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## 1.0 INTRODUCTION

THESE POLICIES AND PROCEDURES HAVE BEEN DEVELOPED TO PROVIDE THE DRAKE UNIVERSITY RESEARCH COMMUNITY WITH AN OVERVIEW OF THE FEDERAL REGULATIONS AND INSTITUTIONAL POLICIES GOVERNING THE USE OF HUMAN SUBJECTS IN RESEARCH.

RESEARCH INVOLVING HUMAN PARTICIPANTS CONDUCTED WITHIN THE DRAKE UNIVERSITY COMMUNITY WILL:

- SAFEGUARD THE RIGHTS AND WELFARE OF RESEARCH PARTICIPANTS.
- BE CONSISTENT WITH THE TEACHING AND MISSION OF THE UNIVERSITY.
- OBEY LAWS AND REGULATIONS AS SET FORTH IN: FEDERAL POLICY FOR PROTECTION OF HUMAN SUBJECTS (COMMON RULE 45CFR46, PART A).

THIS POLICY APPLIES TO ALL RESEARCH INVOLVING HUMAN SUBJECTS, INCLUDING NON-FUNDED AND FUNDED RESEARCH, REGARDLESS OF THE SOURCE OF ANY FUNDING.

THIS POLICY AND THESE PROCEDURES SHALL BE OPERATIVE AS OF THE DATE THEY ARE APPROVED BY A QUORUM OF THE DRAKE IRB AND SHALL BE REVIEWED YEARLY AND REVISED AS NECESSARY. REVISIONS IN STATEMENT OF POLICY REQUIRE APPROVAL OF THE DRAKE UNIVERSITY INSTITUTIONAL OFFICIAL.

## 2.0 INSTITUTIONAL REVIEW BOARD

### 2.1 PURPOSE OF THE INSTITUTIONAL REVIEW BOARD

THE DRAKE UNIVERSITY INSTITUTIONAL REVIEW BOARD (IRB) IS CHARGED WITH THE RESPONSIBILITY OF DETERMINING 1) WHETHER HUMAN SUBJECTS HAVE VOLUNTEERED FOR A RESEARCH ENDEAVOR BY MEANS OF INFORMED CONSENT AND 2) WHETHER RISKS TO THESE SUBJECTS ARE OUTWEIGHED BY POTENTIAL BENEFITS TO THEM AND IMPORTANCE OF THE KNOWLEDGE TO BE GAINED BY THE RESEARCH. IN CONSIDERING ETHICAL ISSUES AND GOVERNMENT GUIDELINES, THE EVALUATION OF RISK INVOLVES ESTIMATING THE POTENTIAL FOR INJURY TO THE SUBJECT BY REASON OF DIRECT APPLICATION OF AN EXPERIMENTAL PROCEDURE OR CIRCUMSTANCE OR BY REASON OF THE SUBJECT'S EXCLUSION FROM ORDINARY STANDARDS OF PRACTICE OF CARE. RIGHTS OF SUBJECTS REGARDING CONFIDENTIALITY AND ACCESS TO PROFESSIONAL CARE AND COUNSEL ARE INCLUDED IN IRB DELIBERATIONS SO THAT HUMAN DIGNITY, RIGHTS, AND PHYSICAL, PSYCHOLOGICAL, BEHAVIORAL AND SOCIAL WELFARE ARE PROTECTED.

### 2.2 IRB SCOPE AND AUTHORITY

**ALL HUMAN RESEARCH AUTHORIZED AND CONDUCTED UNDER THE JURISDICTION OF DRAKE UNIVERSITY IS SUBJECT TO REVIEW BY THE IRB FOR RISK, BENEFIT, AND INFORMED CONSENT WITHOUT REGARD TO THE SOURCE OF FINANCIAL, PHYSICAL (FACILITIES) OR LOGISTICAL SUPPORT. THIS REVIEW MUST BE CONDUCTED BEFORE A PROJECT CAN BE STARTED. THE IRB IS RESPONSIBLE FOR ANY RESEARCH ACTIVITY THAT INVOLVES PHYSICAL, PSYCHOLOGICAL, BEHAVIORAL OR SOCIAL WELFARE OF HUMAN SUBJECTS THAT IS CONDUCTED WITHIN, SUPPORTED BY OR OTHERWISE THE RESPONSIBILITY OF DRAKE UNIVERSITY.**

**THE IRB SHALL HAVE THE AUTHORITY TO DISAPPROVE, DISCONTINUE, SUSPEND OR LIMIT RESEARCH INVOLVING HUMAN SUBJECTS AND, BY ITS RECOMMENDATIONS TO THE PROVOST OF THE UNIVERSITY, CAN EFFECT ACTION THAT WITHHOLDS OR WITHDRAWS FINANCIAL OR APPROVED SUPPORT FROM PROJECTS INVOLVING HUMAN SUBJECTS THAT ARE NOT IN COMPLIANCE WITH UNIVERSITY POLICIES OR FEDERAL REGULATIONS. UNIVERSITY ADMINISTRATORS (DEPARTMENTAL CHAIRS, DEANS, PROVOST, PRESIDENT) SHOULD REMIND PROSPECTIVE INVESTIGATORS OF IRB REQUIREMENTS WHENEVER A PROPOSED ACTIVITY INVOLVES HUMAN SUBJECTS.**

### **2.3 ACTIVITIES REQUIRING IRB REVIEW AND APPROVAL**

**TO DETERMINE IF THE PROPOSED ACTIVITY REQUIRES REVIEW BY THE DRAKE IRB, ANSWER THE FOLLOWING THREE QUESTIONS:**

- **IS THE PROPOSED ACTIVITY RESEARCH?**  
**RESEARCH IS A SYSTEMATIC INVESTIGATION THAT INCLUDES RESEARCH DEVELOPMENT, TESTING AND EVALUATION AND IS INTENDED TO DEVELOP OR CONTRIBUTE TO GENERAL KNOWLEDGE. IF, ACCORDING TO THIS DEFINITION, THE PROPOSED ACTIVITY IS NOT RESEARCH, THEN IRB REVIEW IS NOT REQUIRED. IF THE PROPOSED ACTIVITY IS RESEARCH, CONTINUE WITH THE NEXT QUESTION.**
- **DOES IT INVOLVE HUMAN SUBJECTS?**  
**RESEARCH INVESTIGATORS MUST DETERMINE WHETHER THEIR PROPOSED RESEARCH WILL INVOLVE HUMAN SUBJECTS. REGULATIONS DEFINE "HUMAN SUBJECT" AS A LIVING INDIVIDUAL ABOUT WHOM AN INVESTIGATOR (WHETHER PROFESSIONAL OR STUDENT) CONDUCTING RESEARCH OBTAINS 1) DATA THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL OR 2) IDENTIFIABLE PRIVATE INFORMATION. IF YOU DETERMINE THAT THE RESEARCH DOES NOT INVOLVE HUMAN SUBJECTS, THEN IRB REVIEW IS NOT REQUIRED. IF YOU DETERMINE THAT THE RESEARCH DOES INVOLVE HUMAN SUBJECTS, IRB REVIEW IS REQUIRED. IF IT IS NOT CLEAR WHETHER THE RESEARCH INVOLVES HUMAN SUBJECTS, SEEK ASSISTANCE FROM THE IRB CHAIR.**
- **WILL IT BE AUTHORIZED AND CONDUCTED UNDER THE JURISDICTION OF DRAKE UNIVERSITY?**  
**ALL RESEARCH INVOLVING HUMAN SUBJECTS REGARDLESS OF THE FUNDING STATUS OR THE SOURCE OF ANY FUNDING IS UNDER THE JURISDICTION OF THE UNIVERSITY. IN COOPERATIVE RESEARCH PROJECTS INVOLVING ONE OR MORE INSTITUTIONS IN ADDITION TO DRAKE UNIVERSITY, EACH INSTITUTION IS RESPONSIBLE FOR SAFEGUARDING THE RIGHTS AND WELFARE OF HUMAN SUBJECTS AND FOR COMPLYING WITH THE INDIVIDUAL IRB POLICIES.**
- **DOES RESEARCH NOT INTENDED FOR PUBLICATION REQUIRE IRB REVIEW AND APPROVAL?**  
**EVEN RESEARCH INVOLVING HUMAN SUBJECTS THAT IS NOT INTENDED FOR PUBLICATION REQUIRES IRB APPROVAL.**

**ADDITIONAL ACTIVITIES REQUIRING IRB REVIEW AND APPROVAL INCLUDE CLASSROOM INSTRUCTION INVOLVING RESEARCH ACTIVITIES. (SEE SECTION 5.1 FOR ADDITIONAL INFORMATION.)**

### **2.4 PRINCIPLES GOVERNING THE IRB**

**THE IRB IS GUIDED BY FEDERAL REGULATIONS AND ETHICAL PRINCIPLES REGARDING ALL RESEARCH INVOLVING HUMANS AS SUBJECTS. DHHS (45CFR46) AND FDA (21CFR50 AND 56, 21CFR312 (INVESTIGATIONAL NEW DRUGS) AND 21CFR182 (INVESTIGATIONAL DEVICES) ARE THE PRIMARY AGENCIES THAT REGULATE THE IRB. IN ADDITION, THE IRB IS GUIDED BY THE BELMONT REPORT: ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH (REPORT OF THE NATIONAL COMMISSION FOR THE PROTECTION OF HUMAN SUBJECTS OF BIOMEDICAL AND BEHAVIORAL RESEARCH, 1979).**

**THE IRB WEIGHS RISKS TO WHICH RESEARCH SUBJECTS MAY BE EXPOSED THAT MAY RESULT IN PHYSICAL, PSYCHOLOGICAL, SOCIAL AND ECONOMIC HARMS.**

- **PHYSICAL HARMS: MINOR PAIN, DISCOMFORT OR INJURY**
- **PSYCHOLOGICAL HARMS: STRESS, FEELINGS OF GUILT OR EMBARRASSMENT CAUSED BY TALKING ABOUT SENSITIVE SUBJECTS OR BEING MANIPULATED OR DECEIVED AS PART OF THE RESEARCH**
- **SOCIAL AND ECONOMIC HARMS: INVASIONS OF PRIVACY AND BREACHES OF CONFIDENTIALITY**

## **2.5 SELECTION AND COMPOSITION OF THE IRB**

**IRB MEMBERS ARE SELECTED FROM THE FACULTY AND FROM THE COMMUNITY-AT-LARGE TO ENSURE REPRESENTATION OF PROFESSIONAL EXPERTISE AND COMMUNITY ATTITUDES. MEMBERS SHALL BE DIVERSIFIED AS TO RACE, GENDER, CULTURAL BACKGROUND AND SENSITIVITY TO COMMUNITY ATTITUDES. (45CFR SEC 46.107)**

**INSTITUTIONAL REVIEW BOARD (AT LEAST NINE MEMBERS, THREE-YEAR TERMS)**

**THIS COMMITTEE IS RESPONSIBLE FOR REVIEWING ALL RESEARCH PROPOSALS INVOLVING HUMAN SUBJECTS IN ORDER TO PROTECT AND ASSURE THE RIGHTS OF RESEARCH SUBJECTS AS DEFINED BY ETHICAL CONSIDERATIONS AND GOVERNMENT GUIDELINES. MEMBERS SHOULD HAVE THE PROFESSIONAL COMPETENCE AND KNOWLEDGE NECESSARY TO REVIEW AND EVALUATE RESEARCH PROPOSALS TO DETERMINE COMPLIANCE WITH FEDERAL STANDARDS AND DRAKE UNIVERSITY GUIDELINES, AND TO EVALUATE PROPOSED RESEARCH IN TERMS OF INSTITUTIONAL COMMITMENTS AND REGULATIONS, APPLICABLE LAW, AND STANDARDS OF PROFESSIONAL COMPETENCE AND PRACTICE.**

**THE COMMITTEE SHALL CONSIST OF AT LEAST NINE MEMBERS, AND SHALL MEET THE FOLLOWING SPECIFICATIONS: (A) AT LEAST SIX FACULTY MEMBERS INCLUDING THE CHAIR AT LEAST FOUR OF WHOM SHALL BE TENURED; ONE SHALL HAVE PRIMARY EXPERTISE IN A NONSCIENTIFIC AREA; ALL EXCEPT THE MEMBER FROM THE NON-SCIENTIFIC AREA SHALL HAVE EXPERTISE IN CONDUCTING HUMAN SUBJECTS RESEARCH; (B) AT LEAST ONE INDIVIDUAL WHO IS NEITHER AFFILIATED WITH, NOR A MEMBER OF THE IMMEDIATE FAMILY OF ANYONE AFFILIATED WITH, THE INSTITUTION; (C) ONE DESIGNEE FROM THE OFFICE OF THE PROVOST WHO SHALL SERVE EX-OFFICIO.**

**THE COMMITTEE CHAIR SHALL BE APPOINTED BY THE PROVOST AND SHALL SERVE A TWO-YEAR TERM. THE PROVOST SHALL DESIGNATE A VICE CHAIR FROM AMONG THE TENURED FACULTY ON THE COMMITTEE WHO WILL SERVE AS CHAIR WHEN NECESSARY, INCLUDING SITUATIONS IN WHICH THE CHAIR MUST STEP DOWN DUE TO CONFLICT OF INTEREST.**

**IRB MEMBERS ARE NOT COMPENSATED FOR THEIR SERVICE. THE UNIVERSITY PROVIDES GENERAL LIABILITY INSURANCE COVERAGE FOR IRB MEMBERS WHILE SERVING AS MEMBERS OF THE IRB.**

## **2.6 IRB MEETINGS**

**EXCEPT WHEN AN EXEMPT OR EXPEDITED REVIEW PROCEDURE IS USED, PROPOSED RESEARCH MUST BE REVIEWED AT CONVENED MEETINGS AT WHICH A MAJORITY OF THE MEMBERS OF THE IRB ARE PRESENT (45CFR SEC 46.108). MONTHLY MEETINGS OF THE FULL IRB WILL BE SCHEDULED FOR EACH SEMESTER PRIOR TO ITS START. THESE DATES WILL BE PUBLICIZED, AND PROPOSALS THAT REQUIRE FULL-BOARD REVIEW AT THE NEXT MEETING WILL BE GIVEN A DEADLINE OF ONE WEEK PRIOR TO EACH MEETING. IN ADDITION TO REVIEW OF PROTOCOLS, THE AGENDA SPECIFICALLY ROUTINELY WILL INCLUDE:**

- **REVIEW THE ADMINISTRATIVE PROCEDURES FOR THE INSTITUTIONAL REVIEW BOARD AND HUMAN RESEARCH PROTECTIONS POLICIES, MAKING ADDITIONS AND VOTING ON REVISIONS**
- **CONSIDERATION OF CHANGES TO IRB FORMS AND ANY ADDITIONAL INFORMATION THAT GENERALLY SHOULD BE SOUGHT FROM RESEARCH INVESTIGATORS IN THE FUTURE**

**PRIOR TO EACH MEETING, AN AGENDA IS SENT TO PARTICIPATING INVESTIGATORS AND ALL IRB MEMBERS (AND CONSULTANTS), NOTIFYING THEM OF THE DATE, TIME AND PLACE OF THE MEETING. IN ADDITION TO THE REGULARLY SCHEDULED MEETINGS, THE IRB CHAIR MAY CALL EMERGENCY MEETINGS OF THE IRB AS NECESSARY TO REVIEW RESEARCH PROTOCOLS OR ADDRESS ISSUES OF NONCOMPLIANCE OR SERIOUS AND/OR UNEXPECTED INJURY TO RESEARCH SUBJECT(S).**

**MEETINGS ARE CONDUCTED IN ACCORDANCE WITH ROBERTS RULES OF ORDER AND ALL ACTION REQUIRES A VOICE OR SHOW-OF-HANDS VOTE OF THE MEMBERS PRESENT FOLLOWING DISCUSSION AND THE MAKING AND SECONDING OF A MOTION. THE CHAIR DOES NOT VOTE, EXCEPT TO BREAK A TIE. AN IRB MEMBER MAY ABSTAIN FROM VOTING FOR ANY REASON, WITHOUT EXPLANATION.**

### **2.6.1 MEETING MATERIALS**

**THE CHAIR SHALL PROVIDE EACH MEMBER OF THE BOARD WITH AN ELECTRONIC OR PHYSICAL COPY OF THE FOLLOWING MATERIALS PRIOR TO THE REGULARLY SCHEDULED MEETING:**

- **THE AGENDA**
- **A COPY OF THE MINUTES FROM THE PREVIOUS MEETING THAT WILL INCLUDE INFORMATION ON OFFICIAL IRB ACTIVITIES CONDUCTED THROUGH THE IRB SINCE THE PREVIOUS MAILING OF THE MINUTES, SUCH AS PROTOCOLS REVIEWED TO DETERMINE EXEMPT STATUS, PROTOCOLS REVIEWED BY EXPEDITED REVIEW AND ADVERSE EVENT REPORTS RECEIVED**
- **A COPY OF THE IRB APPLICATION, PROTOCOL AND INFORMED CONSENT DOCUMENT FOR EACH NEW PROJECT SUBJECT TO FULL IRB REVIEW**
- **A COPY OF DOCUMENTS FOR THOSE CONTINUING RESEARCH PROJECTS TO BE REVIEWED BY THE FULL BOARD. IF NECESSARY, THIS SHOULD INCLUDE AN UNSIGNED COPY OF THE MOST RECENTLY APPROVED CONSENT/ASSENT DOCUMENTS(S) FOR THOSE PROJECTS IN WHICH SUBJECTS ARE STILL BEING ENROLLED**
- **ANY OTHER INFORMATION NECESSARY FOR THE MEETING**

**EXCEPT FOR A COPY THAT MUST REMAIN ON FILE WITH THE IRB, SENSITIVE DOCUMENTS SUCH AS PROTOCOLS AND CONSENT FORMS CONSIDERED AT A CONVENED MEETING ARE COLLECTED AND DESTROYED AFTER EACH MEETING.**

## **2.6.2 QUORUM**

**A MAJORITY OF MEMBERS MUST BE PRESENT, IN PERSON OR VIA TELECONFERENCE OR WEBCONFERENCE, TO CONDUCT BUSINESS OF THE IRB, EXCEPT FOR EXPEDITED OR EXEMPT REVIEWS, AND AMONG THIS MAJORITY AT LEAST ONE MEMBER MUST BE A NON-SCIENTIST (45CFR SEC 46.107). NO PROXY VOTES WILL BE ACCEPTED, ALL VOTES MUST BE CAST DURING THE CONVENED MEETING. THE FINAL APPROVAL OR DISAPPROVAL OF ANY RESEARCH PROJECT APPLICATION WILL REQUIRE A MAJORITY VOTE OF IRB MEMBERS PRESENT AND VOTING, WITH AT LEAST ONE MEMBER OF A NON-SCIENTIFIC AREA VOTING. IF A QUORUM IS LOST AT ANY TIME DURING THE MEETING, THE MEETING SHALL BE ADJOURNED AND NO FURTHER ACTION TAKEN UNTIL A QUORUM IS ATTAINED.**

**IRB MEMBERS WITH A CONFLICT OF INTEREST IN A PARTICULAR RESEARCH PROJECT CANNOT PARTICIPATE IN THE BOARD'S DELIBERATIONS AND VOTING CONCERNING THAT PROJECT AND SHALL NOT BE PRESENT DURING IRB INITIAL OR CONTINUING REVIEW OF THAT PROJECT. SHOULD CONFLICTED IRB MEMBERS LEAVE DURING THE MEETING, THE TOTAL NEEDED TO CALCULATE QUORUM WOULD BE REDUCED BY THE NUMBERS WHO LEAVE THE MEETING. THOSE WITH A CONFLICT OF INTEREST MAY PROVIDE INFORMATION REQUESTED BY THE IRB.**

## **2.6.3 ATTENDANCE**

**MEMBERS ARE EXPECTED TO ATTEND A MAJORITY OF CONVENED IRB MEETINGS. IRB ADMINISTRATION WILL MAINTAIN RECORDS OF ATTENDANCE AND MEMBERS WHO ATTEND LESS THAN 50% OF MEETINGS PER YEAR WILL BE CONTACTED AND ENCOURAGED TO INCREASE THEIR ATTENDANCE. ANTICIPATED ABSENCE FROM AN IRB MEETING SHOULD BE COMMUNICATED TO THE IRB CHAIR AT LEAST 24 HOURS PRIOR TO THE MEETING.**

