how local laws affect Section 46.402 with local regulators. After consulting Wisconsin State law, local regulators will discover in Wisconsin that pregnant adolescents may consent for prenatal treatments on behalf of themselves or their fetus. Thus, as defined by Section 46.402, in Wisconsin pregnant adolescents participating in clinical research relating to prenatal care will not be considered children and could provide consent in accordance with Subpart A of Title 45 Part 46.

On the other hand, if the nature of the study did not relate to prenatal care, then the pregnant adolescent would not be considered an adult. Consequently, the pregnant adolescent will be considered a child, provide assent in accordance with Subpart D, and the adolescent's parent will provide parental permission in accordance with Subpart A.

So long as the research relates to prenatal care, the pregnant adolescent will be considered an adult. Subpart A considers individuals bearing children a vulnerable population who require additional protections. The additional protections of Subpart B provide additional measures of protection for individuals bearing children. Regarding consenting adult pregnant research participants, investigators should consider which participant would receive a potential benefit. In other words, who is the target of the research, and who would receive a possible benefit? For this hypothetical, the investigators propose the adolescent mothers will receive

better prenatal treatment and nutrition. According to Subpart B, research benefiting the mother requires only consent on behalf of herself in accordance with federal regulations outlined in Subparts A and B.

In review of the third hypothetical case, the minor could reasonably consent to minimally risky prenatal research in Wisconsin via an interpretation of State and federal regulations. The investigator and IRB members will be convinced of the legal legitimacy of the adolescents' consenting capacity; however, the IRB members will discuss improving the ethical appropriateness of the study. The IRB members will discuss two of the three Belmont principles since IRB members will agree neglecting to study the pregnant adolescent population is unjustified (Santelli et al 2003). The remaining Belmont principles that will be discussed relate the principles of beneficence and autonomy.

The principle of beneficence will be considered by examining the associated amount of risk. When IRB members deem the study to be of minimal risk, the associated amount of risk was not dependent on the associated population. In other words, because the population consists of pregnant adolescents, the threshold of acceptable procedures for a minimal risk trial did not increase. In fact, the amount of risk associated with the study would be considered equivalent if the population consisted of normal healthy children. The condition of pregnancy does not change the estimation of risk, but the condition of pregnancy does increase decisional capacity of the minor. The increase in decisional capacity is granted by the corresponding Wisconsin State statute. Figure 4 shows how an investigator might use the decision tree to solve the described dilemmas.

Discussion

The practical decision tree developed in this study re-identifies the numerous legal complexities associated with enrolling minors who either have children or who are pregnant (Figure 1). It also organizes the legal definitions of children in a practical manner for coordinators and investigators. After coordinators and investigators navigate the legal complexities, the final consideration for coordinators and investigators should be a reasonable ethical evaluation of the proposed research participant. A reasonable approach would be based on a scientific understanding of adolescent decision-making capacity and a balanced understanding of research risk and benefit (Santelli et al 2003).

In general, a nuanced understanding of minimal risk could help investigators navigate IRB obligations such as when IRB review processes could be expedited or exempted. For the purpose of this report, a scientific understanding of minimal risk will be necessary to navigate the practical decision tree, and will be useful to determine if the minor's decision-making capacity is sufficient for the proposed research.

Originally the definition of minimal risk proposed by the National Commission in 1977, is "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical or psychological examination, of healthy children" (Field and Berman 2004). The National Commission's definition is nearly identical to the translated federal definitions of minimal risk. Yet, lost in translation is the reference point of healthy children. This loss has partly led to a definition which has produced much confusion for investigators and IRB members; furthermore, the successive levels of the categorical hierarchy

build on the definition of minimal risk—(minor increase over minimal risk), thereby sharing its confusion and uncertainty (Field and Berman 2004).

Lack of a clear reference point allowed some researchers argue a relative interpretation of minimal risk is justified. Due to the inherent nature of certain high risk study populations, a high level of harm or discomfort may be associated with the study population's daily life; therefore, theoretically using a relative interpretation of minimal risk, IRB members could allow higher risk trials to be conducted under the pretext of minimal risk (Field and Berman 2004). In other words, a relative interpretation of minimal risk could allow a contextual estimation of risk pending for the study population (Wendler 2005).

Also ambiguous is a relative interpretation of routine medical procedures. For example, suppose a researcher wishes to study a population of chronically ill minors who are routinely subjected to numerous tests and procedures. The researcher could apply a relative interpretation of minimal risk and conduct a routine test for the chronically ill population; however, the procedures would be considered more than minimal risk for a normal healthy child (Wendler 2005).

In 2001, the HHS produced additional documents that better describe minimal risk for children. Although not explicitly promulgated, HHS guidance documents suggest a relative interpretation of risk is inaccurate and incongruent with the National Commission's standard of minimal risk. Since this additional guidance, many institutions and organizations have established using healthy children as the reference point of minimal risk; however, still in dispute is how to define the amount of potential harm or discomfort that healthy, normal

children are exposed to either in their daily life or in routine physical or psychological examinations (Wendler 2005).

In truth, there are many reasons for the confusion of minimal risk caused by the lack of consistent IRB interpretation of routine physical or psychological examination of healthy children which has been noted since the National Commission first proposed this standard in 1977 (Field and Berman 2004). For instance, in 1981 Janofsky and Starfield noted the subjectivity of IRB members' identification of minimal risk procedures when exploring the emerging criteria of minimal risk. The subjectivity was illustrated with the amount of varying responses to questions which probed IRB members to determine the amount of risk in various pediatric procedures (Janofsky and Starfield 1981). Subjectivity of IRB members' interpretation of minimal risk has been further demonstrated in several other studies, and has been attributed to several possible causes (Mammel and Kaplan 1995).

Among IRB members who review pediatric research protocols, inconsistent standards of minimal risk are often due to legitimate differences in interpreting federal regulations, different ethical standards, and different treatment and procedural standards. Yet, studies have identified specific treatments and procedures which IRB members deem less than minimal risk and reasonable to waive parental permission. For example, unlike other procedures in the study, Janofsky and Starfield found more than 75% of IRB members agreed that studies involving venipuncture or surveys were of minimal risk. A subsequent study by Mammel and Kappalan found IRB members would often consider waiving parental permission for studies involving venipuncture or surveys at a similar rate (Mammel and Kapplan 1995). In the same

study, Mammel and Kaplan also found 85% of IRB members would consider waiving parental permission for studies involving minimal risk for mature minors.

In summary, the definition of minimal risk is integral to the consenting capacity of adolescents for two primary reasons. First, studies considered to be of minimal risk require less regulation (Field and Berman 2004). In fact, studies have found consensus that for certain treatments and procedures, which are considered to be of minimal risk, it is reasonably acceptable to consider waiving parental permission (Mammel and Kaplan 1995). Second, a nuanced definition of minimal risk is important to understand the successive levels of the categorical hierarchy of risk because at each successive level a higher decisional capacity is necessary. The decision-making capacity of an adolescent is the final consideration factor for investigators to determine the consenting capacity of an adolescent sufficient, and must be viewed in the context of risk associated with the decision.

A central reason institutional IRBs may not permit waiving parental permission is because minors are assumed to lack sufficient maturity or decisional capacity to exercise informed judgment (Santelli 2003). IRB members and investigators are laden with the burden of judging the ability of minors to provide informed consent by purposefully examining the maturity or decisional capability of the potential research participant.

