



**FORSYTH MEDICAL CENTER  
INSTITUTIONAL REVIEW BOARD**

# **INVESTIGATOR'S HANDBOOK**

VERSION DATED JANUARY 1, 2007

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## Review and Actions

**Full Board Review:** Is required for initial and **\*\*continuing reviews**, or when changes to research dictate a full review. Following full board review, one of the following actions will be taken:

- **Approved** as submitted.
- **Approved – Subject to Modifications** - minor modifications required. Upon submission, requested changes will be directed to IRB Chair for final approval.
- **Deferred** – Significant changes required or questions remain to be resolved. The investigator will be informed of the reasons that the review was deferred. He/she will be invited to address the requests for changes and/or clarifications and resubmit. Full board re-review will be required once unresolved issues have been addressed.
- **Disapproved** – The IRB has determined that risks to subjects outweigh benefits to be gained by the research. A detailed explanation will be provided. The investigator or sponsor may appeal the Board's decision in writing.

The Investigator or designee is encouraged to represent the protocol or materials under review at their scheduled meeting. This will prevent unnecessary delay in the review process and optimize the IRB's goal in protecting subjects' rights and safety.

**Expedited Review:** Is available for minor changes in previously approved research material and other categories allowed by FDA regulations (see Expedited Review Application Guidelines). The IRB Chairperson or designee will review these changes and approve them accordingly. They will be reported to the full board at the next scheduled meeting. Requests for expedited review must be accompanied by "Request for Expedited Review" form

### **FDA form 1572 and revisions:**

A copy of the completed form 1572 should accompany all initial submissions for IND research. For device studies a Statement of Investigator must be completed.

All revised 1572 forms should also be submitted to FMC IRB.

Please provide an explanation of the reason for a change of Principal Investigator and include a current signed copy of his/her CV and license.

### **Serious Adverse Event Reporting:**

The protocol usually defines a "Serious Adverse Event" (SAE) as any event that:

- Results in Death.
- Is life threatening.
- Results in persistent or significant disability/incapacity.
- Requires inpatient hospitalization or prolongation of existing hospitalization.
- Is a congenital anomaly/birth defect.
- Important Medical Event - May require intervention to prevent one of the outcomes listed above.

Examples of this could include: Intensive treatment in an emergency room or at home such as for status asthmaticus, Certain clinical laboratory abnormalities (e.g. blood dyscrasias), Development of drug dependency or drug abuse.

- Regardless of the above criteria, any additional adverse experiences which an Investigator or Sponsor considered serious should be reported to the IRB

Good Clinical Practices dictate that investigators report SAEs to the sponsor and IRB within 24 hours of discovery. Following the initial report, a full report to the IRB should be submitted when additional information becomes available.

The investigator should indicate his/her view as to causality, whether the event should require a revision of the informed consent form, and whether it will effect the safety of subsequently enrolled subjects.

FMC IRB has included an SAE reporting form with this Handbook for your use..

**Please use this form to communicate with the IRB rather than Sponsor specific forms.** These reports should be submitted complete with investigator signature to assure adequate review and reporting by the principal investigator.

**IND Safety Reports:**

Forsyth Medical Center IRB requires that all IND safety reports be reported for full board review. These reports should include evidence that the Principal Investigator has reviewed them (initials or signature). Please submit IND safety reports using the FMC IRB reporting form (attached).

**Protocol Deviations:**

Forsyth Medical Center IRB requires that all significant protocol deviations be reported in writing within 3 working days of discovery. This may include informed consent violations or any deviation that affects the rights and safety of the subject or affects the integrity of the study. Other protocol deviations may be reported at quarterly intervals.

**Continuing Review:**

All initial approvals will expire no later than one calendar year from the approval date. The site will be responsible to submit a continuing review report at least one month prior to expiration to allow adequate time for review. More frequent approval or review will be required of certain high-risk studies. The Board will communicate the review interval required with initial approval. Continuing Review reports should include a copy of a signed and dated consent form from the most recently consented patient (patient identifiers blinded) and a copy of the most recent FDA form 1572.

*Any research conducted after the expiration date of an approval is in violation of FDA regulations [21 CFR 56.103 (a)] and may lead to formal suspension of the study at your site.*

**Amendments/Revisions:**

All protocol amendments must be submitted to FMC IRB for approval before they are implemented. A statement from the investigator as to whether this amendment requires a change in the consent form should be included with the submission. This revised consent form should be submitted as well (on disk if possible), with changes noted for review.