**IF REQUESTED, RESEARCH INVESTIGATORS ARE REQUIRED TO ATTEND IRB MEETINGS AT THE DATE AND TIME SCHEDULED FOR FULL IRB REVIEW AND DISCUSSION OF THEIR INITIAL SUBMISSION OR OF CHANGES TO A PREVIOUSLY APPROVED OR DISAPPROVED RESEARCH PROJECT IF REQUESTED. ONCE SCHEDULED, THE PRINCIPAL INVESTIGATOR SHOULD CONTACT THE IRB CHAIR TO REQUEST A SCHEDULING CHANGE IF SUCH A CHANGE IS NECESSARY.**

## **CONFIDENTIALITY**

**ALL MEMBERS ARE EXPECTED TO HOLD IN CONFIDENCE ALL MATTERS COMING BEFORE THE IRB.**

## **2.6.4 MINUTES**

**MINUTES OF MEETINGS SHALL INCLUDE (45CFR SEC 46.115) THE FOLLOWING INFORMATION:**

- **ATTENDANCE OF MEMBERS AND GUESTS**
- **ACTIONS TAKEN BY THE IRB ON EACH RESEARCH PROJECT REVIEWED INCLUDING THE LEVEL OF RISK AS DETERMINED BY THE IRB, THE APPROVAL PERIOD AND ANY REQUIRED MODIFICATIONS FOR IRB APPROVAL**
- **VOTES ON THESE ACTIONS INCLUDING THE NUMBER OF MEMBERS VOTING FOR, AGAINST, AND ABSTAINING, AND RECORD OF MEMBERS WHO WERE NOT PRESENT DURING DELIBERATIONS AND VOTING WHEN REVIEW INVOLVED PROJECTS ON WHICH THEY HAVE A CONFLICT OF INTEREST**
- **THE BASIS FOR REQUIRING MODIFICATIONS OR DISAPPROVING RESEARCH**



- **A WRITTEN SUMMARY OF THE DISCUSSION AND RESOLUTION OF DEBATED ISSUES**

## **2.7 EDUCATION OF IRB MEMBERS**

**ALL NEW MEMBERS APPOINTED TO THE IRB MUST COMPLETE DRAKE UNIVERSITY'S HUMAN SUBJECTS RESEARCH TUTORIAL AND CERTIFICATION REQUIREMENT. INITIAL CERTIFICATION FULFILLMENT REQUIRES THE FOLLOWING:**

- **A COPY OF THE MOST RECENT DRAKE UNIVERSITY'S FEDERAL-WIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS**
- **COMPLETION OF THE WEB-BASED TUTORIAL ON HUMAN SUBJECTS RESEARCH AND ITS ASSOCIATED TESTING**

## **2.8 IRB RECORDS**

**ALL RESEARCH PROTOCOLS SUBMITTED TO THE IRB FOR REVIEW WILL RECEIVE AN IDENTIFYING NUMBER. THE PROPOSALS RECEIVED BEGINNING AT THE ONSET OF THE ACADEMIC YEAR WILL BE SEQUENTIALLY IDENTIFIED USING THE FOLLOWING METHOD:**

**EXAMPLE: 2003-04001**

**2003-04** DESIGNATES THE ACADEMIC YEAR SUBMITTED

**001** REPRESENTING THE FIRST PROTOCOL SUBMITTED, **002** TO FOLLOW, ETC.

**THE IRB SHALL RETAIN AND HAVE ACCESSIBLE IN A CENTRAL LOCATION (45CFR SEC 46.115) THE FOLLOWING RECORDS FOR AT LEAST THREE YEARS AFTER THE COMPLETION OF THE RESEARCH:**

- **ALL RESEARCH PROPOSALS REVIEWED, SCIENTIFIC EVALUATIONS, IF ANY, THAT ACCOMPANY THE PROPOSALS, APPROVED SAMPLE CONSENT DOCUMENTS, REQUIRED YEARLY, OR OTHER PROGRESS REPORTS SUBMITTED BY INVESTIGATORS, CORRESPONDENCE BETWEEN THE IRB AND THE INVESTIGATORS, AND ADVERSE EVENT REPORTS**
- **MINUTES OF IRB MEETINGS, DETAILED APPROPRIATELY**
- **RECORDS OF CONTINUING REVIEW OF PREVIOUSLY APPROVED RESEARCH PROJECTS**
- **LIST OF IRB MEMBERS, IDENTIFIED BY NAME, EARNED DEGREES, REPRESENTATIVE CAPACITY, INDICATIONS OF EXPERIENCE SUFFICIENT TO DESCRIBE EACH MEMBER'S CHIEF ANTICIPATED CONTRIBUTIONS AND EMPLOYMENT RELATIONSHIP (IF ANY) WITH THE INSTITUTION AND DATES OF SERVICE ON THE IRB**
- **STATEMENTS OF SIGNIFICANT NEW FINDINGS PROVIDED TO SUBJECTS AS REQUIRED BY EITHER FDA OR DHHS**
- **WRITTEN PROCEDURES FOR THE IRB.**

**IRB RECORDS, AS OUTLINED ABOVE, SHALL BE AVAILABLE FOR INSPECTION AND COPYING BY THE INSTITUTIONAL OFFICIAL OR HIS/HER DESIGNEES, AFFILIATED ENTITIES, AND DESIGNATED FEDERAL AND OTHER AGENCIES.**

## **3.0 ADMINISTRATIVE ROLES AND RESPONSIBILITIES**

### **3.1 THE INSTITUTIONAL OFFICIAL**

**THE PROVOST OF DRAKE UNIVERSITY SERVES AS THE INSTITUTIONAL OFFICIAL FOR THE IRB. THE PROVOST SIGNS THE INSTITUTION'S FEDERAL-WIDE ASSURANCE OF PROTECTION FOR HUMAN SUBJECTS (FWA) THAT IS REQUIRED BY DHHS. THE PROVOST CAN APPROVE OR DISAPPROVE RESEARCH PROJECTS WITH THE FOLLOWING EXCEPTION: THE PROVOST INDEPENDENTLY CANNOT APPROVE ANY RESEARCH THAT HAS BEEN DISAPPROVED BY THE IRB.**

### **3.2 THE IRB CHAIR**

**THE IRB CHAIR ENSURES THAT THE IRB CARRIES OUT ITS RESPONSIBILITIES IN ACCORDANCE WITH FEDERAL REQUIREMENTS AND THESE POLICIES AND PROCEDURES.**

**THE CHAIR KEEPS THE PROVOST INFORMED OF IRB ACTIVITIES AS REQUIRED AND A LETTER WILL BE PREPARED YEARLY SUMMARIZING THE RESEARCH APPROVED, DISAPPROVED AND TABLED ACTIONS TAKEN ON POLICY AND PROGRAM ISSUES.**

### **3.3 THE IRB**

**THE IRB REVIEWS AND APPROVES, REQUIRES MODIFICATION IN, OR DISAPPROVES ALL RESEARCH ACTIVITIES CONDUCTED UNDER THE JURISDICTION OF DRAKE UNIVERSITY. THE IRB CONDUCTS CONTINUING REVIEW OF PREVIOUSLY APPROVED RESEARCH AT APPROPRIATE INTERVALS BASED ON RISK, BUT NOT LESS THAN ONCE A YEAR. THE IRB HAS AUTHORITY TO SUSPEND OR TERMINATE PREVIOUSLY APPROVED RESEARCH THAT IS NOT CONDUCTED IN ACCORDANCE WITH IRB REQUIREMENTS OR THAT HAS BEEN ASSOCIATED WITH UNEXPECTED SERIOUS HARM TO RESEARCH SUBJECTS. THE IRB HAS AUTHORITY TO PLACE ANY RESTRICTIONS ON AN APPROVED PROJECT AS NECESSARY TO ENSURE PROTECTION OF HUMAN SUBJECTS.**

### **3.4 THE PRINCIPAL INVESTIGATOR**

**THE PRINCIPAL INVESTIGATOR HAS THE PRIMARY RESPONSIBILITY FOR PROTECTING THE RIGHTS AND WELFARE OF HUMAN RESEARCH SUBJECTS AND FOR COMPLYING WITH ALL APPLICABLE PROVISIONS OF THE UNIVERSITY'S FWA, FEDERAL LAWS AND REGULATIONS AND THE UNIVERSITY'S POLICIES AND PROCEDURES AS SET FORTH IN THIS MANUAL.**

## **4.0 HUMAN SUBJECTS RESEARCH EDUCATION PROGRAM**

**DRAKE UNIVERSITY HAS ADOPTED A WEB-BASED HUMAN SUBJECT'S RESEARCH EDUCATION PROGRAM TO ASSIST INVESTIGATORS AND STAFF IN MEETING FEDERAL REGULATIONS AND UNIVERSITY EDUCATION REQUIREMENTS. THE HUMAN SUBJECT'S RESEARCH TUTORIAL AND TESTING PROGRAM INCLUDES INITIAL CERTIFICATION AS WELL AS ONGOING EDUCATION AND RECERTIFICATION. IT SATISFIES THE NIH HUMAN SUBJECTS TRAINING REQUIREMENT FOR OBTAINING FEDERAL FUNDS. YOU WILL HAVE THE OPTION OF PRINTING A CERTIFICATE OF COMPLETION FROM YOUR COMPUTER UPON COMPLETING THE COURSE.**

### **4.1 PROGRAM OBJECTIVES**

#### **THE PROGRAM IS DESIGNED TO:**

- **HELP INVESTIGATORS AND STAFF UNDERSTAND THE SPECIAL REQUIREMENTS ASSOCIATED WITH THE USE OF HUMAN SUBJECTS IN RESEARCH**
- **CLARIFY THE RESPONSIBILITIES OF THOSE INVOLVED IN HUMAN SUBJECTS RESEARCH AND OF THE IRB**
- **INCREASE RECOGNITION OF THE BASIC ETHICAL PRINCIPLES FOR THE USE OF HUMAN SUBJECTS: RESPECT FOR PERSONS, BENEFICENCE AND JUSTICE**
- **PROVIDE EDUCATION ON THE PROTECTION OF HUMAN SUBJECTS AS MANDATED BY DHHS (OHRP) IN TITLE 45 OF THE CODE OF FEDERAL REGULATIONS, SECTION 46 (45CFR46)**
- **PROVIDE EDUCATION ON IRB REVIEW, INFORMED CONSENT, AND POLICIES AND PROCEDURES APPLICABLE TO HUMAN SUBJECTS RESEARCH**

#### **4.2 WHO IS REQUIRED TO COMPLETE THE PROGRAM**

**INDIVIDUALS IN THE FOLLOWING CATEGORIES MUST COMPLETE THE DRAKE UNIVERSITY HUMAN SUBJECT RESEARCH EDUCATION PROGRAM:**

- **THE DRAKE UNIVERSITY INSTITUTIONAL OFFICIAL (PROVOST OF THE UNIVERSITY)**
- **ALL IRB MEMBERS**
- **DRAKE UNIVERSITY FACULTY SERVING AS PRINCIPAL INVESTIGATORS**
- **ANY DRAKE PROJECT STAFF CONDUCTING THE INFORMED CONSENT PROCESS**
- **ALL DRAKE PROJECT STAFF DESIGNATED BY THE PRINCIPAL INVESTIGATOR**
- **DRAKE UNIVERSITY FACULTY SERVING AS TEACHING FACULTY TO DRAKE STUDENTS WHO ARE INVOLVED IN EXEMPT OR NON-EXEMPT RESEARCH PROJECTS**
- **DRAKE STUDENTS WHO ARE CONDUCTING NON-EXEMPT RESEARCH (I.E. RESEARCH THAT IS SUBJECT TO EITHER EXPEDITED REVIEW OR FULL IRB REVIEW; SEE SECTION 5.2)**
- **PRINCIPAL INVESTIGATORS FROM NON-DRAKE FACILITIES WHO DO NOT HAVE CERTIFICATION OF EDUCATION FROM ANOTHER INSTITUTION'S IRB AND WHO ARE CONDUCTING RESEARCH WITH THE CONSENT OF THE DRAKE IRB OR UNDER THE RESPONSIBILITY OF THE UNIVERSITY AND**
- **PROJECT STAFF FROM NON-DRAKE FACILITIES WHO ARE CONDUCTING THE CONSENT PROCESS EITHER WITHIN DRAKE OR WITH THE CONSENT OF THE DRAKE IRB AND WHO DO NOT HAVE CERTIFICATION OF EDUCATION FROM ANOTHER INSTITUTION'S IRB**
- **ANYONE SERVING AS A PRINCIPAL INVESTIGATOR IN A NON-EXEMPT SUBMISSION**

**MANDATORY EDUCATION AND CERTIFICATION MUST BE COMPLETED BEFORE IRB APPROVAL OF ANY NEW PROJECT, REVISIONS OR AMENDMENTS TO EXISTING PROJECTS OR RENEWALS OF EXISTING PROJECTS.**

#### **4.3 WHO IS EXEMPT FROM HUMAN SUBJECTS RESEARCH EDUCATION REQUIREMENTS**

**THE FOLLOWING INDIVIDUALS ARE EXEMPT FROM HUMAN SUBJECT'S RESEARCH EDUCATION REQUIREMENTS:**

- **RESEARCH STAFF WHO PERFORM STANDARD OF CARE PROCEDURES IN CONNECTION WITH A PROTOCOL**
- **RESEARCH STAFF WHO ANALYZE DATA, IF THE DATA DO NOT CONTAIN IDENTIFYING INFORMATION (E.G. NAME, SOCIAL SECURITY NUMBER)**

#### **4.4 ONGOING EDUCATION AND RECERTIFICATION**

**TRAINING EXPIRES AT THREE YEARS. RECERTIFICATION WILL BE REQUIRED FOR ALL ONGOING/CONTINUED AND NEW SUBMISSIONS. FAILURE TO BE IN COMPLIANCE WITH THIS MAY LEAD TO A SUSPENDED PROTOCOL. THE RECERTIFICATION PROCESS WILL INCLUDE WEB-BASED TRAINING AND RENEWED CERTIFICATION AND PERIODIC UPDATES TO INFORM INVESTIGATORS AND STAFF OF CHANGES IN FEDERAL REGULATIONS OR UNIVERSITY REQUIREMENTS.**

#### **4.5 ADDITIONAL EDUCATION**

**THE IRB AND UNIVERSITY MAY PROVIDE ADDITIONAL EDUCATION AS NEEDED, ADDRESSING SUCH ISSUES AS REGULATORY CHANGES AND ISSUES IDENTIFIED THROUGH THE CURRENT IRB INTERNAL MONITORING PROCESS.**

## **5.0 THE REVIEW PROCESS**

**ANY RESEARCH THAT INVOLVES HUMAN SUBJECTS AND IS AUTHORIZED AND CONDUCTED UNDER THE JURISDICTION OF DRAKE UNIVERSITY IS SUBJECT TO REVIEW BY THE DRAKE UNIVERSITY IRB. NO NEW RESEARCH PROJECT OR CHANGES TO PREVIOUSLY APPROVED RESEARCH PROJECTS MAY BE INITIATED UNTIL APPROVED BY THE IRB. THE IRB REVIEWS NEW PROJECTS, CHANGES TO EXISTING PROJECTS AND ONGOING PROJECTS AS FOLLOWS:**

- i. INITIAL REVIEW ALL NEW RESEARCH PROJECTS MUST BE SUBMITTED FOR INITIAL REVIEW. THE THREE TYPES OF INITIAL REVIEW EXEMPT, EXPEDITED AND FULL BOARD ARE DEFINED IN DETAIL IN SECTIONS 5.2 AND 5.3**
- ii. REVIEW OF CHANGES TO PREVIOUSLY APPROVED PROTOCOLS ANY AMENDMENTS, ADDENDA, SUPPLEMENTS OR OTHER CHANGES TO EXISTING PROJECTS MUST BE SUBMITTED TO THE IRB FOR EITHER EXPEDITED OR FULL BOARD REVIEW.**
- iii. CONTINUING REVIEW OF APPROVED RESEARCH PROJECTS CONTINUING REVIEW OF PROJECTS PREVIOUSLY APPROVED BY FULL BOARD REVIEW IS CONDUCTED BY THE FULL BOARD AT ITS REGULAR MEETINGS. CONTINUING REVIEW OF EXEMPT OR EXPEDITED PROJECTS IS CONDUCTED BY THE IRB CHAIR OR OTHER APPOINTED MEMBER.**

### **5.1 WHEN IS IRB REVIEW REQUIRED**

#### **5.1.1 NEW PROJECTS**

**TO DETERMINE IF THE PROPOSED ACTIVITY REQUIRES REVIEW BY THE DRAKE IRB, ANSWER THE FOLLOWING THREE QUESTIONS:**

- IS THE PROPOSED ACTIVITY RESEARCH?  
RESEARCH IS A SYSTEMATIC INVESTIGATION THAT INCLUDES RESEARCH DEVELOPMENT, TESTING AND EVALUATION AND IS INTENDED TO DEVELOP OR CONTRIBUTE TO GENERAL KNOWLEDGE. IF, ACCORDING TO THIS DEFINITION, THE PROPOSED ACTIVITY IS NOT RESEARCH, THEN IRB REVIEW IS NOT REQUIRED. IF THE PROPOSED ACTIVITY IS RESEARCH, CONTINUE WITH THE NEXT QUESTION.**
- DOES IT INVOLVE HUMAN SUBJECTS?  
RESEARCH INVESTIGATORS MUST DETERMINE WHETHER THEIR PROPOSED RESEARCH WILL INVOLVE HUMAN SUBJECTS. REGULATIONS DEFINE "HUMAN SUBJECT" AS A LIVING INDIVIDUAL ABOUT WHOM AN INVESTIGATOR (WHETHER PROFESSIONAL OR STUDENT) CONDUCTING**

RESEARCH OBTAINS 1) DATA THROUGH INTERVENTION OR INTERACTION WITH THE INDIVIDUAL OR 2) IDENTIFIABLE PRIVATE INFORMATION. IF YOU DETERMINE THAT THE RESEARCH DOES NOT INVOLVE HUMAN SUBJECTS, THEN IRB REVIEW IS NOT REQUIRED. IF YOU DETERMINE THAT THE RESEARCH DOES INVOLVE HUMAN SUBJECTS, IRB REVIEW IS REQUIRED. IF IT IS NOT CLEAR WHETHER THE RESEARCH INVOLVES HUMAN SUBJECTS, SEEK ASSISTANCE FROM THE IRB CHAIR.

- **WILL IT BE AUTHORIZED AND CONDUCTED UNDER THE JURISDICTION OF DRAKE UNIVERSITY?** ALL RESEARCH INVOLVING HUMAN SUBJECTS REGARDLESS OF THE FUNDING STATUS OR THE SOURCE OF ANY FUNDING IS UNDER THE JURISDICTION OF THE UNIVERSITY. IN COOPERATIVE RESEARCH PROJECTS INVOLVING ONE OR MORE INSTITUTIONS IN ADDITION TO DRAKE UNIVERSITY, EACH INSTITUTION IS RESPONSIBLE FOR SAFEGUARDING THE RIGHTS AND WELFARE OF HUMAN SUBJECTS AND FOR COMPLYING WITH THE INDIVIDUAL IRB POLICIES.
- **DOES RESEARCH NOT INTENDED FOR PUBLICATION REQUIRE IRB REVIEW AND APPROVAL?** EVEN RESEARCH INVOLVING HUMAN SUBJECTS THAT IS NOT INTENDED FOR PUBLICATION REQUIRES IRB APPROVAL.