There is a paucity of literature that distinctly focuses on the decisional capacity of pregnant minors or minors with children; however, there is a growing amount of literature detailing that the current understanding of decisional capacity of normative minors is at odds with the presumption that minors are incompetent. That body of research focuses on the ability to provide meaningful informed consent using a legal standard. Legal experts define

exercising informed consent as ascertaining an ill-defined level of the following four components: understanding information relevant to the choice; appreciating the risk and benefits of a choice; using the information to make a reasonable choice; and expressing a consistent choice (Laura Dunn et al 2006). When consenting emancipated or mature minors as adults or waiving parental permission, the assumption implied is that the minor has ascertained the cognitive capacities of an adult; thereby, the minor is now able to provide informed consent as an adult to participate in research.

In a classic experiment, Weithorn and Campbell (1982) conducted an empirical study to compare the four components of the legal definition of competency between minors and adults across four age groups. The subject population consisted of 96 total subjects who were equally distributed across 4 age groups (24 subjects per group) and gender (12 female and 12 males). Younger subjects were recruited from the 4^{th} and 9^{th} grade, and older students were college students or recent graduates. The study separately assessed each legal component of competency by using a corresponding decision scale that measured responses from four hypothetical treatment dilemmas revolving around diabetes, epilepsy, depression and enuresis. In general, Weithorn and Campbell (1982) found that healthy, middle-class, otherwise "normal" 14 year old minors, 18 and 21 year old adults did not differ in decisional ability; contrarily, the youngest age group, 9 year olds appeared less competent compared to adults. Subsequent, studies have further expounded on Weithorn and Campbell's findings, thereby, continually challenging the assumption that minors cannot provide informed consent.

Although there is a growing body of research that suggests minors can fulfill the legal definition of informed consent, it is tempered by ethicists who have yet to clearly affirm the

ability of minors to provide informed consent. The ability to provide meaningful informed consent is regarded by many bioethicist as the ability to: comprehend the nature and rationale of experimentation; understand their research rights, including the right to freely volunteer and withdraw participation; to receive and understand information about the study and have their responses remain confidential; and to protect themselves against rights violations. This ethical standard differs from the legal definition given above by demanding the research participant not only understand the nature of the research, but also understand and apply their rights as research participants.

Studies have examined the decisional capacity of minors by using the ethical standard of informed consent. Bruzzese and Fisher (2003) compared 82 grade school, 63 middle school and 75 high school students to 71 college students by testing their ability to comprehend research participants' rights. Similar to the Weithorn and Campbell study (1982), the majority of the 291 research participants were from Caucasian, middle-class or otherwise normative backgrounds. The study tested abilities ethicists deem important by using several multiple choice, true false and hypothetical questions. Bruzzese and Fisher's (2003) study suggests research participants who are fifteen can nearly but not completely understand research participant's rights as well as an adult. Tenth grade responses differed only minimally from adult responses. In fact, overall tenth graders' responses did not differ from college students' responses.

While there is not a clear-cut consensus when an adequate level of decisional capacity has been reached for minors, there is a considerable census that recommends decisional capacity to be related to the amount of risk (Dunn 2006). For example, a lower level of

decisional capacity is required for a low-risk treatment or research protocol than a higher risk protocol or treatment (Dunn et al 2006).

Collectively, studies assessing the decisional capacity or maturity of adolescents have found the consenting capability of minors comparable to adults; however, these studies have focused on normative populations and on trials considered to be of minimal risk. Thus, investigators conducting trials considered to be of minimal risk of normative populations could reasonably accept minors' consent or permission in accordance with federal regulations. This position is consistent with the positions of the *Journal of Adolescent Medicine* and other organization (Santelli et al2003).

Even if minors who have or bear child are not considered part of the normative population, the minor's life experiences are presumed to provide additional decisional capacity. Indeed, several States provide additional laws granting minors additional responsibilities to consent to treatment as adults. In these instances, investigators conducting trials considered to be of minimal risk could also reasonably accept consent or permission in accordance with federal regulations of minors who have borne or bear children. Investigators could implement additional safeguards to ensure proper protections.

Conclusion

The purpose of this practicum report was to generalize the consenting capacity of minors' with children and pregnant minors' ability to provide consent for clinical research on behalf of themselves or their child and develop a practical means for investigators to define acceptable means of recruiting subjects from these unique populations. A subsequent study of

the federal code of regulations demonstrates the challenge imposed by the ambiguities surrounding the issue of consenting minors bearing children. That is, it is unclear to which code of federal regulations investigators are to comply and how the deferment of federal regulations to State laws affects the process of securing informed consent from minors. Particularly, federal regulations defer the promulgation of acceptable informed consent from minors for clinical research by State and local laws. This is deformation occurs when the CFR declares minors as individuals unable to consent to all medical treatments and procedures involved defined by State law.

A review of State law and literature pertaining to the issues of consenting minors bearing children demonstrates considerable variability in State law affecting the consenting capacity of minors; therefore, an exhaustive list of all State statutes pertaining to treating minors bearing children was impractical. However, several patterns are consistent in State statute descriptions of the ability of minors bearing children to consent to treatment. These patterns were assigned too discrete categories and organized into a practical decision tree so that investigators can easily identify general instances when minors with children or pregnant minors can consent to treatment and are thereby qualified to provide informed consent for clinical research either independently or with assistance.

Limitations

The limitations of this study include the following.

1. This study did not consider international guidelines which may be required in certain circumstances.

2. To prevent an overextension of the decision tree, this study is limited to studies of minimal risk.

CHAPTER II

GENERAL INTERNSHIP EXPERIENCE

My internship was with a site actively participating in a competitive high enrollment study. The study revolved around the three phases most research studies follow. Thus, my daily internship consisted of three phases. The initial phase focused on the planning of the trial. During this phase, I observed and focused on learning the various protocols, developing source documents, developing budgets, gathering IRB documents and practicing delivering informed consent. The first step objective of my internship was learning the protocol which gives investigators, coordinators and interns the plan for the entire trial. The trial plan allowed our research team to develop the latter components of the planning phase for instance source documents. The process of creating source documents is very thorough so that during the enrollment phase fewer mistakes occur. Good source documents are parts of the protocol in brief, and are the primary documentation of research subjects. The number of research subjects corresponds with the number of source documents, and likewise the budget of trial corresponds with the number of subjects. The method of budgeting by the number of subjects was made clear after a discussion of negotiating budgets. Primarily two tactics were discussed. Where as developing budgets by line indicates the cost of each procedure for a subject, negotiating by total subjects includes an average cost of each subject. Regardless of the method

implemented, the negotiated amount must be approved by an IRB. This approval was obtained by completing one of many IRB and sponsor documents. Other documents, which I obtained a familiarity include: financial disclosure forms, contractual obligations between with the FDA and investigator, designation of responsibility forms and approval of informed consent documents. IRB approved informed consent documents are only one part of the consenting process. There is quite a bit of information described to subjects by coordinators through mini-presentations. For coordinators, it is important to have a general idea of the planned presentation. After practicing a presentation, I was given critical feedback on methods to improve my performance during a learning workshop. After all the components of the initial phase were completed, the enrollment phase began.