Revisions to a consent form that are not related to an amendment (changes in patient stipend, additional safety information) must also be reviewed prior to implementation. Good Clinical Practices also dictate that previously consented subjects be presented with the most current consent form version for re-consent as the study progresses.

**Study Closure:**

FDA regulations require that the site inform the IRB upon completion of a study. The continuing review report should be used for this purpose. The date that the sponsor formally closes activity at the site is considered the date of closure.

# Application for Initial Review of Research

Investigator: \_\_\_\_\_ Protocol Number: \_\_\_\_\_

This application is designed to provide information necessary for the IRB to complete a substantive and meaningful review of your clinical research project submission, in accordance with the IRB standard operating procedures and the applicable regulations.

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Please Forward submissions to:  
Forsyth Medical Center Institutional Review Board  
3333 Silas Creek Parkway, Box 48  
Winston-Salem, NC 27103  
t. 336-718-5964/F. 336-277-9471

# Initial Review Submission Checklist

Investigator: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

Please choose the applicable category.

## Drugs Or Biologics

- Application for Initial Review of Research
- FDA Form 1572, signed & dated by the Principal Investigator
- Consent Form and Assent form if applicable
- HIPAA Authorization Form
- Protocol
- Recruitment/Advertisement Materials
- Investigator's Drug Brochure
- IND safety reports, drug inserts or other documents relating to the study agent
- Principal Investigator's Current Curriculum Vitae (signed and dated) & Current Medical License
- Sub-Investigator's Current CV (signed and dated) & Current Medical License
- Evidence of Training in Human Subject Protections for PI (s) & anyone else authorized to obtain consent
- IRB Review Fee

## Devices

- Application for Initial Review of Research
- Consent Form and Assent form if applicable
- HIPAA Authorization Form
- Protocol
- Recruitment/Advertisement Materials
- Investigator's Instructions for use
- Principal Investigator's Current Curriculum Vitae (signed and dated) & Current Medical License
- Sub-Investigator's Current CV (signed and dated) & Current Medical License
- Evidence of Training in Human Subject Protections for PI(s) & anyone else authorized to obtain consent
- One of the following:
  - FDA Letter granting the investigational device exemption (IDE);or
  - Letter from Sponsor stating that the study is a non-significant risk device study; or
  - Letter Explaining Why the Investigation Is Exempt from the IDE requirements under 21 CFR 812.2(c) or otherwise exempt
- IRB Review Fee

## Request for Waivers

- HIPAA Waiver request form** (only if your study requires a waiver of the requirement to obtain HIPAA authorization for screening/recruitment or enrollment)
- Data Use Agreement** (only if you plan to share a limited data set of PHI without obtaining HIPAA authorization → must be accompanied by a HIPAA Waiver request)
- Consent Waiver/Alteration request form** (only if your research requires a waiver or alteration of the requirement to obtain informed consent for screening/recruitment or enrollment)

## Principal Investigator Information

1) PI Name:	2) Telephone: (        )
3) Mailing Address for IRB correspondence:	4) Facsimile: (        )
	5) E-mail:
6) Research Site Contact Person:	
7) Site Contact Address (if different than #3)	8) Site Contact Telephone: (        )
	9) Site Contact Facsimile: (        )
	10) Site Contact E-mail:
11) Has the PI ever received an <b>FDA WARNING LETTER</b> that has not previously been submitted to FMC IRB?	<input type="checkbox"/> YES (if yes, attach) <input type="checkbox"/> NO
12) LICENSING INFORMATION:	
MEDICAL LICENSE #: _____	STATE: _____
Expiration date: _____	
13) IF THE STUDY INVOLVES NARCOTICS:	
DEA REGISTRATION#: _____	EXPIRATION DATE: _____
14) Please attach a signed copy of the <b>FDA FORM 1572</b> <input type="checkbox"/> ATTACHED	
15) Conflicts Of Interest:	
<input type="checkbox"/> PI and all key personnel involved in this research project <u>MUST EACH</u> submit the Conflict Of Interest form	
16.) Adequate Staffing & Resource Allocation	
Adequate Staffing is an area which could affect the rights and welfare of research subjects. To ensure those rights are protected, the PI is responsible to ensure that adequate staffing and resources are available for each project conducted	
HOW MANY OF THE FOLLOWING DOES THE PI CURRENTLY SUPERVISE?	
A. OPEN RESEARCH STUDIES (with active participants):	
B. LOCATIONS:	
C. PHYSICIAN SUB-INVESTIGATORS:	
D. RESEARCH STAFF:	
E. APPROX. # OF ACTIVE SUBJECTS:	
F. APPROX. # OF SUBJECTS TO BE ENROLLED IN THIS STUDY AT YOUR SITE:	
17) <u>Emergency Coverage Plan</u>	
ARE RESEARCH PERSONNEL AVAILABLE TO SUBJECTS 24 HOURS A DAY? <input type="checkbox"/> YES <input type="checkbox"/> NO	
IF <b>NO</b> , EXPLAIN HOW SUBJECTS CAN CONTACT RESEARCH PERSONNEL: _____	
17.A) DESCRIBE THE EMERGENCY EQUIPMENT AVAILABLE AT YOUR SITE *complete this section for each study site	
Site Name and Address: _____	
<input type="checkbox"/> CRASH CART	<input type="checkbox"/> EMERGENCY MEDICATIONS
<input type="checkbox"/> ACCESS TO 911	<input type="checkbox"/> CPR TRAINED STAFF
<input type="checkbox"/> OTHER: _____	