### 5.1.2 STUDENT CLASSROOM RESEARCH PROJECTS

MANY OF OUR UNIVERSITY COURSES DEMAND THAT UNDERGRADUATE AND GRADUATE STUDENTS ENGAGE IN RESEARCH ACTIVITIES AS PART OF THE REGULAR ACADEMIC EXPERIENCE. WHERE THAT RESEARCH USES HUMAN SUBJECTS, DRAKE UNIVERSITY WANTS TO INSURE THAT ALL STUDENT RESEARCHERS ARE COGNIZANT OF THE NEED TO PROTECT HUMAN SUBJECTS FROM RISK. WHILE THE VAST MAJORITY OF STUDENT RESEARCH FALLS INTO CATEGORIES THAT IN NO WAY MAY BE CONSTRUED AS EXPOSING SUBJECTS TO MORE THAN MINIMAL RISK, THE IRB, ON BEHALF OF THE UNIVERSITY, HAS A RESPONSIBILITY TO STUDENTS WHO MAY BE SUBJECTS AND TO EXTERNAL RESEARCH PARTICIPANTS TO ENSURE RESEARCHER AWARENESS OF POSSIBLE RISKS. NEVERTHELESS, CLASSROOM PROJECTS THAT MEET CERTAIN CRITERIA (SEE BELOW) MAY NOT REQUIRE IRB REVIEW. FACULTY WHO REQUIRE RESEARCH PROJECTS OF THEIR STUDENTS MUST CERTIFY THAT THE PROJECTS BEING CONDUCTED IN THEIR COURSES WOULD QUALIFY FOR EXEMPT STATUS.

CLASSROOM CURRICULUM PROJECTS IN WHICH STUDENTS CONDUCT RESEARCH INVOLVING HUMAN SUBJECTS NEED NOT BE REVIEWED BY THE IRB IF ALL THREE OF THE FOLLOWING CONDITIONS ARE SATISFIED:

- i. THE PROJECT (S) INVOLVE MINIMAL RISK TO SUBJECTS (I.E., A RISK IS MINIMAL WHERE THE PROBABILITY AND MAGNITUDE OF HARM OR DISCOMFORT ANTICIPATED IN THE PROPOSED RESEARCH ARE NOT GREATER, IN AND OF THEMSELVES, THAN THOSE ORDINARILY ENCOUNTERED IN DAILY LIFE OR DURING THE PERFORMANCE OF ROUTINE PHYSICAL OR PSYCHOLOGICAL EXAMINATIONS OR TESTS [FEDERAL POLICY §\_\_\_\_.102 (1)]. FOR EXAMPLE, THE RISK OF DRAWING A SMALL AMOUNT OF BLOOD FROM A HEALTHY INDIVIDUAL FOR RESEARCH PURPOSES IS NO GREATER THAN THE RISK OF DOING SO AS PART OF ROUTINE PHYSICAL EXAMINATION.)
- ii. THEY DO NOT INVOLVE VULNERABLE POPULATIONS (I.E., CHILDREN YOUNGER THAN 18 YEARS, THOSE WITH INTELLECTUAL DISABILITIES, PRISONERS, PREGNANT WOMEN).
- iii. RESULTS WILL NEVER BE DISTRIBUTED OUTSIDE THE CLASSROOM AND/OR INSTITUTIONAL SETTING (E.G., DISSEMINATED AT A CONFERENCE, SUBMITTED FOR PUBLICATION, PRESENTED AT DUCURS, PUBLISHED IN DRAKE UNDERGRADUATE SOCIAL SCIENCE JOURNAL, POSTED ON THE WORLD WIDE WEB). IF THERE IS EVEN A REMOTE CHANCE THAT THE DATA OR THE

**REPORT/MANUSCRIPT WILL BE USED IN THE FUTURE FOR A CONFERENCE PRESENTATION, OR RELATED RESEARCH PROJECT, THE RESEARCH MUST GO THROUGH IRB REVIEW. IF THE PROJECT IS NOT SUBJECTED TO A PRE-DATA COLLECTION IRB REVIEW, THE DATA WILL MOST LIKELY NOT BE PERMISSIBLE FOR INCLUSION IN FUTURE PRESENTATION OR RESEARCH.**

**INSTRUCTORS WISHING TO HAVE STUDENTS CONDUCT RESEARCH THAT MEET THE AFOREMENTIONED CRITERIA MUST DO THE FOLLOWING:**

- 1. INSTRUCTORS MUST RECEIVE FURTHER TRAINING BY THE IRB ON EVALUATING PROPOSALS AND IDENTIFYING VIOLATIONS (TO BE RENEWED EVERY THREE YEARS),**
- 2. INSTRUCTORS MUST SUBMIT AN APPLICATION TO THE IRB PROVIDING A DESCRIPTION OF GENERAL RESEARCH ASSIGNMENT INFORMATION:**
  - i. THE TYPES OF RESEARCH TO BE UNDERTAKEN**
  - ii. NATURE OF PARTICIPANTS TO BE USED**
  - iii. KINDS OF PROCEDURES TO BE USED IN THE RESEARCH PROJECTS,**
- 3. INSTRUCTORS MUST COMPLETE AND SUBMIT A COURSE RESEARCH CERTIFICATION FORM TO THE IRB (CLICK HERE)**

**INSTRUCTORS ARE TO REQUIRE STUDENTS TO COMPLETE A PROPOSAL FOR THE CLASSROOM ASSIGNMENT THAT ADDRESSES: THE PURPOSE OF THE PROJECT, DESCRIPTION OF PARTICIPANTS, DATA COLLECTION METHODOLOGY, THE CONSENT PROCESS (SEE REQUIREMENTS FOR STUDENT PROPOSALS). FURTHERMORE, INSTRUCTORS MUST SUBMIT A COPY OF THE CONSENT FORM USED BY EACH STUDENT, SIGNED BY THE STUDENT CONDUCTING THE RESEARCH. ANY RESEARCH NOT WITHIN THE DESCRIBED PARAMETERS PROPOSED AND SUBMITTED BY THE INSTRUCTOR TO THE IRB WOULD REQUIRE SEPARATE APPROVAL FROM THE IRB. FURTHERMORE, FACULTY AND STUDENTS SHOULD TAKE NOTE THAT ANY DATA COLLECTED UNDER THE GUISE OF CLASSROOM RESEARCH WILL NOT BE ELIGIBLE FOR PUBLICATION OR PRESENTATION OUTSIDE OF THE CLASSROOM AND POST-HOC REVIEWS WILL NOT BE CONDUCTED FOR THE PURPOSE OF PUBLICATION OR PRESENTATION OUTSIDE OF THE CLASSROOM.**

#### **REQUIREMENTS FOR STUDENT PROPOSALS**

- **OVERVIEW OF THE PROJECT**
  - i. PURPOSE**
  - ii. RATIONALE/SIGNIFICANCE**
  - iii. GENERAL DESCRIPTION OF RESEARCH STRATEGY AND DESIGN**
- **PARTICIPANTS**
  - i. WHO (GENERAL SAMPLE/POPULATION INFORMATION, NOT BY NAME)**
  - ii. CRITERIA FOR SELECTION**
  - iii. HOW SELECTED, E.G. VOLUNTEER OR RECRUITMENT STRATEGIES**
  - iv. RISK FACTORS FOR PARTICIPANTS (BE SPECIFIC)**
- **DATA COLLECTION METHODS**
  - i. SPECIFIC STEPS TO GATHER DATA**
  - ii. INSTRUMENTATION**
  - iii. HOW DATA WILL BE RECORDED (DESCRIBE STEPS FOR CONFIDENTIALITY)**
  - iv. SECURE DATA STORAGE**
  - v. DESTRUCTION OF RAW DATA**
- **CONSENT**
  - i. DESCRIBE THE CONSENT PROCESS**

1. HOW WILL STUDY BE EXPLAINED TO PARTICIPANTS
  2. IMPLICIT OR EXPLICIT CONSENT
- ii. IF EXPLICIT CONSENT IS OBTAINED, COPY OF CONSENT FORM SHOULD:
1. IDENTIFYING AS A PROJECT THROUGH DRAKE UNIVERSITY
  2. OUTLINE DATA COLLECTION PROCEDURES
  3. ENSURE CONFIDENTIALITY
  4. EXPLAIN THE RIGHTS OF THE PARTICIPANT, E.G. TO WITHDRAW AT ANY TIME WITH NO PENALTY, WHAT WILL HAPPEN WITH THEIR DATA IF THEY CHOOSE TO WITHDRAW, ETC.
  5. EXPLAIN THE RISKS TO THE PARTICIPANT
  6. PROVIDE IRB CONTACT INFORMATION, INSTRUCTOR, AND RESEARCHER'S CONTACT INFORMATION
  7. INCLUDE DATE AND SIGNATURE LINE(S)

### **5.1.3 CHANGES TO PREVIOUSLY APPROVED PROJECTS**

RESEARCH INVESTIGATORS SHALL BE RESPONSIBLE FOR SUBMITTING FOR IRB REVIEW ALL AMENDMENTS, ADDENDA, SUPPLEMENTS OR OTHER CHANGES TO PREVIOUSLY APPROVED PROJECTS ALONG WITH A COPY OF THE ORIGINAL PROTOCOL WHEN:

- THE RESEARCH PROJECT PROPOSES TO INVOLVE OR TO CHANGE THE INVOLVEMENT OF HUMAN SUBJECTS AND THE INVOLVEMENT IS SIGNIFICANTLY DIFFERENT FROM THAT WHICH WAS ORIGINALLY APPROVED BY THE IRB
- THE INFORMED CONSENT DOCUMENT IS MATERIALLY MODIFIED FROM THAT WHICH WAS ORIGINALLY APPROVED BY THE IRB
- THE PRINCIPAL INVESTIGATOR WISHES TO ADD OR CHANGE ANY STUDY PERSONNEL
- PRINCIPAL INVESTIGATORS MUST CHECK WITH THE IRB TO DETERMINE IF MODIFICATIONS ARE MATERIAL.

### **5.1.4 CONTINUING REVIEW OF ONGOING PROJECTS**

NOT MORE THAN ONE YEAR FROM THE DATE OF IRB ACTION (NOT FROM THE DATE OF PROJECT INITIATION), PREVIOUSLY APPROVED AND ON-GOING PROTOCOLS MUST BE SUBMITTED FOR RENEWAL. THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR SEEING THAT THE CONTINUING REVIEW APPROVAL IS COMPLETED BEFORE THE DEADLINE. THERE IS NO GRACE PERIOD, THE APPROVAL WILL HAVE LAPSED AND RESEARCH CANNOT CONTINUE.

ROUTINE PROJECTS OF MINIMAL RISK WILL BE REVIEWED AT 12-MONTHS, HOWEVER, PROJECTS OF MODERATE OR HIGH RISK INVOLVING ADULT SUBJECTS AND PROJECTS OF GREATER THAN MINIMAL RISK INVOLVING MINOR SUBJECTS MAY AT THE DISCRETION OF THE IRB BE REVIEWED MORE FREQUENTLY, COMMENSURATE WITH THE RISK INVOLVED. THE EXPERIENCE OF THE INVESTIGATORS WILL ALSO BE CONSIDERED. AT THE TIME OF INITIAL IRB APPROVAL, THE IRB WILL NOTIFY THE INVESTIGATOR OF THE LEVEL OF RISK AND THE APPROVAL PERIOD ASSIGNED TO THE PROJECT. THE IRB MAY MODIFY THE LEVEL OF RISK AND LENGTH OF APPROVAL PERIOD FOLLOWING REVIEW OF CHANGES TO A PROJECT OR FOLLOWING CONTINUING REVIEW OF A PROJECT, AS APPROPRIATE. THE RESEARCH INVESTIGATOR WILL BE NOTIFIED OF ANY SUCH MODIFICATIONS.

**IN ADDITION TO SCHEDULED CONTINUING REVIEWS, THE IRB MAY ELECT TO REVIEW THE DATA ACCUMULATED BY THE INVESTIGATOR(S) OR INTERVIEW BOTH THE INVESTIGATIVE STAFF AND RESEARCH SUBJECTS. THE IRB MAY DESIGNATE AN IRB MEMBER OR INDEPENDENT CONSULTANT TO VERIFY THAT NO MATERIAL CHANGES IN A RESEARCH PROJECT HAVE OCCURRED SINCE THE PREVIOUS REVIEW. IRB MAY CHECK ON ANY PROJECT AT ANY TIME TO ASSURE IT IS MEETING IRB GUIDELINES.**

## **5.2 LEVELS OF REVIEW**

**THERE ARE 3 DIFFERENT LEVELS OF REVIEW FOR A SUBMISSION TO THE IRB. WHILE THE INVESTIGATOR WILL SUBMIT TO A SPECIFIC LEVEL, ANY MEMBER OF THE IRB MAY CHANGE THE LEVEL OF REVIEW REQUIRED. BELOW THE REQUIREMENTS FOR EACH LEVEL ARE EXPLAINED IN DETAIL.**

**THE IRB WILL EVALUATE ALL NON-EXEMPT RESEARCH PROJECTS TO ENSURE THAT THE DEFINED RISKS TO THE SUBJECT ARE OUTWEIGHED BY THE POTENTIAL BENEFITS. THE IRB WILL DETERMINE THAT THE FOLLOWING CRITERIA ARE SATISFIED:**

- **THE RESEARCH IS SIGNIFICANT, HAS SCIENTIFIC MERIT, CONTRIBUTES TO KNOWLEDGE AND RESEARCH AND METHODS ARE APPROPRIATE**
- **THE INVESTIGATOR IS QUALIFIED AND RESEARCH INVESTIGATORS HAVE RECEIVED EDUCATION IN HUMAN SUBJECTS PROTECTION AND ARE CERTIFIED BY THE UNIVERSITY**
- **RISKS TO SUBJECTS ARE MINIMIZED, PROCEDURES USED ARE CONSISTENT WITH SOUND RESEARCH DESIGN AND DO NOT NECESSARILY EXPOSE SUBJECTS TO RISK**
- **RISKS TO SUBJECTS ARE REASONABLE IN RELATION TO ANTICIPATED BENEFITS**
- **SELECTION OF SUBJECTS IS EQUITABLE**
- **INFORMED CONSENT WILL BE SOUGHT AND APPROPRIATELY DOCUMENTED IN ACCORDANCE WITH AND TO THE EXTENT REQUIRED BY 45CFR4.116**
- **PRIVACY IS PROTECTED AND CONFIDENTIALITY OF DATA IS MAINTAINED**
- **SAFEGUARDS FOR THOSE WHO ARE LIKELY TO BE VULNERABLE TO COERCION OR UNDUE INFLUENCE HAVE BEEN INCLUDED TO PROTECT RESEARCH SUBJECTS**
- **ADEQUATE PROVISIONS ARE MADE IF SPECIAL ISSUES ARE A COMPONENT OF THE RESEARCH STUDY**

### **5.2.1 REVIEW FOR DETERMINATION OF EXEMPT STATUS**

**FEDERAL GUIDELINES IDENTIFY THOSE RESEARCH ACTIVITIES THAT ARE EXEMPT AND THEREFORE DO NOT REQUIRE FULL IRB REVIEW. IF YOUR PROPOSED RESEARCH FALLS UNDER ONE OF THE EXEMPT CATEGORIES BELOW, SUBMIT YOUR PROTOCOL TO THE IRB CHAIR FOR DETERMINATION OF EXEMPT STATUS. (SEE SECTION 5.3.1 FOR INFORMATION ON SUBMISSION REQUIREMENTS AND REVIEW PROCESS.)**

**THE FOLLOWING INFORMATION ON EXEMPT CATEGORIES IS FROM 45CFR46.101(b).**

**UNLESS OTHERWISE REQUIRED BY FEDERAL DEPARTMENT OR AGENCY HEADS, RESEARCH ACTIVITIES IN WHICH THE ONLY INVOLVEMENT OF HUMAN SUBJECTS (EXCLUDING PRISONERS, FETUSES, PREGNANT WOMEN OR HUMAN IN VITRO FERTILIZATION) WILL BE IN ONE OR MORE OF THE FOLLOWING CATEGORIES ARE EXEMPT:**



1. RESEARCH CONDUCTED IN ESTABLISHED OR COMMONLY ACCEPTED EDUCATIONAL SETTINGS, INVOLVING NORMAL EDUCATION PRACTICES, SUCH AS (I) RESEARCH ON REGULAR AND SPECIAL EDUCATION INSTRUCTIONAL STRATEGIES, OR (II) RESEARCH ON THE EFFECTIVENESS OF OR THE COMPARISON AMONG INSTRUCTIONAL TECHNIQUES, CURRICULA OR CLASSROOM MANAGEMENT
2. RESEARCH INVOLVING THE USE OF EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES OR OBSERVATION OF PUBLIC BEHAVIOR UNLESS BOTH OF THE FOLLOWING CONDITIONS HOLD:
  - i. INFORMATION OBTAINED IS RECORDED IN SUCH A MANNER THAT HUMAN SUBJECTS CAN BE IDENTIFIED, DIRECTLY OR THROUGH IDENTIFIERS LINKED TO THE SUBJECTS; AND
  - ii. ANY DISCLOSURE OF THE HUMAN SUBJECTS' RESPONSES OUTSIDE THE RESEARCH COULD REASONABLY PLACE THE SUBJECTS AT RISK OF CRIMINAL OR CIVIL LIABILITY OR BE DAMAGING TO THE SUBJECTS' FINANCIAL STANDING, EMPLOYABILITY OR REPUTATION  
NOTE: THIS EXEMPTION DOES NOT APPLY TO MINORS, EXCEPT FOR RESEARCH INVOLVING PUBLIC BEHAVIOR WHEN THE INVESTIGATORS DO NOT PARTICIPATE IN THE ACTIVITIES BEING OBSERVED.
3. RESEARCH INVOLVING THE USE OF EDUCATIONAL TESTS (COGNITIVE, DIAGNOSTIC, APTITUDE, ACHIEVEMENT), SURVEY PROCEDURES, INTERVIEW PROCEDURES OR OBSERVATION OF PUBLIC BEHAVIOR THAT IS NOT EXEMPT UNDER PARAGRAPH 2 ABOVE, IF:
  - i. THE HUMAN SUBJECTS ARE ELECTED OR APPOINTED PUBLIC OFFICIALS OR CANDIDATES FOR PUBLIC OFFICE; OR
  - ii. FEDERAL STATUTE(S) REQUIRE(S) WITHOUT EXCEPTION THAT THE CONFIDENTIALITY OF THE PERSONALLY IDENTIFIABLE INFORMATION WILL BE MAINTAINED THROUGHOUT THE RESEARCH AND THEREAFTER
4. RESEARCH INVOLVING THE COLLECTION OR STUDY OF EXISTING DATA, DOCUMENTS, RECORDS, PATHOLOGICAL SPECIMENS OR DIAGNOSTIC SPECIMENS, IF THESE SOURCES ARE PUBLICLY AVAILABLE OR IF THE INFORMATION IS RECORDED BY THE INVESTIGATOR IN SUCH A MANNER THAT SUBJECTS CANNOT BE IDENTIFIED, DIRECTLY OR THROUGH IDENTIFIERS LINKED TO THE SUBJECTS.
5. RESEARCH AND DEMONSTRATION PROJECTS WHICH ARE CONDUCTED BY OR SUBJECT TO THE APPROVAL OF FEDERAL DEPARTMENT OR AGENCY HEADS, AND WHICH ARE DESIGNED TO STUDY, EVALUATE OR OTHERWISE EXAMINE:
  - i. PUBLIC BENEFIT OR SERVICE PROGRAMS
  - ii. PROCEDURES FOR OBTAINING BENEFITS OR SERVICES UNDER THESE PROGRAMS
  - iii. POSSIBLE CHANGES IN OR ALTERNATIVES TO THESE PROGRAMS OR PROCEDURES
  - iv. POSSIBLE CHANGES IN METHODS OR LEVELS OF PAYMENT FOR BENEFITS OR SERVICES UNDER THESE PROGRAMS
6. TASTE AND FOOD QUALITY EVALUATION AND CONSUMER ACCEPTANCE STUDIES IF:
  - a. WHOLESOME FOODS WITHOUT ADDITIVES ARE CONSUMED, OR
  - b. A FOOD IS CONSUMED THAT CONTAINS A FOOD INGREDIENT AT OR BELOW THE LEVEL AND FOR A USE FOUND TO BE SAFE BY THE FDA OR APPROVED BY THE ENVIRONMENTAL PROTECTION AGENCY OR THE FOOD SAFETY AND INSPECTION SERVICE OF THE U.S. DEPARTMENT OF AGRICULTURE.

IF YOU HAVE ANY QUESTIONS REGARDING THE EXEMPT CATEGORIES DEFINED ABOVE, PLEASE CONTACT THE IRB CHAIR FOR ASSISTANCE.