During the enrollment phase, I observed many informed consent procedures, completed quality assessment of source documents, maintained updated sponsor databases, observed and performed analyses of patient's specimens. This was a pivotal portion of my training because it provided quite a bit of firsthand experience of assisting in clinical trials. The observation of the consenting process demonstrated the comfort that experienced coordinators give to subjects; furthermore, the observation experience suggest completing source documents with a higher level of speed and accuracy coincides with experience. I was responsible for maintaining the accuracy of source documents and informed consent documents so that conflicts would not occur with either FDA inspectors or sponsors' monitors. Also to negate conflicts, I was responsible for maintaining updated electronic databases. Electronic databases serve as records for sponsors and include much of the demographic information in source documents and the results of certain analysis of patient specimens. One such analysis, which I was

assigned responsibility, was testing for pregnancy. The FDA and sponsors need verification that potential research participants are not pregnant before successful enrollment into certain trials. Overall, this was the most time intensive period of my internship experience.

The final portion of my experience was the surveillance phase. During this phase, I observed routine follow up procedures and resolved queries. Follow up procedure usually required minimally invasive procedures such as nasopharyngeal swabs. Such procedures require a training which I lack. Thus, during the surveillance period, I was designated mainly to an observation role; however, during this period, I did resolve queries. Queries are mainly mistakes in the sponsor's electronic database. These mistakes occur for numerous reasons, but each must be resolved. One highlight of my internship experience was the acknowledgement from our monitor that of all sites our site had the fewest queries.

I have had a wonderful opportunity to participate and contribute to the Pediatric Department of the University Of North Texas Health Science Center. Every day, I have had the privilege to work with some of healthcare's finest professionals. While working with these professionals, I have learned so much about the practical matters of conducting clinical research such as negotiating budgets, creating source documents and keeping positive relations with sponsors and IRBs.

Figure 1

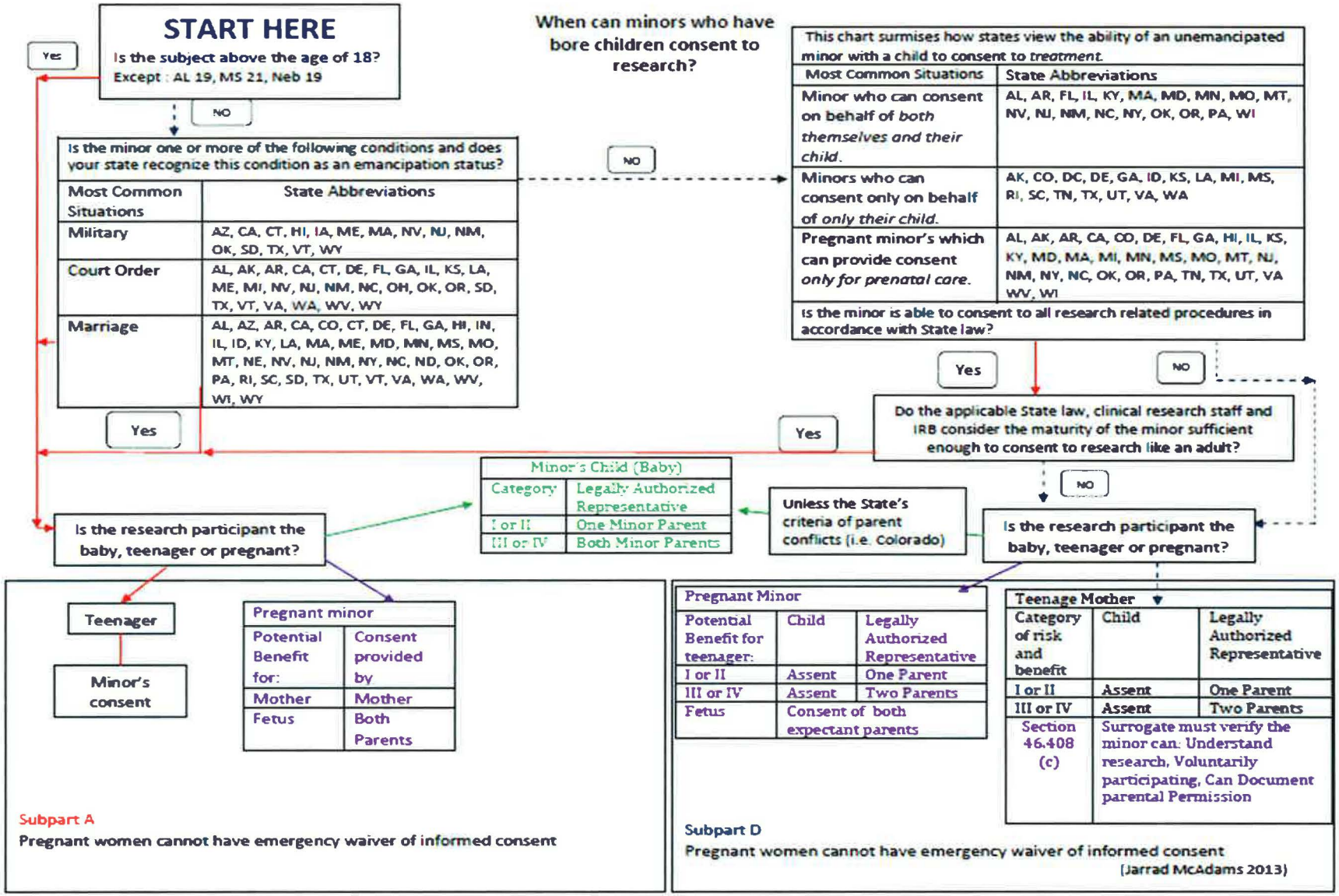

START HERE
Is the subject above the age of 18?
Except : AL 19, MS 21, Neb 19
Yes
NO
When can minors who have bore children consent to research?
Is the minor one or more of the following conditions and does your state recognize this condition as an emancipation status?
Most Common Situations
State Abbreviations
Military
AZ, CA, CT, HI, IA, ME, MA, NV, NJ, NM, OK, SD, TX, VT, WY
Court Order
AL, AK, AR, CA, CT, DE, FL, GA, IL, KS, LA, ME, MI, NV, NJ, NM, NC, OH, OK, OR, SD, TX, VT, VA, WA, WV, WY
Marriage
AL, AZ, AR, CA, CO, CT, DE, FL, GA, HI, IN, IL, ID, KY, LA, MA, ME, MD, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OK, OR, PA, RI, SC, SD, TX, UT, VT, VA, WA, WV, WI, WY
NO
This chart surmises how states view the ability of an unemancipated minor with a child to consent to treatment.
Most Common Situations
State Abbreviations
Minor who can consent on behalf of both themselves and their child.
AL, AR, FL, IL, KY, MA, MD, MN, MO, MT, NV, NJ, NM, NC, NY, OK, OR, PA, WI
Minors who can consent only on behalf of only their child.
AK, CO, DC, DE, GA, ID, KS, LA, MI, MS, RI, SC, TN, TX, UT, VA, WA
Pregnant minor's which can provide consent only for prenatal care.
AL, AK, AR, CA, CO, DE, FL, GA, HI, IL, KS, KY, MD, MA, MI, MN, MS, MO, MT, NJ, NM, NY, NC, OK, OR, PA, TN, TX, UT, VA WV, WI
Is the minor is able to consent to all research related procedures in accordance with State law?
Yes
NO
Do the applicable State law, clinical research staff and IRB consider the maturity of the minor sufficient enough to consent to research like an adult?
Yes
NO
Yes
Minor's Child (Baby)
Category
Legally Authorized Representative
I or II
One Minor Parent
III or IV
Both Minor Parents
Unless the State's criteria of parent conflicts (i.e. Colorado)
Is the research participant the baby, teenager or pregnant?
Is the research participant the baby, teenager or pregnant?
Teenager
Minor's consent
Pregnant minor
Potential Benefit for:
Consent provided by
Mother
Mother
Fetus
Both Parents
Subpart A
Pregnant women cannot have emergency waiver of informed consent
Pregnant Minor
Potential Benefit for teenager:
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Fetus
Consent of both expectant parents
Teenage Mother
Category of risk and benefit
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Section 46.408 (c)
Surrogate must verify the minor can: Understand research, Voluntarily participating, Can Document parental Permission
Subpart D
Pregnant women cannot have emergency waiver of informed consent
(Jarrad McAdams 2013)