**(17 A. Continued) Additional Site Locations:**

**Site Name and Address:** \_\_\_\_\_

DESCRIBE THE EMERGENCY EQUIPMENT AVAILABLE AT YOUR SITE: \*complete this section for each study site

CRASH CART                       EMERGENCY MEDICATIONS                       ACCESS TO 911

CPR TRAINED STAFF                       OTHER: \_\_\_\_\_

**Site Name and Address:** \_\_\_\_\_

DESCRIBE THE EMERGENCY EQUIPMENT AVAILABLE AT YOUR SITE: \*complete this section for each study site

CRASH CART                       EMERGENCY MEDICATIONS                       ACCESS TO 911

CPR TRAINED STAFF                       OTHER: \_\_\_\_\_

**Site Name and Address:** \_\_\_\_\_

DESCRIBE THE EMERGENCY EQUIPMENT AVAILABLE AT YOUR SITE: \*complete this section for each study site

CRASH CART                       EMERGENCY MEDICATIONS                       ACCESS TO 911

CPR TRAINED STAFF                       OTHER: \_\_\_\_\_

## Research Project / Protocol Information

<b>18) PROTOCOL NUMBER:</b>	<b>19) Protocol Version:</b>			
<b>20) PROTOCOL TITLE:</b>				
<b>21) IS THIS RESEARCH INVESTIGATOR-INITIATED?</b> <i>*IF YES, PLEASE PROCEED TO ITEM #26 BELOW.</i>				
<input type="checkbox"/> yes <input type="checkbox"/> No				
<b>22) SPONSOR NAME:</b>	<b>23) Sponsor Contact Name:</b>  Sponsor Contact Telephone: (    )			
<b>24) IS A CONTRACT RESEARCH ORGANIZATION (CRO) INVOLVED WITH THIS RESEARCH? *IF NO, PLEASE PROCEED TO ITEM #40 BELOW.</b>				
<input type="checkbox"/> yes <input type="checkbox"/> No				
<b>25) CRO NAME:</b>	<b>26) CRO Contact Name:</b>  CRO Contact Telephone: (    )			
<b>27) HAS THIS RESEARCH PROJECT BEEN SUBMITTED TO, DISAPPROVED OR TERMINATED BY ANOTHER IRB PRIOR TO SUBMISSION TO THE FMC IRB?</b>				
<input type="checkbox"/> NO <input type="checkbox"/> YES – <i>*IF YES, PLEASE PROVIDE THE IRB DECISION, DISAPPROVAL OR TERMINATION LETTER.</i>				
<b>28) Study Type</b> <input type="checkbox"/> Inpatient <input type="checkbox"/> Outpatient <input type="checkbox"/> Both				
<b>29) Time frame for study (locally, while active with subjects)</b> Start Date: ___/___/___    Anticipated Stop Date: ___/___/___				
<b>30) Research Participants (CHECK ALL THAT APPLY):</b>				
<input type="checkbox"/> Competent Adults	<input type="checkbox"/> Pregnant Women	<input type="checkbox"/> Children (Wards)	<input type="checkbox"/> Minors (UNDER 18 YEARS OLD)	<input type="checkbox"/> Fetuses
<b>31) Is this Research Federally Funded (entirely or partial)?</b> <input type="checkbox"/> Yes <input type="checkbox"/> No If Yes, What Federal Agency is Funding? _____				
<b>32) DOES THIS RESEARCH INVOLVE AN INVESTIGATIONAL NEW <u>DRUG OR BIOLOGIC?</u></b> If no, proceed to question 33 <input type="checkbox"/> yes <input type="checkbox"/> No				