### 5.2.2 EXPEDITED REVIEW

FEDERAL GUIDELINES IDENTIFY THOSE RESEARCH ACTIVITIES ELIGIBLE FOR EXPEDITED IRB REVIEW. IF YOUR PROPOSED RESEARCH MEETS THE APPLICABILITY REQUIREMENTS DESCRIBED BELOW AND FALLS

UNDER ONE OF THE EXPEDITED REVIEW CATEGORIES IDENTIFIED BELOW, SUBMIT YOUR PROTOCOL TO THE IRB FOR EXPEDITED REVIEW. (SEE SECTION 5.3.2 FOR INFORMATION ON SUBMISSION REQUIREMENTS AND REVIEW PROCESS.)

THE FOLLOWING INFORMATION ON EXPEDITED REVIEW CATEGORIES IS FROM THE FEDERAL REGISTER (63 FR 60364-60367, NOVEMBER 9, 1998).

#### APPLICABILITY

1. RESEARCH ACTIVITIES THAT 1) PRESENT NO MORE THAN MINIMAL RISK TO HUMAN SUBJECTS AND 2) INVOLVE ONLY PROCEDURES LISTED IN ONE OR MORE OF THE FOLLOWING CATEGORIES MAY BE REVIEWED BY THE IRB THROUGH EXPEDITED REVIEW. THE ACTIVITIES LISTED SHOULD NOT BE DEEMED TO BE OF MINIMAL RISK SIMPLY BECAUSE THEY ARE INCLUDED ON THIS LIST. INCLUSION ON THIS LIST MERELY MEANS THAT THE ACTIVITY IS ELIGIBLE FOR REVIEW THROUGH THE EXPEDITED REVIEW PROCEDURE WHEN THE SPECIFIC CIRCUMSTANCES OF THE PROPOSED RESEARCH INVOLVE NO MORE THAN MINIMAL RISK TO HUMAN SUBJECTS.
2. THE CATEGORIES LISTED HEREIN APPLY REGARDLESS OF THE SUBJECT'S AGE, EXCEPT AS NOTED.
3. THE EXPEDITED REVIEW PROCEDURE MAY NOT BE USED WHERE IDENTIFICATION OF THE SUBJECTS AND/OR THEIR RESPONSES WOULD REASONABLY PLACE THEM AT RISK OF CRIMINAL OR CIVIL LIABILITY OR BE DAMAGING TO THE SUBJECTS' FINANCIAL STANDING, EMPLOYABILITY, INSURABILITY, REPUTATION OR BE STIGMATIZING, UNLESS REASONABLE AND APPROPRIATE PROTECTIONS WILL BE IMPLEMENTED SO THAT RISKS RELATED TO INVASION OF PRIVACY AND BREACH OF PRIVACY AND BREACH OF CONFIDENTIALITY ARE NO GREATER THAN MINIMAL.
4. THE EXPEDITED REVIEW PROCEDURE MAY NOT BE USED FOR CLASSIFIED RESEARCH INVOLVING HUMAN SUBJECTS.

#### RESEARCH CATEGORIES FOR EXPEDITED REVIEW

1. CLINICAL STUDIES OF DRUGS AND MEDICAL DEVICES ONLY WHEN CONDITION (A) OR (B) IS MET.
  - a. RESEARCH ON DRUGS FOR WHICH AN INVESTIGATIONAL NEW DRUG APPLICATION (21CFR312) IS NOT REQUIRED. NOTE: RESEARCH ON MARKETED DRUGS THAT SIGNIFICANTLY INCREASES RISK OR DECREASES THE ACCEPTABILITY OF RISKS ASSOCIATED WITH THE USE OF THE PRODUCT IS NOT ELIGIBLE FOR EXPEDITED REVIEW.
  - b. RESEARCH ON MEDICAL DEVICES FOR WHICH 1) AN INVESTIGATIONAL DEVICE EXEMPTION (21CFR812) IS NOT REQUIRED; OR 2) THE MEDICAL DEVICE IS CLEARED/APPROVED FOR MARKETING AND THE MEDICAL DEVICE IS BEING USED IN ACCORDANCE WITH ITS CLEARED APPROVED LABELING.
2. PROSPECTIVE COLLECTION OF BIOLOGICAL SPECIMENS FOR RESEARCH PURPOSE BY NONINVASIVE MEANS. EXAMPLES INCLUDE:
  - a. HAIR AND NAIL CLIPPINGS IN A NONDISFIGURING MANNER;
  - b. DECIDUOUS TEETH AT TIME OF EXFOLIATION OR IF ROUTINE PATIENT CARE INDICATES A NEED FOR EXTRACTION;
  - c. PERMANENT TEETH IF ROUTINE PATIENT CARE INDICATES A NEED FOR EXTRACTION;
  - d. EXCRETIA AND EXTERNAL SECRETIONS (INCLUDING SWEAT);
  - e. UNCANNULATED SALIVA COLLECTED EITHER IN AN UNSTIMULATED FASHION OR STIMULATED BY CHEWING GUM BASE OR WAS OR BY APPLYING A DILUTE CITRIC SOLUTION TO THE TONGUE;
  - f. PLACENTA REMOVED AT DELIVERY;

- g. AMNIOTIC FLUID OBTAINED AT THE TIME OF RUPTURE OF THE MEMBRANE PRIOR TO OR DURING LABOR;
  - h. SUPRA- AND SUBGINGIVAL DENTAL PLAQUE AND CALCULUS, PROVIDED THE COLLECTION PROCEDURE IS NOT MORE INVASIVE THAN ROUTINE PROPHYLACTIC TECHNIQUES;
  - i. MUCOSAL AND SKIN CELLS COLLECTED BY BUCCAL SCRAPING OR SWAB, SKIN SWAB, OR MOUTH WASHING;
  - j. SPUTUM COLLECTED AFTER SALINE MIST NEBULIZATION.
3. COLLECTION OF DATA THROUGH NONINVASIVE PROCEDURES (NOT INVOLVING GENERAL ANESTHESIA OR SEDATION) ROUTINELY EMPLOYED IN CLINICAL PRACTICE, EXCLUDING PROCEDURES INVOLVING X-RAYS OR MICROWAVES. WHERE MEDICAL DEVICES ARE EMPLOYED, THEY MUST BE CLEARED/APPROVED FOR MARKETING. STUDIES INTENDED TO EVALUATE THE SAFETY AND EFFECTIVENESS OF THE MEDICAL DEVICE ARE NOT GENERALLY ELIGIBLE FOR EXPEDITED REVIEW, INCLUDING STUDIES OF CLEARED MEDICAL DEVICES FOR NEW INDICATIONS. EXAMPLES INCLUDE:
- a. PHYSICAL SENSORS THAT ARE APPLIED EITHER TO THE SURFACE OF THE BODY OR AT A DISTANCE AND DO NOT INVOLVE INPUT OF SIGNIFICANT AMOUNTS OF ENERGY INTO THE SUBJECT OR AN INVASION OF THE SUBJECT'S PRIVACY;
  - b. WEIGHING OR TESTING SENSORY ACUITY;
  - c. MAGNETIC RESONANCE IMAGING;
  - d. ELECTROCARDIOGRAPHY, ELECTROENCEPHALOGRAPHY, THERMOGRAPHY, DETECTION OF NATURALLY OCCURRING RADIOACTIVITY, ELECTRORETINOGRAPHY, ULTRASOUND, DIAGNOSTIC INFRARED IMAGING, DOPPLER BLOOD FLOW, AND ECHOCARDIOGRAPHY;
  - e. MODERATE EXERCISE, MUSCULAR STRENGTH TESTING, BODY COMPOSITION ASSESSMENT AND FLEXIBILITY TESTING WHERE APPROPRIATE GIVEN THE AGE, WEIGHT AND HEALTH OF THE INDIVIDUAL.
4. RESEARCH INVOLVING MATERIALS (DATA, DOCUMENTS, RECORDS OR SPECIMENS) THAT HAVE BEEN COLLECTED SOLELY FOR NONRESEARCH PURPOSES (SUCH AS MEDICAL TREATMENT OR DIAGNOSIS). NOTE: SOME RESEARCH IN THIS CATEGORY MAY BE EXEMPT FROM THE DHHS REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS (SEE SECTION 5.2.1, #4). THIS LISTING REFERS ONLY TO RESEARCH THAT IS NOT EXEMPT.
5. COLLECTION OF DATA FROM VOICE, VIDEO, DIGITAL OR IMAGE RECORDINGS MADE FOR RESEARCH PURPOSES.
6. RESEARCH ON INDIVIDUAL OR GROUP CHARACTERISTICS OR BEHAVIOR (INCLUDING, BUT NOT LIMITED TO, RESEARCH ON PERCEPTION, COGNITION, MOTIVATION, IDENTIFY, LANGUAGE, COMMUNICATION, CULTURAL BELIEFS OR PRACTICES AND SOCIAL BEHAVIOR) OR RESEARCH EMPLOYING SURVEY, INTERVIEW, ORAL HISTORY, FOCUS GROUP, PROGRAM EVALUATION, HUMAN FACTORS EVALUATION OR QUALITY ASSURANCE METHODOLOGIES. NOTE: SOME RESEARCH IN THIS CATEGORY MAY BE EXEMPT FROM THE DHHS REGULATIONS FOR THE PROTECTION OF HUMAN SUBJECTS (SEE SECTION 5.2.1, #2 AND #3). THIS LISTING REFERS ONLY TO RESEARCH THAT IS NOT EXEMPT.

### 5.2.3 FULL BOARD REVIEW

IF YOUR PROJECT INVOLVES HUMAN SUBJECTS AND DOES NOT QUALIFY FOR EXEMPT STATUS OR EXPEDITED REVIEW, FULL BOARD REVIEW IS REQUIRED. IF FUNDING SUPPORT IS REQUESTED FROM THE FEDERAL GOVERNMENT AND HUMAN SUBJECT RESEARCH IS INVOLVED, FULL BOARD REVIEW IS REQUIRED. ALL EXPEDITED REVIEWS THAT ARE NOT APPROVED WILL BE SUBJECT TO FULL BOARD FOR FINAL DETERMINATION. IN ADDITION, THE IRB CAN REQUEST A FULL BOARD REVIEW OF ANY PROTOCOL THAT

HAS BEEN APPROVED THROUGH THE EXPEDITED REVIEW PROCESS. (SEE SECTION 5.3.3 FOR INFORMATION ON SUBMISSION REQUIREMENTS AND REVIEW PROCESS.)

### **5.3 SUBMISSION REQUIREMENTS AND REVIEW PROCESS**

ONCE YOU HAVE DETERMINED WHICH TYPE OF REVIEW IS REQUIRED FOR YOUR PROJECT (SECTION 5.2), PREPARE YOUR SUBMISSION TO THE IRB ACCORDINGLY, AS DESCRIBED BELOW. THE REVIEW PROCESS FOR EACH TYPE OF IRB REVIEW IS ALSO DESCRIBED IN THIS SECTION.

THROUGHOUT THE REVIEW PROCESS AND SUBSEQUENT ADMINISTRATION OF THE PROJECT, RESEARCH INVESTIGATORS ARE RESPONSIBLE FOR COMPLYING WITH ALL IRB DECISIONS, CONDITIONS AND REQUIREMENTS. IF REVISIONS IN THE PROPOSED PROTOCOL OR INFORMED CONSENT DOCUMENT ARE REQUIRED BY THE IRB, THESE REVISIONS MUST BE SUBMITTED TO AND APPROVED BY THE IRB BEFORE THE RESEARCH PROJECT CAN BEGIN.

#### **5.3.1 DETERMINATION OF EXEMPT STATUS**

##### **SUBMISSION REQUIREMENTS**

IF YOUR PROJECT QUALIFIES FOR EXEMPT STATUS, SEND AN ELECTRONIC VERSION OF EACH OF THE FOLLOWING DOCUMENTS AS ATTACHMENTS IN AN EMAIL MESSAGE REQUESTING EXEMPT REVIEW, TO [IRB@DRAKE.EDU](mailto:IRB@DRAKE.EDU):

- A COMPLETED "APPLICATION FOR DETERMINATION OF EXEMPT STATUS" FORM
- PROTOCOL OR STUDY DESIGN, INCLUDING LIST OF REFERENCES
- QUESTIONNAIRES/SURVEYS
- INTERVIEW QUESTIONS
- OTHER MATERIALS AS NEEDED TO ALLOW A THOROUGH REVIEW

##### **REVIEW PROCESS**

AN IRB DESIGNATE WILL DETERMINE WHETHER A RESEARCH PROTOCOL QUALIFIES FOR EXEMPTION FROM COVERAGE UNDER 45CFR46.101 OR 21CFR56.104. AFTER YOU HAVE SUBMITTED YOUR APPLICATION, YOUR SUBMISSION WILL BE REVIEWED AND YOU WILL BE NOTIFIED IN WRITING OF THE OFFICIAL DETERMINATION WITHIN APPROXIMATELY FOURTEEN (14) DAYS. IF IT IS DETERMINED THAT YOUR PROJECT DOES NOT QUALIFY FOR EXEMPT STATUS, YOU WILL BE ASKED TO SUBMIT YOUR PROTOCOL FOR EITHER EXPEDITED OR FULL BOARD REVIEW, AS APPROPRIATE.

EXEMPT RESEARCH MAY BE SUBJECT TO CONTINUING IRB REVIEW (SEE SECTION 5.2.5)

#### **5.3.2 EXPEDITED REVIEW**

##### **SUBMISSION REQUIREMENTS**

IF YOUR PROJECT QUALIFIES FOR EXPEDITED STATUS SEND AN ELECTRONIC VERSION OF EACH OF THE FOLLOWING DOCUMENTS IN AN E-MAIL MESSAGE REQUESTING EXPEDITED REVIEW TO [IRB@DRAKE.EDU](mailto:IRB@DRAKE.EDU):

- A COMPLETED "APPLICATION FOR EXPEDITED REVIEW" FORM
- PROTOCOL OR STUDY DESIGN, INCLUDING LIST OF REFERENCES
- INFORMED CONSENT DOCUMENT
- ASSENT DOCUMENT(S), IF APPLICABLE
- PARENTAL CONSENT DOCUMENT, IF APPLICABLE
- QUESTIONNAIRES/SURVEYS
- INTERVIEW QUESTIONS
- OTHER MATERIAL AS NEEDED TO ALLOW A THOROUGH REVIEW
- ADVERTISING OR INFORMATION FLYERS, BROCHURES OR MATERIALS, IF ANY
- IF THE RESEARCH PROJECT BEING SUBMITTED HAS BEEN PREVIOUSLY REVIEWED BY A LOCAL OR INSTITUTIONAL IRB OTHER THAN THE DRAKE UNIVERSITY IRB, A COPY OF THE APPROVAL OR DISAPPROVAL NOTIFICATION FROM THAT IRB

## REVIEW PROCESS

AFTER YOU HAVE SUBMITTED YOUR APPLICATION FOR EXPEDITED REVIEW, YOUR SUBMISSION WILL BE REVIEWED BY THE IRB CHAIR AND/OR ONE OR MORE EXPERIENCED IRB MEMBERS DESIGNATED BY THE CHAIR. THE REVIEWER(S) MAY EXERCISE ALL OF THE AUTHORITIES OF THE IRB EXCEPT THAT THE REVIEWER(S) MAY NOT DISAPPROVE THE RESEARCH. THE REVIEWER(S) WILL COMPLETE THE REVIEW WITHIN 2-3 WEEKS AND WILL MAKE ONE OF THE FOLLOWING DETERMINATIONS:

- APPROVED
- APPROVED PENDING MODIFICATIONS
- REQUIRES FULL BOARD REVIEW

YOU WILL BE NOTIFIED IN WRITING OF THE DETERMINATION. IF YOU ARE ASKED TO MAKE CHANGES, ALLOW ONE WEEK FOR THE IRB TO RESPOND ONCE YOU HAVE SUBMITTED THE REQUESTED CHANGES.

ACTIVITIES APPROVED THROUGH THE EXPEDITED REVIEW PROCESS ARE RECORDED IN THE IRB MEETING MINUTES, WHICH ARE DISTRIBUTED TO THE FULL IRB PRIOR TO THE NEXT REGULARLY SCHEDULED IRB MEETING. AT A CONVENED IRB MEETING, ANY MEMBER MAY REQUEST THAT AN ACTIVITY THAT HAS BEEN APPROVED UNDER THE EXPEDITED REVIEW PROCEDURE BE REVIEWED BY THE FULL IRB IN ACCORDANCE WITH FULL BOARD REVIEW PROCEDURES. A VOTE OF THE MEMBERS SHALL BE TAKEN CONCERNING THE REQUEST AND THE MAJORITY SHALL DECIDE THE ISSUE. FULL IRB DECISION SHALL SUPERCEDE ANY EXPEDITED REVIEW DECISIONS.

### 5.3.3 FULL BOARD REVIEW

#### SUBMISSION REQUIREMENTS

IF YOUR PROJECT REQUIRES FULL-BOARD REVIEW, THEN AT LEAST ONE WEEK PRIOR TO THE NEXT SCHEDULED FULL-BOARD IRB MEETING, SEND AN ELECTRONIC VERSION OF EACH OF THE FOLLOWING DOCUMENTS AS ATTACHMENTS IN AN EMAIL MESSAGE REQUESTING FULL-BOARD REVIEW TO IRB@DRAKE.EDU:

- A COMPLETED "APPLICATION FOR FULL BOARD REVIEW" FORM
- PROTOCOL OR STUDY DESIGN, INCLUDING LIST OF REFERENCES

- **INFORMED CONSENT DOCUMENT**
- **ASSENT DOCUMENT(S), IF APPLICABLE**
- **PARENTAL CONSENT DOCUMENT, IF APPLICABLE**
- **QUESTIONNAIRES/SURVEYS**
- **INTERVIEW QUESTIONS**
- **OTHER MATERIAL AS NEEDED TO ALLOW A THOROUGH REVIEW**
- **ADVERTISING OR INFORMATION FLYERS, BROCHURES OR MATERIALS, IF ANY**
- **ANY OTHER DOCUMENTS THAT WILL BE GIVEN TO RESEARCH SUBJECTS**
- **IF THE RESEARCH PROJECT BEING SUBMITTED HAS BEEN PREVIOUSLY REVIEWED BY A LOCAL OR INSTITUTIONAL IRB OTHER THAN THE DRAKE UNIVERSITY IRB, A COPY OF THE APPROVAL OR DISAPPROVAL NOTIFICATION FROM THAT IRB**

## **REVIEW PROCESS**

**IF YOUR PROJECT REQUIRES FULL-BOARD REVIEW, YOU WILL NEED TO SUBMIT YOUR MATERIALS ONE WEEK PRIOR TO THE SCHEDULED FULL-BOARD MEETING AT WHICH YOU WISH TO HAVE YOUR PROPOSAL CONSIDERED. YOU SHOULD ALSO CONTACT THE IRB CHAIR IF YOU WISH TO PERSONALLY PRESENT YOUR PROPOSAL AT THAT MEETING. IN SOME CASES, THE CHAIR MIGHT CONTACT A PRINCIPAL INVESTIGATOR TO ARRANGE FOR THE PI TO ATTEND THE MEETING IN ORDER TO ADDRESS QUESTIONS OR CONCERNS ABOUT A PROPOSAL. IRB MEETINGS ONLY OCCUR MONTHLY, SO IT IS IMPORTANT TO MAKE SUBMISSIONS ON TIME.**

## **IRB REVIEW RESPONSIBILITIES**

**THE IRB SHALL HAVE THE RESPONSIBILITY TO REVIEW AND AUTHORITY TO APPROVE, REQUIRE MODIFICATION IN, TABLE, OR DISAPPROVE ALL RESEARCH ACTIVITIES. EACH BOARD MEMBER WILL STUDY THE PROTOCOL UNDER REVIEW TO ENSURE THAT NO UNNECESSARY OR UNACCEPTABLE RISKS ARE PRESENT AND THAT ADEQUATE PRECAUTIONS ARE PROVIDED FOR RESEARCH SUBJECTS. IRB MEMBERS SHALL HAVE ACCESS TO ALL DOCUMENTS RELATING TO THE RESEARCH PROTOCOL, INCLUDING ALL INFORMATION PROVIDED BY THE RESEARCH INVESTIGATOR AND OTHERS WITH A VESTED INTEREST IN THE RESEARCH (I.E. OTHER INSTITUTION, PHARMACEUTICAL COMPANY OR CORPORATION, ETC., AS APPLICABLE)**