Figure 2

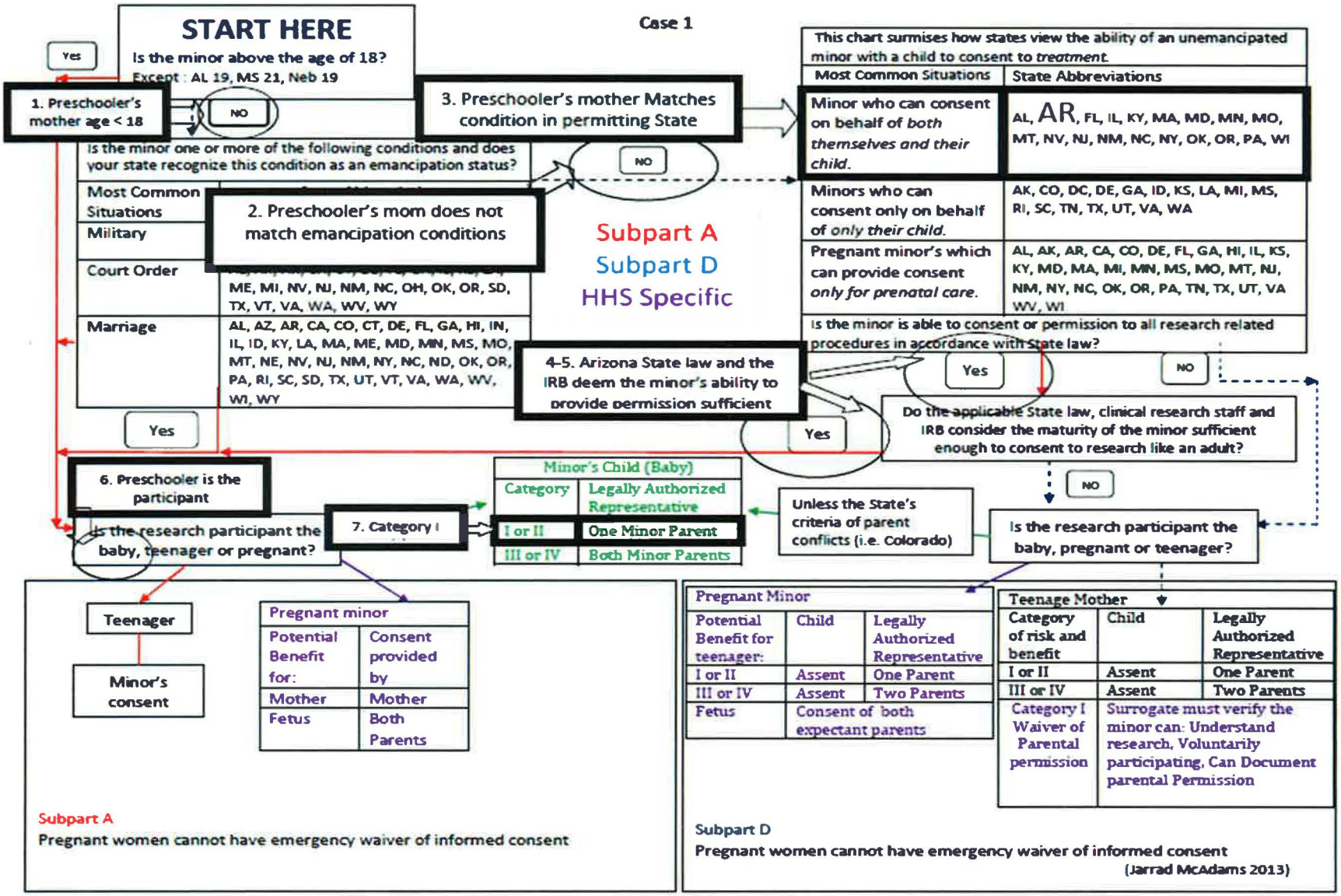

START HERE
Is the minor above the age of 18?
Except : AL 19, MS 21, Neb 19
Yes
NO
1. Preschooler's mother age < 18
Is the minor one or more of the following conditions and does your state recognize this condition as an emancipation status?
Most Common Situations
Military
Court Order
ME, MI, NV, NJ, NM, NC, OH, OK, OR, SD, TX, VT, VA, WA, WV, WY
Marriage
AL, AZ, AR, CA, CO, CT, DE, FL, GA, HI, IN, IL, ID, KY, LA, MA, ME, MD, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OK, OR, PA, RI, SC, SD, TX, UT, VT, VA, WA, WV, WI, WY
2. Preschooler's mom does not match emancipation conditions
3. Preschooler's mother Matches condition in permitting State
NO
Case 1
Subpart A
Subpart D
HHS Specific
This chart surmises how states view the ability of an unemancipated minor with a child to consent to treatment.
Most Common Situations
State Abbreviations
Minor who can consent on behalf of both themselves and their child.
AL, AR, FL, IL, KY, MA, MD, MN, MO, MT, NV, NJ, NM, NC, NY, OK, OR, PA, WI
Minors who can consent only on behalf of only their child.
AK, CO, DC, DE, GA, ID, KS, LA, MI, MS, RI, SC, TN, TX, UT, VA, WA
Pregnant minor's which can provide consent only for prenatal care.
AL, AK, AR, CA, CO, DE, FL, GA, HI, IL, KS, KY, MD, MA, MI, MN, MS, MO, MT, NJ, NM, NY, NC, OK, OR, PA, TN, TX, UT, VA WV, WI
Is the minor is able to consent or permission to all research related procedures in accordance with State law?
Yes
NO
4-5. Arizona State law and the IRB deem the minor's ability to provide permission sufficient
Yes
Do the applicable State law, clinical research staff and IRB consider the maturity of the minor sufficient enough to consent to research like an adult?
NO
Yes
6. Preschooler is the participant
Is the research participant the baby, teenager or pregnant?
7. Category I
Minor's Child (Baby)
Category
Legally Authorized Representative
I or II
One Minor Parent
III or IV
Both Minor Parents
Unless the State's criteria of parent conflicts (i.e. Colorado)
Is the research participant the baby, pregnant or teenager?
Teenager
Minor's consent
Pregnant minor
Potential Benefit for:
Consent provided by
Mother
Mother
Fetus
Both Parents
Pregnant Minor
Potential Benefit for teenager:
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Fetus
Consent of both expectant parents
Teenage Mother
Category of risk and benefit
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Category I Waiver of Parental permission
Surrogate must verify the minor can: Understand research, Voluntarily participating, Can Document parental Permission
Subpart A
Pregnant women cannot have emergency waiver of informed consent
Subpart D
Pregnant women cannot have emergency waiver of informed consent
(Jarrad McAdams 2013)