<b>32.A) PROVIDE THE INVESTIGATIONAL NEW DRUG (IND) NUMBER ASSIGNED BY THE FDA:</b> _____ <i>IF IND NUMBER IS NOT AVAILABLE, YOU MUST ATTACH EXPLANATION OF WHY IND WAS NOT OBTAINED.</i>				
<b>32.B) Phase of Study</b> I- <input type="checkbox"/> , II- <input type="checkbox"/> , III- <input type="checkbox"/> , IV <input type="checkbox"/>				
<b>32. C). Provide PLAN FOR DISPENSATION OF THE STUDY DRUG?</b> _____				
<b>33) DOES THIS RESEARCH INVOLVE AN INVESTIGATIONAL NEW <u>DEVICE?</u></b> If no, proceed to question 34 <input type="checkbox"/> yes <input type="checkbox"/> No				
IF YES, THE RESEARCH SPONSOR CLASSIFIES THIS DEVICE AS A (CHECK ONE):				
<input type="checkbox"/> SIGNIFICANT RISK DEVICE (SR)	<input type="checkbox"/> non significant risk device (NSR)			
<b>33.A) FOR ALL DEVICE STUDIES, YOU MUST PROVIDE ONE (1) OF THE FOLLOWING:</b>				
<b>PLEASE CHECK BOX TO INDICATE WHICH IS INCLUDED:</b>				
1. <input type="checkbox"/> FDA LETTER GRANTING AN INVESTIGATIONAL DEVICE EXEMPTION FOR THE PROPOSED USE;	<input type="checkbox"/> N/A			
2. <input type="checkbox"/> LETTER FROM THE SPONSOR STATING THAT THE STUDY IS A NON-SIGNIFICANT RISK DEVICE STUDY;				
<b>OR</b>				
3. <input type="checkbox"/> LETTER EXPLAINING WHY THE INVESTIGATION IS EXEMPT FROM THE IDE REQUIREMENTS UNDER 21 CFR 812.2 © OR OTHERWISE EXEMPT.				

34) IF THIS RESEARCH DOES NOT INVOLVE AN INVESTIGATIONAL DRUG OR DEVICE, HOW WOULD YOU DESCRIBE IT? (CHECK ONE)

RETROSPECTIVE CHART REVIEW

BLOOD DRAW

N/A

SURVEY STUDY

OTHER: \_\_\_\_\_

DATA COLLECTION DURING ROUTINE CLINICAL CARE

**35) Protocol Summary**

*(Please do not copy and paste directly from the consent form- this section provides the IRB protocol information which prevents distributing a protocol for each member to review)*

**36.) Study Objectives:**

**37.) Summary of Study Procedures:**

**38.) Summary of Risks to Subjects (include invasive procedures, venipunctures, anticipated AE's, etc.):** *(Please do not copy and paste directly from the consent form- this section provides the IRB protocol information which prevents distributing a protocol for each member to review)*

**39) DOES THE PROTOCOL DESIGN MINIMIZE RISK TO SUBJECTS?**     YES     NO

IF **NO**, DESCRIBE THE ADDITIONAL MEASURES THE INVESTIGATOR WILL ADD TO THE RESEARCH PROJECT TO HELP MINIMIZE RISK: \_\_\_\_\_

**Please list all items submitted for review (include dates / versions of documents):**

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

# INFORMED CONSENT

**40) Obtaining Consent**

I / OR MY DESIGNEE WILL OBTAIN INFORMED CONSENT FROM POTENTIAL SUBJECTS PRIOR TO PERFORMING ANY STUDY-RELATED PROCEDURES.