## **PRESENTING AT THE IRB MEETING**

**THE PRINCIPAL INVESTIGATOR OR CO-INVESTIGATOR MAY BE ASKED TO EXPLAIN THE PURPOSE FOR, RISKS OF, AND ALTERNATIVES TO THE PROPOSED RESEARCH, INCLUDING SUBJECT SELECTION AND EXCLUSION CRITERIA AT THE IRB MEETING IRB MEMBERS ARE THEN ENCOURAGED TO ASK CLARIFYING QUESTIONS CONCERNING THE PROTOCOL AND CONSENT PROCESS. THE INVESTIGATOR IS DISMISSED FROM THE INQUIRY AND ANY IRB MEMBERS WHO HAVE A CONFLICT OF INTEREST WITH THE PROJECT ARE EXCUSED FROM THE MEETING.**

**IRB ACTION IRB MEMBERS WILL MAKE DETERMINATIONS REGARDING THE CATEGORY OF RISK, RISK AND BENEFIT ISSUES AND WHETHER INFORMED CONSENT PROCEDURES ARE ADEQUATE. THE IRB TAKES ONE OF THE FOLLOWING ACTIONS:**

- **APPROVAL: THE IRB INFORMS THE PRINCIPAL INVESTIGATOR OF ITS APPROVAL ALONG WITH A COPY OF THE APPROVED INFORMED CONSENT DOCUMENT WITH THE IRB DATE**

**NOTED ON EACH PAGE. THE PRINCIPAL INVESTIGATOR MAY BEGIN THE RESEARCH PROJECT UPON RECEIPT OF IRB WRITTEN APPROVAL.**

- **APPROVAL SUBJECT TO MODIFICATION: THE IRB SHALL PROVIDE WRITTEN NOTICE TO THE PRINCIPAL INVESTIGATOR OF ITS APPROVAL SUBJECT TO MODIFICATION, IDENTIFYING SPECIFIC AREAS OF MODIFICATION REQUIRED. THE PRINCIPAL INVESTIGATOR MUST PROVIDE THE IRB WITH A REVISED PROTOCOL AND/OR INFORMED CONSENT DOCUMENT INCORPORATING THE MODIFICATIONS. THE IRB CHAIR OR DESIGNATED MEMBER OF THE IRB SHALL REVIEW THE REVISED PROTOCOL AND/OR CONSENT DOCUMENT WITHIN ONE WEEK OF RECEIPT OF THE REVISED DOCUMENTS. THE IRB REVIEWER WILL THEN PROVIDE WRITTEN NOTICE TO THE PRINCIPAL INVESTIGATOR GRANTING FINAL APPROVAL OF THE PROTOCOL IF THE REQUIRED MODIFICATIONS HAVE BEEN MADE. THE NOTICE OF FINAL APPROVAL WILL INCLUDE A COPY OF THE APPROVED INFORMED CONSENT DOCUMENT WITH THE IRB DATE NOTED ON EACH PAGE, IF APPROPRIATE. THE PRINCIPAL INVESTIGATOR MAY BEGIN THE RESEARCH PROJECT UPON RECEIPT OF IRB WRITTEN APPROVAL.**
- **TABLED: IF THE IRB REQUIRES ADDITIONAL INFORMATION AND HAS A CONCERN REGARDING THE PROPOSED RESEARCH PROJECT, THE PRINCIPAL INVESTIGATOR WILL BE NOTIFIED OF THE IRB DECISION AND WILL BE ALLOWED TO ADDRESS THE ISSUE AT THE NEXT REGULARLY SCHEDULED IRB MEETING.**
- **DISAPPROVAL: IF THE IRB DISAPPROVES A RESEARCH PROTOCOL, THE IRB SHALL PROVIDE TO THE PRINCIPAL INVESTIGATOR, IN WRITING, THE REASONS FOR THE IRB DECISION AND AN OPPORTUNITY FOR THE PRINCIPAL INVESTIGATOR TO APPEAL THE DECISION.**

**APPEAL PROCESS THE APPEAL PROCESS CONSISTS OF RESUBMISSION OF THE PROJECT TO THE IRB, WITH OR WITHOUT MODIFICATION, ACCOMPANIED BY A LETTER FROM THE PRINCIPAL INVESTIGATOR INDICATING WHY HE OR SHE FEELS THE PROJECT SHOULD BE AGAIN CONSIDERED BY THE IRB.**

**ALL ACTIONS TAKEN ARE RECORDED IN THE MINUTES. MINUTES OF THE IRB MEETINGS ARE FORWARDED TO IRB MEMBERS AND ARE AVAILABLE TO THE PROVOST OR OTHER INSTITUTIONAL OFFICIALS OR ADMINISTRATORS. SPECIFIC LETTERS OF INSTRUCTION BASED ON THE IRB REVIEW ARE SENT TO EACH PRINCIPAL INVESTIGATOR.**

#### **5.3.4 CHANGES TO PREVIOUSLY APPROVED PROJECTS**

##### **SUBMISSION REQUIREMENTS**

**THE PRINCIPAL INVESTIGATOR SHALL SUBMIT AS ATTACHMENTS TO AN EMAIL MESSAGE TO IRB@DRAKE.EDU:**

- **A LETTER THAT SUMMARIZES THE CHANGES AND INDICATES THEIR LOCATION IN THE PROTOCOL AND/OR INFORMED CONSENT DOCUMENT**
- **AN ELECTRONIC COPY OF THE REVISED PROTOCOL AND INFORMED CONSENT DOCUMENT. ANY CHANGES IN THE LANGUAGE OF THE INFORMED CONSENT MUST BE NOTED**
- **A CLEAN COPY OF THE REVISED INFORMED CONSENT DOCUMENT (TO BE DATED BY THE IRB UPON APPROVAL)**
- **A COPY OF ANY REVISED ADVERTISING MATERIAL**

- **A COPY OF ANY OTHER RELEVANT DOCUMENTATION**

#### **REVIEW PROCESS**

- **EXPEDITED REVIEW—THE IRB MAY USE THE EXPEDITED REVIEW PROCEDURE TO REVIEW MINOR CHANGES TO PREVIOUSLY APPROVED RESEARCH PROJECTS DURING THE PERIOD FOR WHICH APPROVAL WAS AUTHORIZED.**
- **FULL BOARD REVIEW—AMENDMENTS, ADDENDA, SUPPLEMENTS, OR OTHER CHANGES THAT DO NOT QUALIFY FOR EXPEDITED REVIEW SHALL BE REVIEWED AS SET FORTH IN THE PRECEDING EXPLANATION FOR FULL BOARD REVIEW.**

#### **5.3.5 CONTINUING REVIEW OF ONGOING PROJECTS**

##### **SUBMISSION REQUIREMENTS**

**THE RESEARCH INVESTIGATOR IS SOLELY RESPONSIBLE FOR TIMELY SUBMISSION OF CONTINUING REVIEW MATERIALS. THE IRB WILL SEND A COURTESY REMINDER AND A REPORTING FORM FOR CONTINUING REVIEW OR PROJECT TERMINATION TO THE PRINCIPAL INVESTIGATOR LISTED ON THE PROJECT PRIOR TO THE EXPIRATION DATE OF THE CURRENT APPROVAL PERIOD. FOR PROJECTS PREVIOUSLY APPROVED BY EXPEDITED OR FULL BOARD REVIEW, CONTINUING REVIEW MATERIALS SHOULD BE SUBMITTED AT LEAST ONE MONTH PRIOR TO THE EXPIRATION DATE KEEPING IN MIND THE DATE SCHEDULED FOR THE NEXT IRB CONVENED MEETING. THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR SUBMITTING THE FOLLOWING DOCUMENTS TO THE IRB FOR CONTINUING REVIEW. THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR SUBMITTING THE FOLLOWING DOCUMENTS AS ATTACHMENTS TO AN EMAIL MESSAGE TO IRB@DRAKE.EDU FOR CONTINUING REVIEW.**

- **A COMPLETED "CONTINUING REVIEW OR PROJECT TERMINATION" FORM**
- **A CLEAN COPY OF THE CURRENT CONSENT/ASSENT DOCUMENT, IF SUBJECTS ARE STILL ENROLLED IN THE STUDY**
- **IF RESEARCH SUBJECTS WERE ENROLLED IN THE LAST APPROVAL PERIOD, COPIES OF ASSENT/CONSENT FORMS AVAILABLE FOR IRB REVIEW UPON REQUEST.**

**FAILURE TO COMPLETE AND SUBMIT THE CONTINUING REVIEW FORM IN THE TIME STIPULATED WILL LEAD TO CORRECTIVE ACTION RESULTING IN THE RESEARCH PROJECT BEING CLOSED. IF THIS OCCURS, THE RESEARCH INVESTIGATOR WILL HAVE TO RESUBMIT A NEW APPLICATION FOR FULL BOARD REVIEW AND RECEIVE IRB APPROVAL FOR THAT SUBMISSION BEFORE CONTINUING THE RESEARCH.**

##### **REVIEW PROCESS**

**THE IRB USES THE SAME CRITERIA FOR CONTINUING REVIEW AS IT DOES FOR INITIAL REVIEW. THE IRB CONDUCTS CONTINUING REVIEW PROJECTS PREVIOUSLY APPROVED BY EXPEDITED OR FULL BOARD REVIEW AND MAY CONDUCT REVIEW OF EXEMPT PROJECTS.**

**CONTINUING REVIEW OF A RESEARCH PROJECT MAY NOT BE CONDUCTED THROUGH AN EXPEDITED REVIEW UNLESS:**

- **THE PROJECT WAS ELIGIBLE FOR, AND INITIALLY REVIEWED BY AN EXPEDITED PROCEDURE, OR**
- **THE STUDY HAS CHANGED SUCH THAT THE ONLY ACTIVITIES REMAINING ARE ELIGIBLE FOR EXPEDITED REVIEW**



### **5.3.6 SUBMITTING A PROJECT PREVIOUSLY REVIEWED BY ONE IRB TO A DIFFERENT IRB**

#### **PREVIOUSLY DISAPPROVED BY DRAKE UNIVERSITY IRB**

**IF THE DRAKE UNIVERSITY IRB DISAPPROVES A RESEARCH PROJECT THAT IS SUBSEQUENTLY SUBMITTED TO ONE OR MORE OTHER IRBs, THE DRAKE IRB DISAPPROVAL MUST BE MADE KNOWN BY THE PRINCIPAL INVESTIGATOR TO THE OTHER IRB.**

#### **PREVIOUSLY REVIEWED BY AN IRB OTHER THAN DRAKE UNIVERSITY IRB**

**IF YOU ARE SUBMITTING A PROTOCOL TO THE DRAKE UNIVERSITY IRB THAT HAS BEEN REVIEWED BY ONE OR MORE OTHER IRBs, THEN YOU MUST PROVIDE THE DRAKE IRB WITH COPIES OF THE APPROVAL OR DISAPPROVAL LETTER(S) ALONG WITH YOUR INITIAL SUBMISSION.**

### **5.4 PROVOST REVIEW OPTION**

**THE INSTITUTIONAL OFFICIAL (THE PROVOST OF DRAKE UNIVERSITY) MAY FURTHER REVIEW AND/OR DISAPPROVE RESEARCH PROJECTS PREVIOUSLY APPROVED BY THE IRB, WITH THE FOLLOWING EXCEPTION: THE PROVOST MAY NOT APPROVE ANY RESEARCH PROJECT THAT HAS BEEN PREVIOUSLY DISAPPROVED BY THE IRB.**

### **5.5 IRB SUSPENSION OR TERMINATION OF A PROTOCOL**

**THE IRB HAS THE AUTHORITY TO SUSPEND OR TERMINATE A PROTOCOL WHEN 1) THE PROTOCOL IS NOT CONDUCTED IN ACCORDANCE WITH IRB REQUIREMENTS AND/OR 2) THERE IS UNEXPECTED SERIOUS HARM TO SUBJECTS. THE IRB SHALL PROMPTLY NOTIFY THE PRINCIPAL INVESTIGATOR, INSTITUTIONAL OFFICIAL, AND, IF APPROPRIATE, DHHS AND OTHER INVOLVED FEDERAL DEPARTMENT/AGENCY HEADS OR SPONSOR WHEN IT SUSPENDS OR TERMINATES A RESEARCH PROJECT.**

## **6.0 PREPARING FOR IRB REVIEW**

### **6.1 PROTOCOL PREPARATION REQUIREMENTS**

**RESEARCH INVESTIGATORS SHALL PREPARE A PROTOCOL GIVING A COMPLETE DESCRIPTION OF THE PROPOSED RESEARCH INVOLVING HUMAN SUBJECTS. ALL PROTOCOLS SHALL CONTAIN PROVISIONS FOR THE ADEQUATE PROTECTION AND RIGHTS AND WELFARE OF PROSPECTIVE RESEARCH SUBJECTS AND FOR ENSURING THAT PERTINENT LAWS AND REGULATIONS ARE OBSERVED.**

**THE PROTOCOL SHALL BE DETAILED AND INCLUDE THE FOLLOWING INFORMATION:**

- **DESCRIBE THE CHARACTERISTICS OF THE SUBJECT POPULATION, SUCH AS THEIR ANTICIPATED NUMBER, AGE RANGES, SEX, ETHNIC BACKGROUND AND/OR HEALTH STATUS. IDENTIFY THE CRITERIA FOR INCLUSION OR EXCLUSION.**
- **EXPLAIN THE RATIONALE FOR THE USE OF SPECIAL CLASSES OF SUBJECTS, SUCH AS CHILDREN, PREGNANT WOMEN AND FETUSES, INSTITUTIONALIZED MENTALLY DISABLED PERSONS, PRISONERS OR OTHERS WHO ARE LIKELY TO BE VULNERABLE. (SEE SECTION 9.0, VULNERABLE RESEARCH POPULATIONS)**
- **DESCRIBE THE PURPOSE OF THE STUDY, THE RESULTS OF PREVIOUS RELATED RESEARCH, STUDY DESIGN, THE PROCEDURES TO BE PERFORMED AND, IF APPROPRIATE, THE IDENTITY OF THE SPONSOR**

- **DESCRIBE PLANS FOR THE RECRUITMENT OF SUBJECTS AND THE CONSENT PROCEDURES TO BE FOLLOWED, INCLUDING THE CIRCUMSTANCES UNDER WHICH CONSENT WILL BE SOUGHT AND OBTAINED, WHO WILL SEEK IT, THE NATURE OF THE INFORMATION TO BE PROVIDED TO PROSPECTIVE SUBJECTS AND THE METHOD OF DOCUMENTING CONSENT. (SEE SECTION 7.0, INFORMED CONSENT) STATE IF THE IRB HAS AUTHORIZED A MODIFICATION OR WAIVER OF CONSENT OR OF THE REQUIREMENT FOR DOCUMENTATION OF CONSENT.**
- **DESCRIBE ANY POTENTIAL RISKS (PHYSICAL, PSYCHOLOGICAL, SOCIAL, LEGAL OR OTHER) AND ASSESS THEIR LIKELIHOOD, SERIOUSNESS AND MANAGEMENT.**
- **DESCRIBE THE PROCEDURES FOR PROTECTING AGAINST OR MINIMIZING ANY POTENTIAL RISKS, INCLUDING RISKS TO CONFIDENTIALITY AND ASSESS THEIR LIKELY EFFECTIVENESS. WHERE APPROPRIATE, DISCUSS PROVISIONS FOR INSURING PROFESSIONAL INTERVENTION IN THE CASE OF ADVERSE EFFECTS TO THE SUBJECTS AND FOR MONITORING THE DATA COLLECTED TO ENSURE THE WELFARE OF THE SUBJECTS.**
- **DISCUSS WHY THE RISKS TO SUBJECTS ARE REASONABLE IN RELATION TO THE ANTICIPATED BENEFITS TO SUBJECTS AND IN RELATION TO THE IMPORTANCE OF THE KNOWLEDGE THAT MAY REASONABLY BE EXPECTED TO RESULT.**
- **IDENTIFY THE COSTS TO RESEARCH SUBJECTS AND/OR ANY THIRD PARTY PAYERS. WHERE APPLICABLE, DESCRIBE THE COMPENSATION OR BENEFIT(I.E., EXTRA CREDIT FOR STUDENTS) TO BE PROVIDED TO RESEARCH SUBJECTS FOR PARTICIPATION.**
- **DESCRIBE THE TIMELINE AND PROCEDURE FOR DISPOSING OF OR DESTROYING ANY EASILY IDENTIFIABLE INFORMATION RECEIVED FROM RESEARCH SUBJECTS.**

## **6.2 SPECIAL RESEARCH ISSUES**

**THIS SECTION PRESENTS AN OVERVIEW OF RESEARCH ISSUES THAT REQUIRE SPECIAL CONSIDERATION AND MUST BE ADDRESSED PRIOR TO IRB REVIEW.**

### **6.2.1 USE OF PROTECTED HEALTH INFORMATION FOR RESEARCH**

**THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA) OF 1996 ("PRIVACY RULE") ESTABLISHES THE CONDITIONS UNDER WHICH PROTECTED HEALTH INFORMATION (PHI) MAY BE USED OR DISCLOSED BY COVERED ENTITIES OR THEIR "BUSINESS ASSOCIATES" FOR RESEARCH PURPOSES.**

**THE PRIVACY RULE DEFINES THE MEANS BY WHICH HUMAN RESEARCH SUBJECTS ARE INFORMED OF HOW MEDICAL INFORMATION (WRITTEN, ELECTRONIC OR VERBAL) ABOUT THEM WILL BE USED OR DISCLOSED AND THEIR RIGHTS WITH REGARD TO GAINING ACCESS TO INFORMATION ABOUT THEMSELVES WHEN SUCH INFORMATION IS HELD BY ENTITIES. WHERE RESEARCH IS CONCERNED, THE PRIVACY RULE PROTECTS THE PRIVACY OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION, WHILE AT THE SAME TIME, ENSURING THAT RESEARCHERS CONTINUE TO HAVE ACCESS TO MEDICAL INFORMATION NECESSARY TO CONDUCT RESEARCH. RESEARCH INFORMATION PROTECTED BY THE PRIVACY RULE INCLUDES:**

- **ALL RESEARCH, REGARDLESS OF FUNDING SOURCE, INVOLVING/ASSOCIATED WITH TREATMENT (BECAUSE PHI IS CREATED)**
- **MEDICAL RECORDS REVIEW**
- **MEDICAL REGISTRY REVIEW**
- **RESEARCH OF IDENTIFIABLE OR CODED DATA (I.E., RESEARCH INVOLVING DATA THAT HAS BEEN CODED WHERE RESEARCHER DOES THE CODING)**

**ALTHOUGH A RESEARCH INVESTIGATOR WHO HOLDS A PH.D. AS A GENERAL RULE IS NOT SUBJECT TO HIPAA (NOT HEALTH CARE PROVIDERS) THERE ARE EXCEPTIONS (POSSIBLE EXCEPTION: A PH.D. WORKING OUT OF A LAB WHO PROVIDES FEEDBACK TO SUBJECTS REGARDING TESTING). BECAUSE OF THE AMBIGUITY OF SUCH EXCEPTIONS, THE RESEARCH INVESTIGATOR MUST IN ADDITION TO RECEIVING INFORMED CONSENT FROM THE HUMAN SUBJECT PARTICIPANTS PROVIDE WRITTEN DOCUMENTATION TO THE IRB THAT:**

- **USE OR DISCLOSURE IS SOUGHT SOLELY TO REVIEW PHI AS NECESSARY TO PREPARE A RESEARCH PROTOCOL OR FOR SIMILAR PURPOSES PREPARATORY TO RESEARCH**
- **NO PHI IS TO BE REMOVED FROM THE ENTITY OR THE CUSTODY OF THE RESEARCH INVESTIGATOR IN THE COURSE OF THE REVIEW**
- **THE PHI FOR WHICH USE OR ACCESS IS SOUGHT IS NECESSARY FOR RESEARCH PURPOSES**