Figure 3

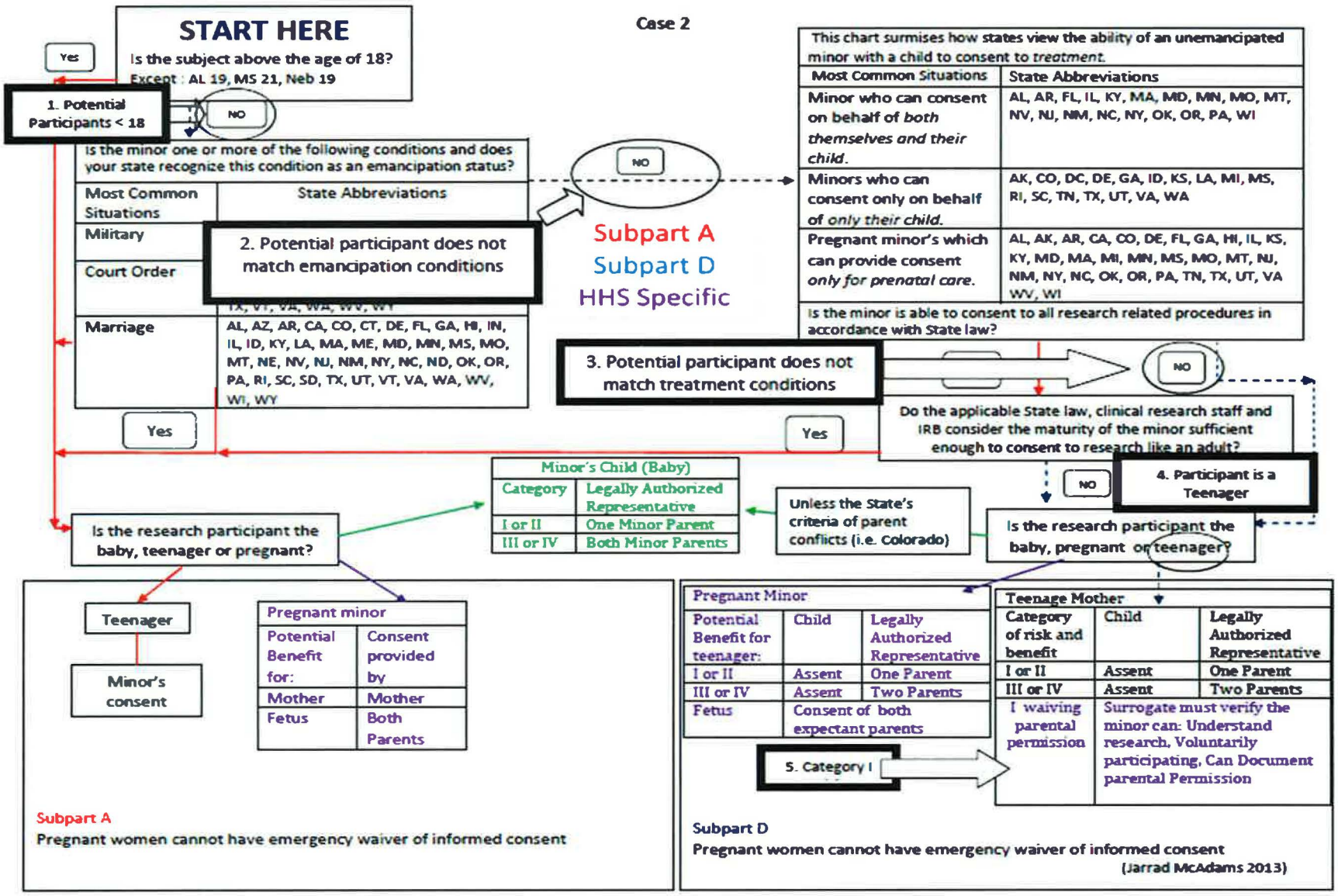
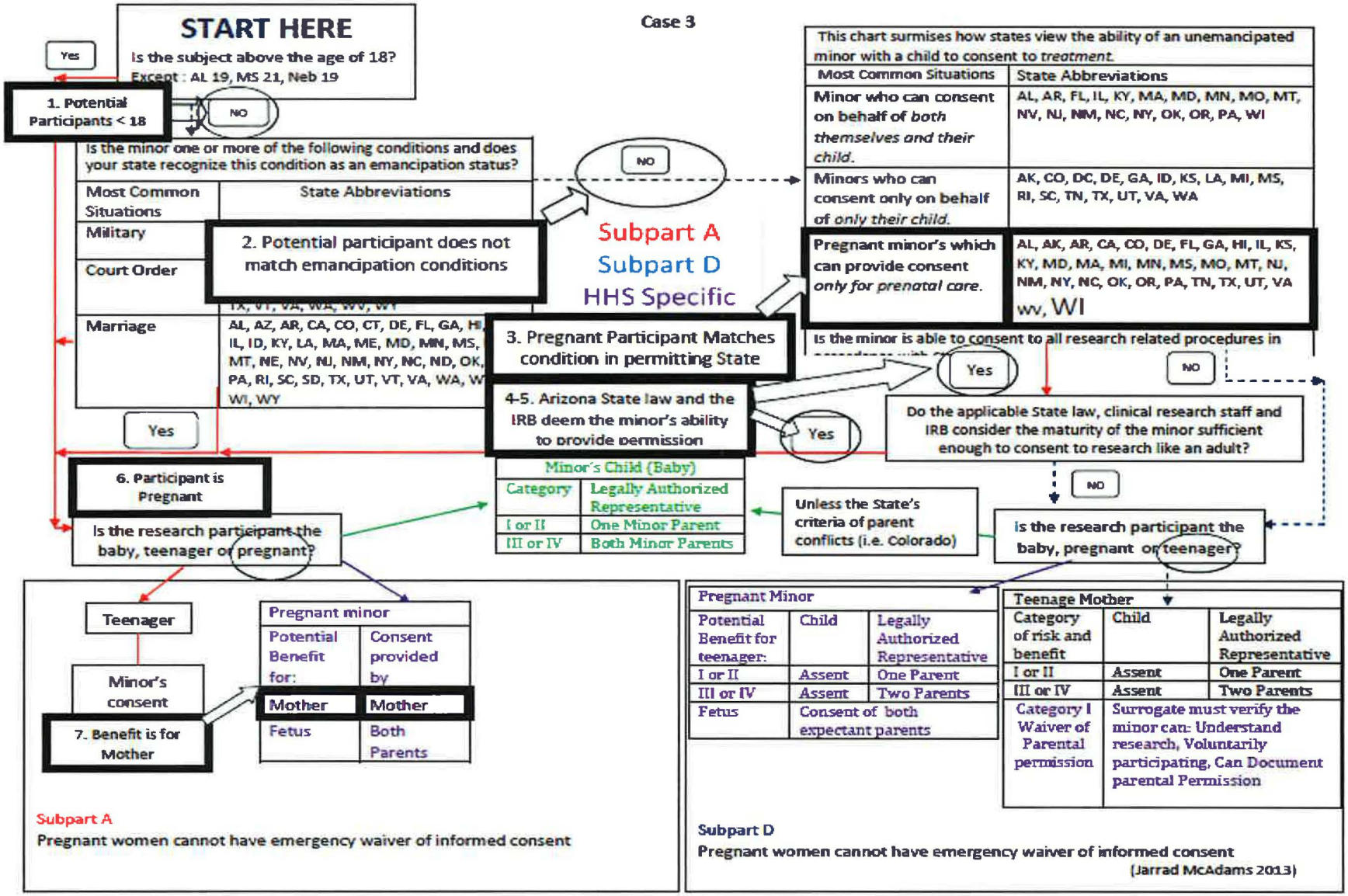