**THE OFFICE FOR CIVIL RIGHTS (DHHS) IS CHARGED WITH ENFORCEMENT OF HIPAA AND THE REVIEW OF ALL PHI COMPLIANCE.**

### **6.2.2 GENDER DIFFERENCES IN CLINICAL EVALUATION OF DRUGS**

**ON JULY 22, 1993, FDA PUBLISHED IN THE FEDERAL REGISTER "GUIDELINE FOR THE STUDY AND EVALUATION OF GENDER DIFFERENCES IN CLINICAL EVALUATION OF DRUGS." (58 FR 39406, JULY 22, 1993) THIS GUIDELINE PRESENTED TWO MAJOR CHANGES IN FDA REGULATIONS. FIRST THE GUIDELINE LIFTS THE RESTRICTION ON THE PARTICIPATION OF WOMEN OF CHILDBEARING POTENTIAL IN EARLY CLINICAL TRIALS, INCLUDING CLINICAL PHARMACOLOGY STUDIES AND EARLY THERAPEUTIC STUDIES. SECOND, THE GUIDELINE STATES THAT SPONSORS SHOULD COLLECT GENDER-RELATED DATA DURING RESEARCH AND DEVELOPMENT AND SHOULD ANALYZE THE DATA FOR GENDER EFFECTS IN ADDITION TO OTHER VARIABLES SUCH AS AGE AND RACE. IN RESPONSE TO THIS GUIDELINE AND TO ENSURE ADEQUATE PROTECTION OF WOMEN IN RESEARCH STUDIES OR EARLY CLINICAL TRIALS, THE IRB WILL CONSIDER THE FOLLOWING IN ITS REVIEW OF BOTH DRUG/BIOLOGIC PRODUCT AND DEVICE PROTOCOLS:**

- **WOMEN OF CHILDBEARING POTENTIAL: WOMEN OF CHILDBEARING POTENTIAL MAY ENTER RESEARCH STUDIES OR LIMITED CLINICAL TRIALS. CLINICAL TRIAL PROTOCOLS SHOULD INCLUDE PROVISIONS FOR TESTING FOR PREGNANCY AS WELL AS TO MEDICALLY ACCEPTABLE METHODS OF BIRTH CONTROL.**
- **PHARMACOKINETIC ISSUES: THREE SPECIFIC PHARMACOKINETIC ISSUES THAT SHOULD BE CONSIDERED IN SUCH A PROTOCOL ARE:**
  - **EFFECT OF MENSTRUAL STATUS ON THE DRUG'S PHARMACOKINETICS, INCLUDING BOTH COMPARISONS OF PRE-MENOPAUSAL AND POSTMENOPAUSAL SUBJECTS AND CONTINUATION OF WITHIN CYCLE CHANGES**
  - **EFFECT OF EXOGENOUS HORMONAL THERAPY INCLUDING ORAL CONTRACEPTION**
  - **EFFECT OF THE TEST ARTICLE ON THE PHARMACOKINETICS OF ORAL CONTRACEPTIVES**

**WHEN PRECLINICAL TERATOLOGY AND REPRODUCTIVE TOXICOLOGY STUDIES HAVE NOT BEEN COMPLETED PRIOR TO INITIAL HUMAN STUDIES, SUBJECTS SHOULD BE INFORMED OF THIS INCOMPLETE DATA IN THE INFORMED CONSENT DOCUMENT AS WELL AS THE POTENTIAL EFFECTS OF THE TEST ARTICLE ON CONCEPTION AND FETAL DEVELOPMENT. ANY NEW PERTINENT INFORMATION ARISING FROM PRECLINICAL STUDIES AS WELL AS ANY NEW CLINICAL DATA THAT EMERGE REGARDING GENERAL SAFETY AND EFFECTIVENESS (INCLUDING GENDER DIFFERENCES) SHOULD BE PROVIDED TO SUBJECTS AND THE INFORMED CONSENT DOCUMENT SHOULD BE UPDATED, WHEN APPROPRIATE.**

### **6.2.3 GENETIC RESEARCH**

**BECAUSE OF THE SPECIFIC ETHICAL, REGULATORY AND PUBLIC RELATIONS CONCERNS ASSOCIATED WITH RESEARCH WITH GENETIC MATERIAL, RESEARCH INVESTIGATORS SHOULD REVIEW AND BE FAMILIAR WITH ALL APPLICABLE REGULATIONS PRIOR TO SUBMITTING TO THE IRB ANY PROJECT INVOLVING GENETIC RESEARCH, INCLUDING THE COLLECTION AND/OR USE OF SAMPLES FOR DNA ANALYSIS OR ESTABLISHMENT OF CELL LINES, WITH OR WITHOUT LONG-TERM STORAGE.**

### **6.2.4 STUDIES INVOLVING INVESTIGATIONAL NEW DRUGS**

**IF THE RESEARCH STUDY INVOLVES AN INVESTIGATIONAL NEW DRUG, OR A MARKETED DRUG THAT IS BEING USED FOR AN INDICATION NOT IN THE APPROVED LABELING, THE RESEARCH INVESTIGATOR MUST FOLLOW THE REQUIREMENTS OF FDA'S INVESTIGATIONAL NEW DRUG APPLICATION (IND) REGULATION (21CFR312). THE IRB WILL NOT REVIEW ANY PROTOCOL INVOLVING AN INVESTIGATIONAL NEW DRUG WITHOUT AUTHORIZATION FROM FDA.**

### **6.2.5 USE OF BIOHAZARDOUS MATERIALS**

**ALTHOUGH NOT PRESENTLY ACTIVE AT DRAKE UNIVERSITY, ANY RESEARCH INVOLVING THE USE OF BIOHAZARDOUS MATERIALS (RECOMBINANT DNA AND/OR INFECTIOUS BIOLOGICAL AGENTS) AND HUMAN SUBJECTS MUST BE REVIEWED AND APPROVED BY THE UNIVERSITY BIOSAFETY OFFICER, ENVIRONMENTAL HEALTH AND SAFETY OFFICER AND/OR PROVOST PRIOR TO REVIEW BY THE IRB. A COPY OF ANY APPROVAL OR EXEMPTION MUST BE PROVIDED TO THE IRB BEFORE ANY REVIEW CAN BEGIN.**

### **6.2.6 USE OF RADIOISOTOPES, RADIATION, AND RADIOACTIVE DRUGS**

**ALTHOUGH NOT PRESENTLY ACTIVE AT DRAKE UNIVERSITY, ANY RESEARCH INVOLVING THE USE OF RADIOISOTOPES, RADIATION AND RADIOACTIVE DRUGS AND HUMAN SUBJECTS MUST BE REVIEWED AND APPROVED BY THE UNIVERSITY RADIATION OFFICER, ENVIRONMENTAL HEALTH AND SAFETY OFFICER AND/OR PROVOST PRIOR TO REVIEW BY THE IRB. A COPY OF ANY APPROVAL OR EXEMPTION MUST BE PROVIDED TO THE IRB BEFORE ANY REVIEW CAN BEGIN.**

### **6.2.7 STUDIES INVOLVING INVESTIGATIONAL NEW DEVICES**

**ALTHOUGH NOT PRESENTLY ACTIVE AT DRAKE UNIVERSITY, ANY RESEARCH INVOLVING AN INVESTIGATIONAL NEW DEVICE, OR A MARKETED DEVICE THAT IS BEING USED FOR AN INDICATION NOT IN THE APPROVED LABELING, AND HUMAN SUBJECTS MUST FOLLOW THE REQUIREMENTS OF FDA'S INVESTIGATIONAL EXEMPTION (IDE) REGULATION (21CFR812). THE IDE REGULATION APPLIES TO ALL CLINICAL INVESTIGATIONS OF DEVICES TO DETERMINE SAFETY AND EFFECTIVENESS. THE RESEARCH MUST BE REVIEWED AND APPROVED BY THE UNIVERSITY ENVIRONMENTAL HEALTH AND SAFETY OFFICER AND/OR PROVOST PRIOR TO REVIEW BY THE IRB. A COPY OF ANY APPROVAL OR EXEMPTION MUST BE PROVIDED TO THE IRB BEFORE ANY REVIEW CAN BEGIN.**

## **7.0 INFORMED CONSENT**

### **7.1 GENERAL REQUIREMENTS**

RESEARCH INVESTIGATORS SHALL ENSURE THAT NO HUMAN SUBJECT WILL BE INVOLVED IN THEIR RESEARCH ACTIVITY APPROVED IN THE IRB PROTOCOL PRIOR TO OBTAINING INFORMED CONSENT FROM THE SUBJECT OR HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE.

#### 7.1.1 OBTAINING INFORMED CONSENT

RESEARCH INVESTIGATORS SHALL OBTAIN INFORMED CONSENT FROM THE SUBJECT OR THE SUBJECT'S PARENT, GUARDIAN OR OTHER LEGALLY AUTHORIZED REPRESENTATIVE (HEREAFTER REFERRED TO AS THE LEGALLY AUTHORIZED REPRESENTATIVE) IN ACCORDANCE WITH 45CFR46.116, 21CFR50.20 AND THESE POLICIES. THIS RESPONSIBILITY CANNOT BE DELEGATED TO PERSONNEL WHO ARE NOT LISTED AS INVESTIGATORS ON THE RESEARCH PROTOCOL APPROVED BY THE IRB. RESEARCH INVESTIGATORS SHALL ENSURE THAT NO HUMAN SUBJECT WILL BE INVOLVED IN ANY RESEARCH PROJECT PRIOR TO OBTAINING INFORMED CONSENT FROM THE SUBJECT OR HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE. INFORMED CONSENT MUST BE OBTAINED PRIOR TO ANY STAGE OR PROCEDURE PERFORMED SOLELY FOR THE PURPOSE OF DETERMINING ELIGIBILITY FOR THE RESEARCH PROJECT.

INFORMED CONSENT MUST BE OBTAINED UNDER CIRCUMSTANCES THAT OFFER THE SUBJECT OR HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE SUFFICIENT OPPORTUNITY TO CONSIDER WHETHER THE SUBJECT SHOULD OR SHOULD NOT PARTICIPATE. THE INFORMED CONSENT MUST NOT INCLUDE EXCULPATORY LANGUAGE THROUGH WHICH THE SUBJECT OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE IS MADE TO WAIVE OR APPEAR TO WAIVE ANY OF THE SUBJECT'S LEGAL RIGHTS OR RELEASES, OR THAT APPEARS TO RELEASE THE RESEARCH INVESTIGATOR, THE SPONSOR, THE INSTITUTION OR ITS AGENTS FROM LIABILITY FOR NEGLIGENCE.

- **IN PERSON CONSENT:** THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR PROVIDING INFORMED CONSENT IN THE PRESENCE OF THE HUMAN SUBJECT, HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE IF APPLICABLE, AND AN ADULT WITNESS IF THE SUBJECT IS A MINOR. THE WITNESS MUST BE AN ADULT PERSON NOT INVOLVED IN THE RESEARCH STUDY AND MAY BE AN ADULT RELATIVE OF THE HUMAN SUBJECT. THE WRITTEN INFORMED CONSENT DOCUMENT MUST BE SIGNED BY THE HUMAN SUBJECT, HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE IF APPLICABLE, AND THE ADULT WITNESS BEFORE THE HUMAN SUBJECT CAN PARTICIPATE IN THE RESEARCH. EACH PERSON THAT SIGNS THE WRITTEN CONSENT DOCUMENT SHALL BE GIVEN A COPY OF THE SIGNED DOCUMENT.
- **TELEPHONE CONSENT:** THE RESEARCH INVESTIGATOR MAY OBTAIN CONSENT BY TELEPHONE, AS APPROVED BY THE IRB. IN SUCH INSTANCES, THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR PROVIDING INFORMED CONSENT TO THE HUMAN SUBJECT AND HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE, IF APPLICABLE, OVER THE TELEPHONE. IF THE SUBJECT IS A MINOR, AN ADULT WITNESS MUST BE PRESENT DURING THE INFORMED CONSENT PROCESS. THE RESEARCH INVESTIGATOR SHALL DOCUMENT IN THE RESEARCH RECORD THE INFORMED CONSENT PROCESS. THE WRITTEN INFORMED CONSENT DOCUMENT SHALL BE SENT BY MAIL OR FACSIMILE TO THE HUMAN SUBJECT AND HIS/HER LEGALLY AUTHORIZED REPRESENTATIVE IF APPLICABLE AND THE WITNESS (IF WITNESSED BY AN ADULT PRESENT WITH THE HUMAN SUBJECT) FOR SIGNATURE AND RETURNED BEFORE THE HUMAN SUBJECT CAN PARTICIPATE IN THE RESEARCH. IF A WITNESS IS PRESENT WITH THE RESEARCH INVESTIGATOR, THEN HE/SHE SHALL SIGN THE INFORMED CONSENT DOCUMENT ONCE THE SIGNED DOCUMENT HAS BEEN RECEIVED FROM THE HUMAN SUBJECT. A FACSIMILE OF THE SIGNED INFORMED CONSENT DOCUMENT IS AS VALID AS THE ORIGINAL. EACH

PERSON THAT SIGNS THE WRITTEN CONSENT DOCUMENT SHALL BE GIVEN A COPY OF THE SIGNED DOCUMENT.

- **ELECTRONIC CONSENT:** THE RESEARCH INVESTIGATOR MAY OBTAIN CONSENT ELECTRONICALLY. THE INFORMED CONSENT MUST BE PRESENTED PRIOR TO PARTICIPATION IN THE STUDY. CONSENT CAN BE CONSIDERED RECEIVED IF AFTER THE PAGE WITH THE INFORMED CONSENT IS PRESENTED THE PARTICIPANT CLICKS TO CONTINUE ON THE ELECTRONIC STUDY, OR BY ANSWERING A QUESTION SAYING CONSENT IS GIVEN. A COPY OF THE INFORMED CONSENT SHOULD BE AVAILABLE TO THE PARTICIPANT UPON REQUEST AND ALL ELECTRONIC INFORMED CONSENTS MUST HAVE WRITTEN IN THEM 'PRINT FOR YOUR RECORDS.'

### **7.1.2 INFORMED CONSENT LANGUAGE**

INFORMED CONSENT MUST BE OBTAINED IN LANGUAGE UNDERSTANDABLE TO THE SUBJECT AND/OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE. THE RESEARCH INVESTIGATOR SHOULD USE LANGUAGE THAT THE AVERAGE PERSON OF THE AGE OF THE PROPOSED RESEARCH SUBJECT IS LIKELY TO UNDERSTAND. TECHNICAL AND SCIENTIFIC TERMS SHOULD BE ADEQUATELY EXPLAINED OR COMMON TERMS SUBSTITUTED. RESEARCH INVESTIGATORS ARE URGED TO WRITE THE CONSENT USING THE SECOND PERSON WRITING STYLE (I.E., "YOU," "I/WE") AS IT HELPS COMMUNICATE THAT THERE IS A CHOICE TO BE MADE BY THE PROSPECTIVE SUBJECT. IN ALL CASES, THE WRITING STYLE SHOULD BE CONSISTENT THROUGHOUT THE WRITTEN CONSENT DOCUMENT. IN CASES WHERE THE STUDY POPULATION INCLUDES NON-ENGLISH SPEAKING PEOPLE, THE IRB WILL REQUIRE THAT THE INFORMED CONSENT DOCUMENT BE WRITTEN IN EACH SUBJECT POPULATION'S LANGUAGE AND THAT AN INDEPENDENTLY QUALIFIED TRANSLATOR BE AVAILABLE DURING THE CONSENT PROCESS FOR THOSE SUBJECT POPULATIONS THAT DO NOT UNDERSTAND ENGLISH. IF ANY MEMBER OF THE RESEARCH POPULATION IS ILLITERATE, THEN THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR HAVING THE INFORMED CONSENT DOCUMENT EXPLAINED IN THE RESEARCH SUBJECT'S NATIVE LANGUAGE BY AN INDIVIDUAL FLUENT IN THAT RESEARCH SUBJECT'S NATIVE LANGUAGE.

## **7.2 EXCEPTIONS FROM INFORMED CONSENT REQUIREMENTS**

### **7.2.1 EMERGENCY USE OF A TEST ARTICLE**

A TEST ARTICLE IS DEFINED AS A DRUG, BIOLOGICAL PRODUCT, MEDICAL DEVICE, FOOD ADDITIVE, COLOR ADDITIVE, ELECTRONIC PRODUCT OR ANY OTHER ARTICLE SUBJECT TO REGULATION BY FDA 21CFR56.101(1) OR UNDER SECTIONS 351 OR 354-360F OF THE PUBLIC HEALTH SERVICE ACT. SINGLE EMERGENCY USE OF A TEST ARTICLE IS EXEMPTED FROM PROSPECTIVE IRB REVIEW (21CFR50.23) AND INFORMED CONSENT REQUIREMENTS PROVIDED THAT WRITTEN CERTIFICATION OF SUCH USE, AS OUTLINED IN ALL OF THE CRITERIA BELOW, IS REPORTED TO THE IRB WITHIN FIVE WORKING DAYS AFTER USE.

- THE SUBJECT IS CONFRONTED BY A LIFE-THREATENING SITUATION
- INFORMED CONSENT CANNOT BE OBTAINED FROM THE SUBJECT DUE TO AN "INABILITY TO COMMUNICATE" SUBJECT'S INABILITY TO SPEAK A PARTICULAR LANGUAGE WOULD NOT BE CONSIDERED AN "INABILITY TO COMMUNICATE"
- TIME IS INSUFFICIENT TO OBTAIN CONSENT FROM THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE
- NO ALTERNATIVE METHOD IS AVAILABLE THAT PROVIDES AN EQUAL OR GREATER LIKELIHOOD OF SAVING THE SUBJECT'S LIFE

### **7.2.2 EMERGENCY RESEARCH CONSENT WAIVER (FDA STUDIES ONLY)**

**IN VERY LIMITED EMERGENCY RESEARCH SITUATIONS, THE IRB MAY APPROVE FDA-REGULATED RESEARCH WITHOUT REQUIRING PRIOR INFORMED CONSENT FROM THE RESEARCH SUBJECT. A PROTOCOL THAT CLEARLY IS IDENTIFIED AS ONE THAT MAY INCLUDE SUBJECTS WHO ARE UNABLE TO CONSENT BECAUSE OF THEIR LIFE-THREATENING MEDICAL CONDITION AND WHO DO NOT HAVE A LEGALLY AUTHORIZED REPRESENTATIVE.**

**IN BOTH SITUATIONS LISTED ABOVE THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE TO ENSURING THAT PROCEDURES ARE IN PLACE TO INFORM, AT THE EARLIEST FEASIBLE OPPORTUNITY, EACH SUBJECT OR HIS/HER LEGALLY AUTHORIZED AND THE IRB. IF THE IRB DETERMINES THAT IT CANNOT APPROVE THE RESEARCH BECAUSE THE RESEARCH FAILS TO MEET THE CRITERIA FOR WAIVER OF INFORMED CONSENT OR BECAUSE OF OTHER ETHICAL CONCERNS, THE IRB MUST DOCUMENT ITS FINDINGS AND PROVIDE THEM IN WRITING TO THE PRINCIPAL INVESTIGATOR AND ANY SPONSOR.**

### **7.3 ELEMENTS OF INFORMED CONSENT**

**FDA (21CFR50.25(A)) AND DHHS(45CFR46.116(A)) BOTH REQUIRE THAT THE FOLLOWING BASIC INFORMATION BE PROVIDED TO SUBJECTS ASKED TO PARTICIPATE IN A RESEARCH PROJECT:**

- **A STATEMENT THAT THE STUDY INVOLVES RESEARCH, AN EXPLANATION OF THE PURPOSES AND DURATION OF THE SUBJECT'S PARTICIPATION, DESCRIPTION OF THE PROCEDURES TO BE FOLLOWED AND IDENTIFICATION OF ANY PROCEDURES THAT ARE EXPERIMENTAL**
- **A DESCRIPTION OF ANY ANTICIPATED RISKS OR DISCOMFORTS TO THE SUBJECT**
- **A DESCRIPTION OF THE EXPECTED BENEFITS TO THE SUBJECT OR OTHERS**
- **ALTERNATIVE TREATMENTS AVAILABLE (IF APPLICABLE)**
- **PLANS FOR MAINTAINING CONFIDENTIALITY OF SUBJECT INFORMATION**
- **A STATEMENT REGARDING ANY COMPENSATION THAT WILL BE PROVIDED TO STUDY PARTICIPANTS**
- **A CONTACT PERSON FOR THE RESEARCH**
- **A STATEMENT THAT PARTICIPATION IS VOLUNTARY, REFUSAL TO PARTICIPATE WILL INVOLVE NO PENALTY OR LOSS OF BENEFITS TO WHICH THE SUBJECT IS OTHERWISE ENTITLED, AND THE SUBJECT MAY DISCONTINUE PARTICIPATION AT ANY TIME WITHOUT PENALTY OR LOSS OF BENEFITS TO WHICH THE SUBJECT IS OTHERWISE ENTITLED**
- **A STATEMENT THAT A COPY OF THE CONSENT FORM WILL BE GIVEN TO THE SUBJECT**
- **THE DATE THAT THE CONSENT FORM WAS APPROVED BY THE IRB (21CFR50.27(A))**
- **A STATEMENT EXPLAINING PROCEDURE FOR STUDY PARTICIPANTS TO BE PROVIDED RESULTS OF RESEARCH STUDY, IF APPROPRIATE**

### **7.4 DOCUMENTATION OF INFORMED CONSENT**

**THE INFORMED CONSENT DOCUMENT MUST BE PREPARED IN AT LEAST A 12-POINT EASILY-READABLE FONT WITH ADEQUATE MARGINS ON THE SIDES, TOP AND BOTTOM.**

**RESEARCH INVESTIGATORS ARE RESPONSIBLE FOR INSURING THAT INFORMED CONSENT IS DOCUMENTED BY THE USE OF A WRITTEN CONSENT DOCUMENT MOST RECENTLY APPROVED BY THE IRB. RESEARCH INVESTIGATORS SHALL ALSO BE RESPONSIBLE FOR ENSURING THAT THE MOST RECENTLY IRB-APPROVED CONSENT DOCUMENT IS**

USED TO ENROLL EACH RESEARCH SUBJECT AND IS SIGNED BY THE SUBJECT OR THE SUBJECT'S LEGALLY AUTHORIZED REPRESENTATIVE, UNLESS THIS REQUIREMENT IS SPECIFICALLY WAIVED BY THE IRB.

## **7.5 ASSENT OF MINORS AND CONSENT OF PARENT(S)/ GUARDIAN(S)**

### **7.5.1 MINOR'S ASSENT**

**ASSENT IS DEFINED AS A CHILD'S AFFIRMATIVE AGREEMENT TO PARTICIPATE IN A RESEARCH PROJECT. ASSENT IS NOT GRANTED BY A CHILD'S PASSIVE RESIGNATION TO AN INTERVENTION PROCEDURE. WHEN A RESEARCH STUDY INVOLVES MINORS AS RESEARCH SUBJECTS, BOTH FDA AND DHHS REQUIRE THAT THE RESEARCH INVESTIGATOR OBTAIN AND DOCUMENT THE MINORS' ASSENT (WHERE THE MINORS ARE CAPABLE OF PROVIDING ASSENT) PRIOR TO INITIATING THE RESEARCH PROJECT. FOR RESEARCH STUDIES INVOLVING MINORS AGED 7-17, THE RESEARCH INVESTIGATOR SHALL PREPARE AND SUBMIT AN INFORMED ASSENT DOCUMENT FOR IRB APPROVAL, WHICH OUTLINES THE STUDY IN SIMPLIFIED LANGUAGE. A SEPARATE ASSENT DOCUMENT OUTLINING THE KEY ASPECTS OF THE RESEARCH IN VERY SIMPLE TERMS SHOULD BE PREPARED FOR MINORS AGED 7-12. THE ASSENT DOCUMENT FOR MINORS AGED 13-17 MAY BE MORE COMPREHENSIVE, BUT MUST STILL USE SIMPLIFIED, AGE-APPROPRIATE LANGUAGE.**

**RESEARCH INVESTIGATORS ARE RESPONSIBLE FOR OBTAINING EACH MINOR'S ASSENT AND FOR INSURING THAT ASSENT IS DOCUMENTED BY USE OF A WRITTEN DOCUMENT RECENTLY APPROVED BY THE IRB, AS INDICATED BY THE DATED BOTTOM PAGE OF THE ASSENT DOCUMENT. THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR INSURING THAT THE MINOR SIGNS THE MOST AGE-APPROPRIATE ASSENT DOCUMENT AND THAT A COPY OF THE ASSENT IS GIVEN TO THE MINOR AND HIS/HER PARENT(S)/GUARDIAN(S). ONCE A MINOR SUBJECT TURNS 18 YEARS OF AGE, THE RESEARCH INVESTIGATOR MUST RE-CONSENT THE SUBJECT WITH A MORE RECENTLY APPROVED ADULT CONSENT DOCUMENT.**

### **7.5.2 CONSENT OF PARENT(S)/GUARDIAN(S)**

**RESEARCH INVESTIGATORS ARE RESPONSIBLE FOR OBTAINING PARENTAL CONSENT FROM THE PARENTS OR GUARDIANS OF EACH MINOR SUBJECT ENROLLED IN A RESEARCH PROJECT. PARENTAL CONSENT SHOULD BE OBTAINED USING THE PARENTAL CONSENT DOCUMENT MOST RECENTLY APPROVED BY THE IRB, AS INDICATED BY THE DATE ENTERED AT THE BOTTOM OF THE CONSENT DOCUMENT. IF THE PARENTS OF A POTENTIAL SUBJECT ARE MINORS THEMSELVES, THEY ARE NOT ALLOWED TO CONSENT TO THEIR CHILD'S PARTICIPATION AS A RESEARCH SUBJECT UNLESS THE IRB HAS GRANTED A WAIVER TO THIS REQUIREMENT. THE IRB MAY GRANT WAIVERS FOR PROJECTS THAT INCLUDE NO INVASIVE PROCEDURES AND PRESENT NO MORE THAN MINIMAL RISK TO THE MINOR SUBJECTS. IN RARE INSTANCES, WAIVERS MAY ALSO BE GRANTED IN SITUATIONS WHERE PARENT/GUARDIAN CONSENT DOES NOT PROVIDE REASONABLE PROTECTION TO THE SUBJECTS (E.G., NEGLECTED OR ABUSED CHILDREN). HOWEVER, AN ADEQUATE MECHANISM TO PROTECT THE CHILDREN AS RESEARCH SUBJECTS MUST BE IN PLACE AND ACCURATELY DOCUMENTED.**

## **7.6 RETENTION OF SIGNED CONSENT DOCUMENTS**



RESEARCH INVESTIGATORS ARE RESPONSIBLE FOR RETAINING ALL CONSENT AND ASSENT DOCUMENTS SIGNED BY HUMAN SUBJECTS OR THE SUBJECTS' LEGALLY AUTHORIZED REPRESENTATIVES. THESE DOCUMENTS SHALL BE MAINTAINED BY THE RESEARCH INVESTIGATOR FOR A MINIMUM OF THREE (3) YEARS AFTER COMPLETION OF THE RESEARCH PROJECT.

## 7.7 IOWA LAW

THE INFORMED CONSENT REQUIREMENTS IN THIS POLICY ARE NOT INTENDED TO PREEMPT ANY APPLICABLE FEDERAL, STATE OR LOCAL LAWS WHICH REQUIRE ADDITIONAL INFORMATION TO BE DISCLOSED IN ORDER FOR INFORMED CONSENT TO BE LEGALLY EFFECTIVE.

## 8.0 RECRUITING RESEARCH SUBJECTS

THE IRB IS RESPONSIBLE FOR ENSURING THE EQUITABLE SELECTION OF RESEARCH SUBJECTS (45CFR46.111(A)(3) AND 21CFR576.111(A)(3)). IN FULFILLING THIS RESPONSIBILITY, THE IRB SHALL REVIEW THE METHODS THAT INVESTIGATORS USE TO RECRUIT SUBJECTS.

DRAKE UNIVERSITY IRB FOLLOWS THE REIMBURSEMENT MODEL WHEN CONSIDERING PAYMENTS MADE TO RESEARCH SUBJECTS. THIS MODEL ALLOWS PAYMENTS TO BE MADE TO RESEARCH SUBJECTS FOR DIRECT EXPENSES INCURRED WHILE PARTICIPATING IN A PARTICULAR RESEARCH PROJECT. HOWEVER, THIS PAYMENT MUST NOT BE LUCRATIVE ENOUGH TO SERVE AS AN INDUCEMENT OR PROVIDE COERCION FOR PARTICIPATION IN THE STUDY. A PAYMENT IS REIMBURSEMENT WHEN IT IS MEANT TO DIRECTLY OFFSET THE OUT-OF-POCKET COSTS THAT A SUBJECT MAY INCUR. THIS COULD INCLUDE REIMBURSEMENT FOR EXPENSES SUCH AS GAS, PARKING, TRAVEL EXPENSES, CHILDCARE, FOOD, LOST WAGES, AND OTHER EXPENSES THAT THE SUBJECT MAY INCUR WHILE PARTICIPATING IN THE STUDY. MODEST ENTICEMENTS TO PARTICIPATE IN THE RESEARCH PROJECT WILL BE CONSIDERED ON A CASE BY CASE BASIS, BUT COULD IMPEDE THE APPROVAL OF A PROPOSAL. THE RESEARCHER SHOULD JUSTIFY ANY PAYMENTS AND ENTICEMENTS TO RESEARCH SUBJECTS IN THEIR APPLICATION MATERIALS.

### 8.1 ADVERTISING FOR RESEARCH SUBJECTS

WHEN ADVERTISING IS TO BE USED TO RECRUIT HUMAN SUBJECTS FOR RESEARCH THAT IS TO BE CONDUCTED WITHIN, SUPPORTED BY OR UNDER THE RESPONSIBILITY OF DRAKE UNIVERSITY, THE IRB SHALL REVIEW THE INFORMATION CONTAINED IN THE ADVERTISEMENT AND THE MODE OF ITS COMMUNICATION TO DETERMINE IF THE PROCEDURE FOR RECRUITING SUBJECTS AFFORDS ADEQUATE PROTECTION. THE FOLLOWING ARE NOT INCLUDED IN THIS REQUIREMENT FOR IRB REVIEW:

- PEER COMMUNICATION INTENDED TO BE SEEN OR HEARD BY OTHER EDUCATORS
- NEWS STORIES
- PUBLICITY INTENDED FOR OTHER AUDIENCES, BUT INCLUDING REFERENCE TO THE RESEARCH PROJECT

ADVERTISEMENTS USED TO RECRUIT HUMAN SUBJECTS SHOULD BE SEEN AS AN EXTENSION OF THE INFORMED CONSENT AND SUBJECT SELECTION PROCESSES. IRB REVIEW IS NECESSARY TO ENSURE THAT INFORMATION IS NOT MISLEADING TO SUBJECTS, ESPECIALLY WHEN A STUDY WILL INVOLVE PERSONS WITH PHYSICAL OR MENTAL ILLNESS OR PERSONS WHO ARE ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED.

GENERALLY, ANY ADVERTISEMENT TO RECRUIT SUBJECTS SHOULD BE LIMITED TO:

- **NAME AND ADDRESS OF THE RESEARCH INVESTIGATOR**
- **PURPOSE OF THE RESEARCH AND ELIGIBILITY CRITERIA THAT WILL BE USED TO ADMIT SUBJECTS INTO THE STUDY**
- **DESCRIPTION OF THE BENEFITS (E.G., COMPENSATION OR CREDIT) TO THE SUBJECT FOR PARTICIPATION IN THE STUDY**
- **TIME OR OTHER COMMITMENT REQUIRED OF SUBJECTS**
- **LOCATION OF THE RESEARCH AND THE PERSON TO CONTACT FOR FURTHER INFORMATION**

**ADVERTISEMENTS MAY NOT BE DIRECTED TO MINORS. ADVERTISEMENTS INTENDED TO RECRUIT MINOR SUBJECTS MUST BE DIRECTED TO MINORS' PARENTS OR GUARDIANS AND MUST BE SENT TO THE IRB FOR PRIOR REVIEW.**

## **8.2 FINDER'S FEES**

**THE DRAKE UNIVERSITY IRB CONSIDERS IT UNETHICAL FOR INVESTIGATORS TO PROVIDE "FINDER'S FEES" TO THOSE WHO REFER SUBJECTS TO THEM FOR POSSIBLE INVOLVEMENT IN RESEARCH STUDIES. THE IRB WILL NOT APPROVE RESEARCH PROPOSALS THAT INVOLVE SUCH PAYMENTS.**

# **9.0 VULNERABLE RESEARCH POPULATIONS**

**THE REGULATIONS SPECIFY ADDITIONAL PROTECTIONS FOR CERTAIN CLASSES OF HUMAN RESEARCH INVOLVING CHILDREN (45CFR46.401 AND 21CFR50.50 AND 56.101), PREGNANT WOMEN, HUMAN FETUSES, AND HUMAN IN VITRO FERTILIZATION (45CFR46.201) AND PRISONERS (45CFR46.301 AND 21CFR56.107). IN ADDITION, OTHER VULNERABLE POPULATIONS, SUCH AS MEMBERS OF NATIVE AMERICAN TRIBES, THE MENTALLY DISABLED, IMMIGRANT, AND ECONOMICALLY OR EDUCATIONALLY DISADVANTAGED PERSONS MAY REQUIRE SPECIAL PROTECTIONS AND PROCEDURES AS SET FORTH IN THIS POLICY OR AS REQUIRED BY THE IRB.**

## **9.1 RESEARCH INVOLVING CHILDREN**

### **9.1.1 CATEGORIES OF RESEARCH**

**THERE ARE FOUR BASIC CATEGORIES OF RESEARCH THAT MAY BE CONDUCTED ON MINORS. IN ALL CASES ADEQUATE PROVISIONS MUST BE MADE FOR SOLICITING THE ASSENT OF THE MINOR SUBJECTS AND PERMISSION OF THEIR PARENTS OR GUARDIANS (SEE SECTION 7.5). THE FOUR CATEGORIES OF RESEARCH ARE BASED ON THE LEVEL OF RISK AND BENEFIT, AS FOLLOWS:**

- 1. RESEARCH INVOLVING MINIMAL RISK**
- 2. RESEARCH INVOLVING GREATER THAN MINIMAL RISK THAT PRESENTS THE PROSPECT OF DIRECT BENEFIT TO INDIVIDUAL MINOR RESEARCH SUBJECTS. THE IRB MAY APPROVE THE RESEARCH ONLY IF THE FOLLOWING CONDITIONS ARE MET:**
  - **THE RISK IS JUSTIFIED BY THE ANTICIPATED BENEFIT**
  - **THE RELATION OF THE ANTICIPATED BENEFIT TO THE RISK IS AT LEAST AS FAVORABLE TO THE MINOR SUBJECTS AS THAT PRESENTED BY AVAILABLE ALTERNATIVE APPROACHES**
- 3. RESEARCH INVOLVING GREATER THAN MINIMAL RISK WITH NO PROSPECT OF DIRECT BENEFIT TO MINOR SUBJECTS, BUT LIKELY TO YIELD GENERALIZABLE KNOWLEDGE ABOUT THE MINOR SUBJECT. THE IRB MAY APPROVE SUCH RESEARCH ONLY IF ALL THE FOLLOWING CONDITIONS ARE MET:**

- THE RISK REPRESENTS A MINOR INCREASE OVER MINIMAL RISK
  - THE RESEARCH PRESENTS EXPERIENCES TO MINOR SUBJECTS THAT ARE REASONABLY COMMENSURATE WITH THOSE INHERENT IN THEIR ACTUAL PHYSICAL OR SOCIAL CONDITIONS
  - THE RESEARCH IS LIKELY TO YIELD GENERALIZABLE KNOWLEDGE ABOUT THE MINOR SUBJECT AND IS OF VITAL IMPORTANCE FOR THE UNDERSTANDING OF THE RESEARCH
4. RESEARCH NOT OTHERWISE APPROVABLE BY THE IRB THAT THE IRB DETERMINES PRESENTS AN OPPORTUNITY TO UNDERSTAND, PREVENT OR ALLEVIATE A SERIOUS PROBLEM AFFECTING THE HEALTH OR WELFARE OF CHILDREN. THE IRB MAY APPROVE SUCH RESEARCH ONLY IF THE SECRETARY OF DHHS (OR THE FDA COMMISSIONER FOR FDA-REGULATED RESEARCH), AFTER CONSULTATION WITH A PANEL OF EXPERTS, DETERMINES THAT THE RESEARCH MEETS DEFINED CRITERIA (45CFR46.407(B)).

WHEN PLANNING A RESEARCH PROJECT THAT WILL INVOLVE MINORS AS SUBJECTS, THE PRINCIPAL INVESTIGATOR IS RESPONSIBLE FOR MAKING THE INITIAL DETERMINATION REGARDING WHICH OF THE ABOVE CATEGORIES APPLIES TO HIS/HER RESEARCH. THE IRB SHALL MAKE THE FINAL DETERMINATION REGARDING THE CATEGORY OF RESEARCH PRIOR TO APPROVAL OF THE RESEARCH.

#### 9.1.2 RESEARCH INVOLVING MINOR STUDENTS

THE U.S. DEPARTMENT OF EDUCATION (ED) ISSUED GUIDELINES UNDER THE PROTECTION OF PUPIL RIGHTS AMENDMENT REGARDING RESEARCH INVOLVING MINOR STUDENTS. HERE AND THROUGHOUT THIS DOCUMENT, A "MINOR" IS DEFINED TO BE A PERSON UNDER EIGHTEEN YEARS OF AGE. THE AMENDMENT APPLIES TO PROGRAMS THAT RECEIVE FUNDING FROM ED, AND IT IS INTENDED TO PROTECT THE RIGHTS OF PARENTS AND STUDENTS IN THE FOLLOWING WAYS:

- IT SEEKS TO ENSURE THAT SCHOOLS AND CONTRACTORS MAKE INSTRUCTIONAL MATERIALS AVAILABLE FOR INSPECTION BY PARENTS IF THOSE MATERIALS WILL BE USED IN CONNECTION WITH AN ED-FUNDED SURVEY, ANALYSIS OR EVALUATION IN WHICH THEIR CHILDREN PARTICIPATE.
- IT SEEKS TO ENSURE THAT SCHOOLS AND CONTRACTORS OBTAIN WRITTEN PARENTAL INFORMED CONSENT BEFORE MINOR STUDENTS ARE REQUIRED TO PARTICIPATE IN ANY ED-FUNDED SURVEY, ANALYSIS OR EVALUATION THAT REVEALS INFORMATION CONCERNING:
  - POLITICAL AFFILIATIONS
  - MENTAL AND PSYCHOLOGICAL PROBLEMS POTENTIALLY EMBARRASSING TO THE STUDENT OR HIS/HER FAMILY
  - SEXUAL BEHAVIOR AND ATTITUDES
  - ILLEGAL, ANTI-SOCIAL, SELF-INCRIMINATING AND DEMEANING BEHAVIOR
  - CRITICAL APPRAISALS OF OTHER INDIVIDUALS WITH WHOM THE RESPONDENTS HAVE CLOSE FAMILY RELATIONSHIPS
  - LEGALLY-RECOGNIZED PRIVILEGED OR ANALOGOUS RELATIONSHIPS, SUCH AS THOSE OF LAWYERS, PHYSICIANS AND MINISTERS
  - INCOME (OTHER THAN THAT REQUIRED BY LAW TO DETERMINE ELIGIBILITY FOR PARTICIPATION IN A PROGRAM OR FOR RECEIVING FINANCIAL ASSISTANCE UNDER SUCH PROGRAMS)

#### 9.2 RESEARCH INVOLVING PREGNANT WOMEN, FETUSES OR NEONATES

**DHHS HAS ESTABLISHED CERTAIN CRITERIA THAT MUST BE MET BEFORE PREGNANT WOMEN, FETUSES OR NEONATES CAN BE INVOLVED AS SUBJECTS IN RESEARCH. ACCORDING TO DHHS CRITERIA, "FETUS" AND "NEONATE" ARE DEFINED AS FOLLOWS: FETUS MEANS THE PRODUCT OF CONCEPTION FROM IMPLANTATION UNTIL DELIVERY AND NEONATE MEANS A NEWBORN.**

### **9.2.1 PREGNANT WOMEN OR FETUSES**

**DHHS HAS ESTABLISHED THE FOLLOWING CRITERIA (45CFR46.201, 66 FR 56775, NOVEMBER 13, 2001) THAT MUST BE MET PRIOR TO CONDUCTING RESEARCH ACTIVITIES THAT INVOLVE PREGNANT WOMEN OR FETUSES AS RESEARCH SUBJECTS:**