START HERE
Is the subject above the age of 18?
Except : AL 19, MS 21, Neb 19
Yes
NO
1. Potential Participants < 18
Case 2
This chart surmises how states view the ability of an unemancipated minor with a child to consent to treatment.
Most Common Situations
State Abbreviations
Minor who can consent on behalf of both themselves and their child.
AL, AR, FL, IL, KY, MA, MD, MN, MO, MT, NV, NJ, NM, NC, NY, OK, OR, PA, WI
Minors who can consent only on behalf of only their child.
AK, CO, DC, DE, GA, ID, KS, LA, MI, MS, RI, SC, TN, TX, UT, VA, WA
Pregnant minor's which can provide consent only for prenatal care.
AL, AK, AR, CA, CO, DE, FL, GA, HI, IL, KS, KY, MD, MA, MI, MN, MS, MO, MT, NJ, NM, NY, NC, OK, OR, PA, TN, TX, UT, VA WV, WI
Is the minor is able to consent to all research related procedures in accordance with State law?
Is the minor one or more of the following conditions and does your state recognize this condition as an emancipation status?
Most Common Situations
State Abbreviations
Military
Court Order
Marriage
AL, AZ, AR, CA, CO, CT, DE, FL, GA, HI, IN, IL, ID, KY, LA, MA, ME, MD, MN, MS, MO, MT, NE, NV, NJ, NM, NY, NC, ND, OK, OR, PA, RI, SC, SD, TX, UT, VT, VA, WA, WV, WI, WY
2. Potential participant does not match emancipation conditions
NO
Subpart A
Subpart D
HHS Specific
3. Potential participant does not match treatment conditions
NO
Do the applicable State law, clinical research staff and IRB consider the maturity of the minor sufficient enough to consent to research like an adult?
Yes
Yes
NO
4. Participant is a Teenager
Minor's Child (Baby)
Category
Legally Authorized Representative
I or II
One Minor Parent
III or IV
Both Minor Parents
Unless the State's criteria of parent conflicts (i.e. Colorado)
Is the research participant the baby, teenager or pregnant?
Is the research participant the baby, pregnant or teenager?
Teenager
Minor's consent
Pregnant minor
Potential Benefit for:
Consent provided by
Mother
Mother
Fetus
Both Parents
Pregnant Minor
Potential Benefit for teenager:
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Fetus
Consent of both expectant parents
5. Category I
Teenage Mother
Category of risk and benefit
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
I waiving parental permission
Surrogate must verify the minor can: Understand research, Voluntarily participating, Can Document parental Permission
Subpart A
Pregnant women cannot have emergency waiver of informed consent
Subpart D
Pregnant women cannot have emergency waiver of informed consent
(Jarrad McAdams 2013)

Figure 4


Case 3
START HERE
Is the subject above the age of 18?
Except : AL 19, MS 21, Neb 19
Yes
NO
1. Potential Participants < 18
Is the minor one or more of the following conditions and does your state recognize this condition as an emancipation status?
Most Common Situations
State Abbreviations
Military
Court Order
Marriage
AL, AZ, AR, CA, CO, CT, DE, FL, GA, HI, IL, ID, KY, LA, MA, ME, MD, MN, MS, MT, NE, NV, NJ, NM, NY, NC, ND, OK, PA, RI, SC, SD, TX, UT, VT, VA, WA, WI, WY
2. Potential participant does not match emancipation conditions
Subpart A
Subpart D
HHS Specific
3. Pregnant Participant Matches condition in permitting State
4-5. Arizona State law and the IRB deem the minor's ability to provide permission
Yes
6. Participant is Pregnant
Is the research participant the baby, teenager or pregnant?
Minor's Child (Baby)
Category
Legally Authorized Representative
I or II
One Minor Parent
III or IV
Both Minor Parents
Unless the State's criteria of parent conflicts (i.e. Colorado)
This chart surmises how states view the ability of an unemancipated minor with a child to consent to treatment.
Most Common Situations
State Abbreviations
Minor who can consent on behalf of both themselves and their child.
AL, AR, FL, IL, KY, MA, MD, MN, MO, MT, NV, NJ, NM, NC, NY, OK, OR, PA, WI
Minors who can consent only on behalf of only their child.
AK, CO, DC, DE, GA, ID, KS, LA, MI, MS, RI, SC, TN, TX, UT, VA, WA
Pregnant minor's which can provide consent only for prenatal care.
AL, AK, AR, CA, CO, DE, FL, GA, HI, IL, KS, KY, MD, MA, MI, MN, MS, MO, MT, NJ, NM, NY, NC, OK, OR, PA, TN, TX, UT, VA
WV, WI
Is the minor is able to consent to all research related procedures in
Yes
NO
Do the applicable State law, clinical research staff and IRB consider the maturity of the minor sufficient enough to consent to research like an adult?
NO
Is the research participant the baby, pregnant or teenager?
Teenager
Minor's consent
7. Benefit is for Mother
Pregnant minor
Potential Benefit for:
Consent provided by
Mother
Mother
Fetus
Both Parents
Subpart A
Pregnant women cannot have emergency waiver of informed consent
Pregnant Minor
Potential Benefit for teenager:
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Fetus
Consent of both expectant parents
Teenage Mother
Category of risk and benefit
Child
Legally Authorized Representative
I or II
Assent
One Parent
III or IV
Assent
Two Parents
Category I Waiver of Parental permission
Surrogate must verify the minor can: Understand research, Voluntarily participating, Can Document parental Permission
Subpart D
Pregnant women cannot have emergency waiver of informed consent
(Jarrad McAdams 2013)

APPENDIX

8/9/2012

9:00-9:15 AM Signed and dated CV

9:15-12:00 PM Introduction to facilitates: Dr. Fling's office, Research Labs and Storage Rooms. One of the storage rooms doubles as an office.

12:00-1:00 PM Lunch

1:00-2:00 PM Introduction to Reveal. A financial study manager and database for UNT HSC

2:00-5:00 PM Informal Discussion of delivering informed consent to research participants

8/10/12

8:00-12:00 PM Studied the protocol of the pediatric meningococcal vaccine study with a focus on the subject exclusion/inclusion criteria.

12:00-1:00 PM Lunch

1:00-3:00 PM Studied the protocol of the pediatric meningococcal vaccine study with a focus on theIRB approved informed consent documents.

8/13/12

8:00-12:00 Reviewed notes associated with the protocol for pediatric meningococcal study.

12:00-1:00 PM Lunch

1:00-3:00 PM Participated in workshop detailing crucial aspects for obtaining parental permission for infants

8/14/12

8:00 AM—5:00PM Research and Literature Review for proposal

8/15/12

8:00-10:30 AM Read protocol for an investigational flu study that participants were mainly elderly adults with a focus on inclusion/exclusion criteria

10:30-11:00 AM Observed Coordinator Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

8/16/12

8:00-10:30 AM Read protocol for an investigational flu study that participants were mainly elderly adults with a focus on inclusion/exclusion criteria

10:30-11:00 AM Observed Coordinator Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

8/17/12

8:00-10:30 AM Read protocol for an investigational flu study that participants were mainly elderly adults with a focus on informed consent documents

10:30-11:00 AM Observed Coordinator Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

17 Apr 2013

Postdated for 8/9-17/12

8/20/12

8:00-10:30 AM Read protocol for an investigational flu study participants were mainly elderly adults with a focus on informed consent documents

10:30-11:00 AM Observed Coordiantor Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

8/21/12

8:00-10:30 AM Read protocol for an investigational flu study who participants were mainly adults

10:30-11:00 AM Observed Coordinator Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

8/22/12

8:00-10:30 AM Read protocol for an investigational flu study who participants were mainly adults

10:30-11:00 AM Observed Coordinator Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

8/23/12

8:00-10:30 AM Read protocol for an investigational flu study who participants were mainly adults

10:30-11:00 AM Observed Coordinator Adams enroll pediatric subjects

11:00-12:00 PM Began Safe Transport of Division Infection Substances, Biological Specimens and Dry Ice. (STIBD)

12:00-12:20 PM Observed Coordinator Torres prepare serum samples for shipment

12:00-1:00 PM Lunch

1:00-4:00 PM STIBD Training continued; Training modules consisted of several videos and quizzes

8/24/12

8:00-12:00 AM International Air Transport Association(IATA) training primarily useful to transport, receive or otherwise transport hazardous goods.

Guidelines for IATA training are more the strictest guidelines for transporting hazardous material

12:00-1:00 PM Lunch

1:00-4:00 PM Training and Data entry for the Reveal Program

8/27/12

8:00-12:00 AM International Air Transport Association(IATA) training primarily useful to transport, receive or otherwise transport hazardous goods.

Guidelines for IATA training are more the strictest guidelines for transporting hazardous material

12:00-1:00 PM Lunch

1:00-4:00 PM Training and Data entry for the Reveal Program

8/28/12

8:00-12:00 AM International Air Transport Association(IATA) training primarily useful to transport, receive or otherwise transport hazardous goods.

Guidelines for IATA training are more the strictest guidelines for transporting hazardous material

12:00-1:00 PM Lunch

1:00-4:00 Data entry for the Reveal Program

8/29/30

8:00-12:00 PM Observed Coordinator Adams enroll pediatric patients

12:00-1:00PM Lunch

1:00-5:00 PM Research and Literature Review for Proposal.

8/30

8:00-12:00 PM Research and Literature Review for Proposal

12:00-1:00 PM Lunch

1:00-3:00 PM Discussed several ideas of surveying participants to study the patients perception of the informed consent process with Research Staff

8/31/12

Self Directed Research and Literature Review for Proposal

Julie Cannon RN 17 Apr 2013

Postdated for 8/20-31/12

9/3/12

Self Directed Research and Literature Review for Proposal

9/4/12

8:00-10:00 AM Updated 1572 for prior trials conducted at site. Obtained current CV's and license for prior studies. Filled each document into the appropriate Regulatory Binder

10:00-12:00 PM Literature Review for proposal

12:00-1:00 PM Lunch

1:00-3:00 PM Studied prior informed consent documents, and Compared the trend of language to the current trial's language.

3:00-5:00 PM Entered subject data for prior trials in the Reveal system.

9/5/12

8:00-10:30 AM Reseach Literature and Information for Proposal

10:30-12:00 PM Filled Investigators Brochures and Corresponding communication into Regulatory Binders for current trial

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/6/12

8:00 AM-11:00 AM Assisted Coordinator Adams revise and negotiate budget for flu trials

11:00 AM-2:00 PM Teleconference with Sponsor which focused on understanding the primary and secondary end points of the study.

2:00-4:00 PM debriefing of phone conference, discussing on site personnel roles and responsibilities. Brainstormed how to efficiently enroll a high number of subjects.

9/7/12

Self Directed Research and Literature Review for Proposal

9/10/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Filled Central IRB and Sponsor document into Regulatory Binders for first investigational trial

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/11/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Filled Central IRB and Sponsor document into Regulatory Binders for first investigational trial

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/12/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Reviewed notes on the first investigational flu study to identify crucial elements for source documents

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/13/12

8:00-10:30 AM Research Literature and Information for Proposal

10:30-12:00 PM Reviewed prior similar studies source documents which would serve as templates for the first investigational flu trial source documents.

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/14/12

8:00-12:00 PM Conference with Coordinator Cannon concerning creating source documents for the first investigational flu stud. Included re-identifying crucial elements for source documents and a discussion prior learning experiences

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

Vicki Cannon RN 17 Apr 2013

Postdated 9/3-14/12

9/17/12

8:00-10:30 AM Research Literature and Information for Proposal

10:30-12:00 PM Filled Central IRB and Sponsor document into Regulatory Binders for first investigational trial, and observed Coordinator Cannon beginning to develop source documents for the first investigational flu study.

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/18/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Editing Source Documents for first investigational flu study

12:00-1:00 PM Lunch

1:00-3:00 PM Data Entry into the system reveal

9/19/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Editing Source Documents for first investigational flu study

12:00-1:00 PM Lunch

1:00-3:00 PM Data Entry into the system reveal

3:00-5:00 PM Studied protocol of the second of two investigational flu trials.

9/20/12

8:00-10:30 AM Research Conflict of Interest Training

10:30-12:00 PM Editing Updated Regulatory Binders for investigational flu study with financial disclosure forms for the second investigational study

12:00-1:00 PM Lunch

1:00-3:00 PM Data Entry into the system reveal

3:00-5:00 PM Studied protocol of the second of two investigational flu trials.

9/21/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Reviewed notes on the second investigational flu study to identify crucial elements for source documents

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/24/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Research Conflict of Interest Training

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/25/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Assisted Coordinator Cannon develop source documents for the second investigational flu study

12:00-1:00 PM Lunch

1:00-5:00 PM Research on Literature Review for Proposal

9/26/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Observed monitor and coordinator pre-enrollment meeting for first investigational flu trial

12:00-1:00 PM Lunch

1:00-5:00 PM Observed monitor conduct pretrial site inspections.

9/2712

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Assisted Coordinator Cannon develop source documents for the second investigational flu study

12:00-1:00 PM Lunch

1:00-5:00 PM Edited Source documents for the second investigational flu study

9/28/12

8:00-10:30 AM Observed Coordinators Cannon and Adams enroll pediatric patients to meningococcal study

10:30-12:00 PM Assisted Coordinator Cannon develop source documents for the second investigational flu study

12:00-1:00 PM Lunch

1:00-3:00 PM Edited Source documents for the second investigational flu study

3:00-5:00 PM Writing and Editing Proposal

Vicki Cannon RN 17 Apr 2013

Postdated for 9/17-28/12

10/1/12

8:00-11:00 AM Electronically applied for access into the scheduling and call Center Accelovance. This call center provides much of the surveillance for research participants

11:00-12:00 PM Training to manage surveillance system for the first flu trial.