- **WHERE SCIENTIFICALLY APPROPRIATE, PRECLINICAL STUDIES, INCLUDING STUDIES ON PREGNANT ANIMALS, AND CLINICAL STUDIES ON NON-PREGNANT WOMEN, HAVE BEEN CONDUCTED AND PROVIDE DATA FOR ASSESSING POTENTIAL RISKS TO PREGNANT WOMEN AND FETUSES**
- **RISK TO THE FETUS IS CAUSED SOLELY BY INTERVENTIONS OR PROCEDURES THAT HOLD OUT THE PROSPECT OF BENEFIT, THE RISK TO THE FETUS IS NOT GREATER THAN MINIMAL AND THE PURPOSE OF THE RESEARCH IS THE DEVELOPMENT OF IMPORTANT BIOMEDICAL KNOWLEDGE WHICH CANNOT BE OBTAINED BY OTHER MEANS**
- **ANY RISK IS THE LEAST POSSIBLE FOR ACHIEVING THE OBJECTIVES OF THE RESEARCH**
- **THE WOMAN'S CONSENT OR THE CONSENT OF HER LEGALLY AUTHORIZED REPRESENTATIVE IS OBTAINED IN ACCORD WITH THE INFORMED CONSENT PROVISIONS, UNLESS ALTERED OR WAIVED BY THE IRB AS ALLOWED UNDER THE REGULATIONS. IF THE RESEARCH HOLDS OUT THE PROSPECT OF DIRECT BENEFIT SOLELY TO THE FETUS THEN THE CONSENT OF THE PREGNANT WOMAN AND THE FATHER MUST BE OBTAINED IN ACCORD WITH THE INFORMED CONSENT PROVISIONS, UNLESS THE FATHER IS UNABLE TO CONSENT BECAUSE OF UNAVAILABILITY, INCOMPETENCE OR TEMPORARY INCAPACITY OR THE PREGNANCY RESULTED FROM RAPE OR INCEST**
- **INDIVIDUALS PROVIDING CONSENT ARE FULLY INFORMED REGARDING THE REASONABLY FORESEEABLE IMPACT OF THE RESEARCH ON THE FETUS OR NEONATE**
- **FOR PREGNANT MINORS, ASSENT AND PERMISSION ARE OBTAINED IN ACCORD WITH THE PROVISIONS FOR ASSENT OF MINORS (SECTION 7.5)**
- **NO INDUCEMENTS, MONETARY OR OTHERWISE, WILL BE OFFERED TO TERMINATE A PREGNANCY**
- **INDIVIDUALS ENGAGED IN THE RESEARCH WILL HAVE NO PART IN 1) ANY DECISIONS AS TO THE TIMING, METHOD OR PROCEDURES USED TO TERMINATE A PREGNANCY, OR 2) DETERMINING THE VIABILITY OF A NEONATE**

### **9.2.2 NEONATES**

**DHHS HAS ESTABLISHED THE FOLLOWING CRITERIA (45CFR46.201, 66 FR 56775, NOVEMBER 13, 2001) THAT MUST BE MET PRIOR TO CONDUCTING RESEARCH ACTIVITIES THAT INVOLVE NEONATES:**

- **NEONATES OF UNCERTAIN VIABILITY AND NONVIABLE NEONATES MAY BE INVOLVED IN RESEARCH IF ALL OF THE FOLLOWING CONDITIONS ARE MET:**
  - **WHERE SCIENTIFICALLY APPROPRIATE, PRECLINICAL AND CLINICAL STUDIES HAVE BEEN CONDUCTED AND PROVIDE DATA FOR ASSESSING POTENTIAL RISKS TO NEONATES**
  - **INDIVIDUALS PROVIDING CONSENT ARE FULLY INFORMED REGARDING THE REASONABLE FORESEEABLE IMPACT OF THE RESEARCH ON THE NEONATE**
  - **INDIVIDUALS ENGAGED IN THE RESEARCH WILL HAVE NO PART IN DETERMINING THE VIABILITY OF THE NEONATE**

- THE REQUIREMENTS SET FORTH BELOW HAVE BEEN MET AS APPLICABLE
- NEONATES OF UNCERTAIN VIABILITY MAY NOT BE INVOLVED IN RESEARCH UNLESS THE FOLLOWING ADDITIONAL CONDITIONS ARE MET:
  - THE RESEARCH MUST HOLD OUT THE PROSPECT OF ENHANCING THE PROBABILITY OF SURVIVAL OF THE NEONATE TO THE POINT OF VIABILITY, AND ANY RISK IS THE LEAST POSSIBLE FOR ACHIEVING THAT OBJECTIVE, OR
  - THE PURPOSE OF THE RESEARCH IS THE DEVELOPMENT OF IMPORTANT BIOMEDICAL KNOWLEDGE WHICH CANNOT BE OBTAINED BY OTHER MEANS AND THERE WILL BE NO ADDED RISK TO THE NEONATE RESULTING FROM THE RESEARCH, AND
  - INFORMED CONSENT OF EITHER PARENT OR EITHER PARENT'S LEGALLY AUTHORIZED REPRESENTATIVE IS OBTAINED, UNLESS ALTERED OR WAIVED BY THE IRB AS ALLOWED UNDER THE REGULATION
- NONVIABLE NEONATES MAY NOT BE INVOLVED IN RESEARCH UNLESS THE FOLLOWING ADDITIONAL CONDITIONS ARE MET:
  - VITAL FUNCTIONS OF THE NEONATE WILL NOT BE ARTIFICIALLY MAINTAINED
  - THE RESEARCH WILL NOT TERMINATE THE HEARTBEAT OR RESPIRATION OF THE NEONATE
  - THE PURPOSE OF THE RESEARCH IS THE DEVELOPMENT OF IMPORTANT BIOMEDICAL KNOWLEDGE THAT CANNOT BE OBTAINED BY OTHER MEANS, AND
  - INFORMED CONSENT OF BOTH PARENTS IS OBTAINED, UNLESS ONE PARENT IS UNABLE TO CONSENT BECAUSE OF UNAVAILABILITY, INCOMPETENCE OR TEMPORARY INCAPACITY, IN WHICH CASE THE CONSENT OF ONE PARENT IS SUFFICIENT. THE CONSENT OF A LEGALLY AUTHORIZED REPRESENTATIVE CANNOT BE SUBSTITUTED FOR PARENTAL CONSENT AND INFORMED CONSENT CANNOT BE WAIVED OR ALTERED
- VIABLE NEONATES MAY BE INCLUDED IN RESEARCH ONLY TO THE EXTENT PERMITTED BY AND IN ACCORD WITH INFORMED CONSENT REQUIREMENTS, IRB APPROVAL AND REQUIREMENTS FOR RESEARCH INVOLVING CHILDREN (SEE SECTION 9.1)

### **9.2.3 RESEARCH INVOLVING, AFTER DELIVERY, THE PLACENTA, THE DEAD FETUS OR FETAL MATERIAL**

IF INFORMATION ASSOCIATED WITH THE PLACENTA, THE DEAD FETUS OR FETAL MATERIAL IS RECORDED FOR RESEARCH PURPOSES IN A MANNER SUCH THAT LIVING INDIVIDUALS CAN BE IDENTIFIED, THEN THOSE INDIVIDUALS ARE RESEARCH SUBJECTS AND ALL PERTINENT CONSENTS AND IRB APPROVAL REQUIREMENTS APPLY AND RESEARCH MUST BE CONDUCTED IN ACCORDANCE WITH ANY APPLICABLE FEDERAL, IOWA OR LOCAL LAWS REGARDING SUCH ACTIVITIES.

### **9.2.4 RESEARCH NOT OTHERWISE APPROVABLE BY THE IRB**

IF THE IRB DETERMINES THAT THE RESEARCH PRESENTS A REASONABLE OPPORTUNITY TO FURTHER THE UNDERSTANDING, PREVENTION OF A SERIOUS PROBLEM AFFECTING THE HEALTH OR WELFARE OF PREGNANT WOMEN, FETUSES OR NEONATES, THE IRB MAY APPROVE THE RESEARCH ONLY IF THE SECRETARY OF DHHS, IN CONSULTATION WITH EXPERTS, DETERMINES THAT CERTAIN CRITERIA (45CFR46.207) ARE MET.

## **9.3 RESEARCH INVOLVING PRISONERS**

INVOLVEMENT OF PRISONERS IN BEHAVIORAL OR BIOMEDICAL RESEARCH REQUIRES ADDITIONAL SAFEGUARDS (45CFR SEC 46.301), AS PRISONERS MAY BE UNDULY INFLUENCED TO PARTICIPATE AS SUBJECTS IN RESEARCH

BECAUSE OF THEIR INCARCERATION. THE FOLLOWING MUST BE MET AS SPECIFIC REQUIREMENTS FOR PRISONER RESEARCH:

- **THE IRB MUST HAVE AT LEAST ONE MEMBER WHO HAS A BACKGROUND IN PRISONER MATTERS (E.G., A FORMER PRISONER, SOCIAL WORKER)**
- **A MAJORITY OF THE IRB (EXCLUSIVE OF PRISONER MEMBERS) SHALL HAVE NO ASSOCIATION WITH THE PRISON(S) INVOLVED, APART FROM MEMBERSHIP ON THE BOARD.**

## **9.4 RESEARCH INVOLVING OTHER VULNERABLE POPULATIONS**

### **9.4.1 MEMBERS OF NATIVE AMERICAN TRIBES**

**THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR OBTAINING APPROVAL FROM THE APPROPRIATE TRIBAL COUNSEL(S) FOR RESEARCH INVOLVING MEMBERS OF NATIVE AMERICAN TRIBES PRIOR TO SUBMITTING THE PROTOCOL TO THE IRB FOR REVIEW AND APPROVAL.**

### **9.4.2 MENTALLY DISABLED PERSONS OR ECONOMICALLY/EDUCATIONALLY DISADVANTAGED PERSONS**

**INVOLVEMENT OF PERSONS IN RESEARCH WHO ARE MENTALLY DISABLED OR ECONOMICALLY/EDUCATIONALLY DISADVANTAGED REQUIRES ADDITIONAL SAFEGUARDS AS THOSE INDIVIDUALS MAY, BECAUSE OF THEIR CONDITIONS, BE SUSCEPTIBLE TO UNDUE INFLUENCE DURING THE ENROLLMENT PROCESS OR BE UNABLE TO UNDERSTAND THE INFORMED CONSENT PROCESS. THE IRB WILL REVIEW EACH CASE WHERE RESEARCH MAY INVOLVE MENTALLY DISABLED OR ECONOMICALLY/EDUCATIONALLY DISADVANTAGED PERSONS AND MAY REQUIRE ADDITIONAL SAFEGUARDS TO PROTECT THESE VULNERABLE SEGMENTS OF THE POPULATION.**

## **10.0 PROCEDURES FOR REPORTING AND RESPONDING TO CONCERNS INVOLVING HUMAN PARTICIPANT RESEARCH**

### **10.1 ADVERSE EVENT REPORTING**

**IF DURING THE COURSE OF A RESEARCH STUDY, AN ADVERSE REACTION (INCLUDING UNEXPECTED EVENTS) DOES OCCUR, A FULL BOARD OF THE IRB MUST REVIEW THESE ADVERSE EVENTS AND REASSESS THE BALANCE BETWEEN THE RISKS AND BENEFITS TO THE SUBJECTS. THE PRINCIPAL INVESTIGATOR HAS THE PRIMARY RESPONSIBILITY OF EVALUATING EACH ADVERSE EVENT FOR SEVERITY, LIKELIHOOD OF OCCURRENCE AND RELATIONSHIP, IF ANY, TO THE STUDY.**

- **SERIOUS ADVERSE EVENTS A SERIOUS ADVERSE EVENT IS SUCH THAT RESULTS IN ANY OF THE FOLLOWING: 1) DEATH, 2) A LIFE-THREATENING ADVERSE EVENT, 3) INPATIENT HOSPITALIZATION, 4) A SIGNIFICANT DISABILITY/CAPACITY, 5) A CONGENITAL ANOMALY/BIRTH DEFECT, 6) ANY MEDICAL EVENT THAT REQUIRES TREATMENT (21CFR312.32)**
- **UNEXPECTED ADVERSE EVENTS AN UNEXPECTED ADVERSE EVENT IS ANY ADVERSE EVENT THE SPECIFICITY OR SEVERITY OF WHICH IS NOT CONSISTENT WITH THE CONSENT DOCUMENT OR PROTOCOL. UNEXPECTED REFERS TO AN ADVERSE EVENT THAT HAS NOT BEEN PREVIOUSLY OBSERVED**

**RATHER THAN FROM THE PERSPECTIVE OF SUCH EXPERIENCE NOT BEING ANTICIPATED  
(21CFR312.32)**

### **10.1.1 REPORTING REQUIREMENTS**

**IT IS THE RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR TO REPORT SERIOUS ADVERSE EVENTS AND UNEXPECTED ADVERSE EVENTS THAT OCCUR DURING THE COURSE OF THE RESEARCH TO THE IRB, THE SPONSOR AND FEDERAL MONITORING AGENCIES, IF APPLICABLE AND APPROPRIATE.**

### **10.1.2 IRB REVIEW OF ADVERSE EVENT REPORTS**

**THE IRB CHAIR SHALL REVIEW ALL SERIOUS ADVERSE EVENTS THAT OCCUR UNDER THE JURISDICTION OF THE IRB WITHIN ONE BUSINESS DAY OF RECEIPT. ALL OTHER REPORTS OF ADVERSE EVENTS SHALL BE INITIALLY REVIEWED BY A MEMBER OF THE IRB WITHIN FIVE BUSINESS DAYS OF RECEIPT BY THE IRB CHAIR. AFTER INITIAL REVIEW, THE ADVERSE EVENT SHALL BE REPORTED TO THE IRB MEMBERS AT A SCHEDULED MEETING AND THE IRB SHALL TAKE ONE OF THE FOLLOWING ACTIONS:**

- NOTE THE OCCURRENCE OF THE ADVERSE EVENT BUT TAKE NO ACTION**
- REQUEST ADDITIONAL INFORMATION**
- REQUIRE MODIFICATIONS TO THE PROTOCOL OR CONSENT DOCUMENT**
- REVISE THE CONTINUING REVIEW TIMETABLE, OR**
- SUSPEND THE PROJECT**

**THE PRINCIPAL INVESTIGATOR WILL BE IMMEDIATELY NOTIFIED IN WRITING IF HIS/HER PROTOCOL IS SUSPENDED. THE PRINCIPAL INVESTIGATOR WILL ALSO BE CONTACTED SHOULD ADDITIONAL INFORMATION BE REQUIRED AT ANY STAGE OF THE IRB REVIEW PROCESS OR IF CHANGES NEED TO BE MADE TO THE PROTOCOL OR INFORMED CONSENT DOCUMENT.**

**IT IS THE RESPONSIBILITY OF THE PRINCIPAL INVESTIGATOR TO INFORM SUBJECTS PARTICIPATING IN AN ONGOING STUDY OF THE OCCURRENCE OF ANY ADVERSE EVENTS RELATED TO THE RESEARCH THAT WERE UNKNOWN AT THE TIME THE ORIGINAL INFORMED CONSENT DOCUMENT WAS SIGNED. THE IRB MAY MAKE A DETERMINATION AS TO WHETHER OR NOT SUBJECTS NEED BE INFORMED. THE PRINCIPAL INVESTIGATOR MUST NOTIFY THE IRB OF WHEN AND HOW SUBJECTS ARE TO BE INFORMED. MODIFICATIONS TO THE CONSENT DOCUMENT THAT INCLUDE THIS NEW INFORMATION MUST BE APPROVED BY THE IRB.**

## **10.2 NOTIFICATION OF PROCEDURES PERFORMED IN VARIANCE WITH THE PROTOCOL**

**THE PRINCIPAL INVESTIGATOR MUST SUBMIT A WRITTEN REPORT TO THE IRB WITHIN FIVE WORKING DAYS OF ANY ACTIVITY THAT IS CONDUCTED IN VARIANCE WITH THE PROTOCOL. THE IRB CHAIR SHALL REVIEW THE DEVIATIONS THAT OCCUR UNDER THE JURISDICTION OF THE IRB. AFTER INITIAL REVIEW, THE DEVIATION SHALL BE REPORTED TO THE IRB MEMBERS AT A SCHEDULED MEETING AND THE IRB SHALL TAKE ONE OF THE FOLLOWING ACTIONS:**

- NOTE THE OCCURRENCE OF THE ADVERSE EVENT BUT TAKE NO ACTION**
- REQUEST ADDITIONAL INFORMATION**
- REQUIRE MODIFICATIONS TO THE PROTOCOL OR CONSENT DOCUMENT**
- REVISE THE CONTINUING REVIEW TIMETABLE, OR**

- **SUSPEND THE PROJECT**

**THE PRINCIPAL INVESTIGATOR WILL BE IMMEDIATELY NOTIFIED IN WRITING IF HIS/HER PROTOCOL IS SUSPENDED. THE PRINCIPAL INVESTIGATOR WILL ALSO BE CONTACTED SHOULD ADDITIONAL INFORMATION BE REQUIRED AT ANY STAGE OF THE IRB REVIEW PROCESS OR IF CHANGES NEED TO BE MADE TO THE PROTOCOL OR INFORMED CONSENT DOCUMENT.**

### **10.3 PROTECTION FOR WHISTLEBLOWERS**

**RETALIATION AGAINST WHISTLEBLOWERS IS CONSIDERED SCIENTIFIC MISCONDUCT. THEREFORE, IT IS THE POLICY OF DRAKE UNIVERSITY THAT PERSONS EXPRESSING CONCERNS OR MAKING ALLEGATIONS ABOUT A PROTOCOL INVOLVING HUMAN SUBJECTS WILL NOT BE SUBJECT TO RETALIATION, DISCIPLINARY ACTION OR OTHER ACTIONS BY THE UNIVERSITY IF THEY ACT IN GOOD FAITH. THIS PROTECTION HOLDS EVEN IF THE CONCERNS OR ALLEGATIONS ARE FOUND, UPON INVESTIGATION, TO BE WITHOUT MERIT.**

## **11.0 CONCLUSION OF RESEARCH PROJECT**

### **11.1 NOTIFICATION OF CONCLUSION OF RESEARCH PROJECT**

**THE RESEARCH INVESTIGATOR IS RESPONSIBLE FOR NOTIFYING THE IRB THAT A RESEARCH PROJECT HAS BEEN CONCLUDED AT WHICH POINT THE IRB WILL CLOSE ITS FILE. THE PRINCIPAL INVESTIGATOR SHOULD SUBMIT A COMPLETED "CONTINUING REVIEW OR PROJECT TERMINATION" FORM NOTING THAT THE RESEARCH PROJECT HAS BEEN COMPLETED AND SHOULD BE CLOSED.**

### **11.2 RETENTION OF RECORDS**

#### **11.2.1 PRINCIPAL INVESTIGATOR**

**RESEARCH DATA REMAIN THE PROPERTY OF THE PRINCIPAL INVESTIGATOR AND SHOULD BE RETAINED FOR AT LEAST 3 YEARS AFTER COMPLETION OF THE PROJECT. INDIVIDUALLY IDENTIFIABLE DATA SHOULD BE SAFEGUARDED BY THE RESEARCH INVESTIGATOR AND DESTROYED IN THE PERIOD DEFINED UNDER THE APPROVED PROTOCOL. INDIVIDUALLY IDENTIFIABLE DATA WILL NOT BE RELINQUISHED TO ANY SPONSOR OR OUTSIDE ENTITY. SUMMARIZED RESEARCH RESULTS REMAIN THE PROPERTY OF THE RESEARCH INVESTIGATOR.**

#### **11.2.2 IRB**

**PROTOCOLS AND APPROVED INFORMED CONSENT FORMS WILL BE RETAINED BY THE IRB IN A CENTRAL ACCESSIBLE LOCATION FOR AT LEAST 3 YEARS AFTER COMPLETION OF THE PROJECT. ALL MINUTES AND IRB DOCUMENTATION OF DISCUSSION WILL ALSO BE HELD FOR AT LEAST 3 YEARS AFTER PROJECT COMPLETION.**