12:00-1:00 PM Lunch

1:00-3:00 PM Data Entry into the system reveal

3:00-5:00 PM Writing and Editing Proposal

10/2/12

8:00 AM-12:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information and patient charts.

12:00-1:00 PM Lunch

1:00- 5:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information and patient charts.

10/3/12

8:00 AM-12:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information and patient charts.

12:00-1:00 PM Lunch

1:00- 5:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information and patient charts

10/4/12

8:00 AM-12:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information and patient charts.

12:00-1:00 PM Lunch

1:00- 5:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information, patient charts and developing contact lists with current phone numbers and addresses.

10/5/12

8:00 AM-12:00 PM Assisted coordinators contact and screen patients for first investigational flu study. Participation included: finding prior study participants contact information and patient charts.

12:00-1:00 PM Lunch

1:00-5:00 PM Create, bind and copy source document and informed consent documents or patient records. Each source documents was approximately 15 pages and placed into labeled subject folders.

10/8/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

10/9/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

10/10/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

1:00-3:00 PM Observed Dr. Fling provide additional instruction to patients in the consenting process

3:00-5:00 PM Reviewed source documents, informed condsent documents for accuracy and completion, and entered Patient data into the sponsor's electronic database

10/11/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

1:00-3:00 PM Observed Dr. Fling provide additional instruction to patients in the consenting process

3:00-5:00 PM Reviewed source documents, informed consent documents for accuracy and completion, and entered Patient data into the sponsor's electronic database

10/12/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

1:00-3:00 PM Observed Dr. Fling provide additional instruction to patients in the consenting process

3:00-5:00 PM Reviewed source documents, informed consent documents for accuracy and completion, and entered Patient data into the sponsor's electronic database

Nikki Cannon RN 17 Apr 2013

Postdated for 10/1-12/12

10/15/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

1:00-3:00 PM Observed Dr. Fling provide additional instruction to patients in the consenting process

3:00-5:00 PM Reviewed source documents, informed consent documents for accuracy and completion, and entered Patient data into the sponsor's electronic database

10/16/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

1:00-3:00 PM Observed Dr. Fling provide additional instruction to patients in the consenting process

3:00-5:00 PM Reviewed source documents, informed consent documents for accuracy and completion, and entered Patient data into the sponsor's electronic database

10/17/12

8:00-10:00 AM Shadowed Coordinator Cannon and Adams as they enrolled and consented patients to participate in first investigation flu trial

10:00-12:00 PM Quality assessment of completed source documents for the first investigational flu study and Informed consent documents primarily assessing for accuracy and completion

12:00-1:00 PM Lunch

1:00-3:00 PM Observed Dr. Fling provide additional instruction to patients in the consenting process

3:00-5:00 PM Reviewed source documents, informed consent documents for accuracy and completion, and entered Patient data into the sponsor's electronic database

10/18/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/19/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/22/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/23/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/24/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/25/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/26/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

Vicki Cannon RN 17 Apr 2013

Postdated for 10/15-26/12

10/29/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor

10/30/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

10/31/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/1/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/2/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/5/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM Reviewed source documents and Informed Consent Documents for accuracy and completion.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/6/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/7/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/8/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/9/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

Vicki Cannon RN 17 Apr 2013

Postdated for 10/29/12-11/9/12

11/12/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/13/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/14/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/15/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/16/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/19/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/20/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/21/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/22/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/23/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

Vicki Ch— RN 17 Apr 2013

Postdated for 11/12-23/12

11/26/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

11/27/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/3/12

Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor

12/4/12

Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor

12/5/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/6/12

8:00-12:00 PM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/7/12

8:00-12:00 PM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

RN 17 Apr 2013

Postdated for 11/26-12/7/12

12/10/12

8:00-12:00 PM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/11/12

8:00-12:00 PM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/12/12

8:00-12:00 PM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/13/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/14/12

8:00-10:00 AM Review for accuracy and completion, and entered Patient contact information into Accelovance (subject call center)

10:00-12:00 PM The second investigational flu trial required pregnancy test to excluded pregnant individuals. A quick test of eligible patients was performed.

12:00-1:00 PM Lunch

1:00-5:00 PM Reviewed source documents, Informed Consent Documents for accuracy and completion, and entered Patient Data into the electronic database center for the sponsor.

12/17/12

8:00-12:00 PM Resolved electronic quires in sponsor EDC

12:00-1:00 PM Lunch

1:00-3:00 PM Entered remaining the subject follow up records into the EDC

12/18/12

8:00-12:00 PM Resolved electronic quires in sponsor EDC

12:00-1:00 PM Lunch

1:00-3:00 PM Entered remaining the subject follow up records into the ED

12/19/12

8:00-12:00 PM Resolved electronic quires in sponsor EDC

12:00-1:00 PM Lunch

1:00-3:00 PM Entered remaining the subject follow up records into the ED

12/20/12

8:00-12:00 PM Resolved electronic quires in sponsor EDC

12:00-1:00 PM Lunch

1:00-3:00 PM Entered remaining the subject follow up records into the ED

Vicki Cann RN 17 Apr 2013

Postdated for 12/10-20/12

1/15/13

8:00-10:00 AM Studied the incomplete electronic records in Reveal and noted missing field parts of investigational trials.

10:00-12:00 PM Conference with Coordinators about missing components of the electronic records

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient demographic data into the system Reveal for investigational flu studies

3:00-5:00 PM Editing and Developing my Thesis

1/16/13

8:00-10:00 AM Setup a meeting with other associates to learn how to manage and create the missing Reveal field parts of investigational trials.

10:00-12:00 PM Conference with Coordinators about missing components of the electronic records

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient demographic data into the system Reveal for investigational flu studies

3:00-5:00 PM Editing and Developing my Thesis

1/17/13

8:00-10:00 AM Setup a meeting with other associates to learn how to manage and create the missing Reveal field parts of investigational trials.

10:00-12:00 PM Conference with Coordinators about missing components of the electronic records

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient demographic data into the system Reveal for investigational flu studies

3:00-5:00 PM Editing and Developing my Thesis

1/18/12

8:00-10:00 AM Create the missing Reveal field parts of investigational trials.

10:00-12:00 PM Conference with Coordinators about missing components of the electronic records

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient demographic data into the system Reveal for investigational flu studies

3:00-5:00 PM Editing and Developing my Thesis

1/21/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/22/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/23/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/24/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/25/12

Editing and Developing Thesis Day

Vicki Chan RN 17 Apr 2013

Postdated for 1/15-25/12

1/28/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/29/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/30/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

1/31/12

8:00-12:00 PM Entered data detailing subject visits and procedures

12:00-1:00 PM Lunch

1:00-3:00 PM Entered patient detailing subject visits and procedures

3:00-5:00 PM Editing and Developing my Thesis

2/1/12

Editing and Developing Thesis Day

2/2-15/12

At this time the Principal investigators and Head Coordinator were present at an investigator meeting. During this period, I was assigned to develop and edit my practicum Report.

2/16/12

Cleaned out my office and said goodbye to an amazing staff

RN 17 Apr 2013

Postdated for 1/28-2/16/12

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