**41)  LIST ALL KEY STUDY PERSONNEL & INDICATE THOSE WHO WILL OBTAIN CONSENT**

Submit the following for each who will be obtaining consent:

Documentation of Human Research Subject Training

**LIST ALL INVOLVED STAFF MEMBERS – ATTACH ADDITIONAL PAGE IF NECESSARY**

NAME	ROLE	WILL OBTAIN CONSENT?	
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No
		<input type="checkbox"/> yes	<input type="checkbox"/> No

**42) Where will consent occur for this research project?** \_\_\_\_\_

N/A

**43) Opportunity for prospective subjects to consider whether or not to participate? (CHECK ALL THAT APPLY):**

- SCHEDULE SCREENING VISITS THAT ALLOW FOR ADEQUATE DISCUSSION OF THE RESEARCH AND ALTERNATIVES
- REVIEW INFORMED CONSENT FORM IN DETAIL WITH POTENTIAL SUBJECT
- PROVIDE OPPORTUNITY FOR SUBJECT TO DIGEST INFORMATION AND COME BACK WITH QUESTIONS AT A LATER TIME
- MAIL CONSENT DOCUMENT IN ADVANCE OF VISIT TO ALLOW EXTRA TIME FOR REVIEW
- OTHER (PLEASE SPECIFY): \_\_\_\_\_
- N/A (ONLY IF CONSENT WAIVER IS REQUESTED)

**44.) SUBJECT POPULATIONS (CHECK ALL THAT APPLY):**

- Males
- Females
- Members of Minority Groups included when possible and scientifically desirable:
  - If no, please explain: \_\_\_\_\_
- SUBJECTS FROM THE FOLLOWING “VULNERABLE” CATEGORIES:
 

<input type="checkbox"/> Mentally ill	<input type="checkbox"/> mentally disabled	<input type="checkbox"/> nursing home residents
<input type="checkbox"/> Institutionalized	<input type="checkbox"/> chronic condition	<input type="checkbox"/> terminally ill
<input type="checkbox"/> Hospitalized	<input type="checkbox"/> pregnant women	<input type="checkbox"/> limited or non-readers
<input type="checkbox"/> Poor/uninsured	<input type="checkbox"/> children	<input type="checkbox"/> Prisoners
<input type="checkbox"/> children (WARDS)		
- OTHERS VULNERABLE TO COERCION (SPECIFY): \_\_\_\_\_

**45) JUSTIFICATION FOR EACH “VULNERABLE” CATEGORY OF SUBJECTS?**

\_\_\_\_\_

N/A

**46) ARE THE SAFEGUARDS AFFORDED TO ALL SUBJECTS IN THE PROTOCOL SUFFICIENT TO PROTECT THE “VULNERABLE” SUBJECTS INDICATED ABOVE?**

- YES
- NO – IF NO, WHAT ADDITIONAL SAFEGUARDS ARE NEEDED? \_\_\_\_\_
- N/A

**47) PRIMARY LANGUAGE of subjects:**

**\*NOTE: MUST USE A TRANSLATED INFORMED CONSENT FORM**

- ENGLISH
- SPANISH
- OTHER: \_\_\_\_\_

48) Involving children:

Ages of Children: \_\_\_\_\_

N/A

PROVISIONS WILL BE MADE TO SOLICIT THE CONSENT OF AT LEAST ONE PARENT OR LEGAL GUARDIAN (NOTE: THE IRB MAY, AT ITS DISCRETION, REQUIRE PERMISSION OF BOTH PARENTS).

PROVISIONS WILL BE MADE FOR SOLICITING THE **ASSENT** OF THE CHILDREN (CHECK ALL THAT APPLY):

INTERVIEW CHILD WITHOUT PARENTS

INTERVIEW CHILD WITH PARENTS

INTERVIEW CHILD WITH AN IMPARTIAL WITNESS PRESENT (\*REQUIRED BY BRANY)

OTHER: \_\_\_\_\_

THIS RESEARCH WILL INVOLVE CHILDREN WHO ARE **WARDS**

AN ADVOCATE HAS BEEN APPOINTED

ADVOCATE'S NAME & CONTACT INFORMATION: \_\_\_\_\_

49.) WOMEN IN LABOR

THE PREGNANT WOMAN IN LABOR WILL BE APPROACHED FOR HER INFORMED CONSENT

CONSENT WILL ALSO BE ASKED OF A SECOND PERSON, TYPICALLY HER HUSBAND, FATHER OF THE BABY, OR WOMAN'S MOTHER, OR CLOSE RELATIVE ACCOMPANYING HER.

EFFORTS WILL BE MADE TO OBTAIN INFORMED CONSENT DURING A PRENATAL VISIT, IF POSSIBLE.

• OTHER CONSENT ISSUES/SAFEGUARDS: \_\_\_\_\_

N/A

50.) INVOLVING SURGICAL PATIENTS:

EFFORTS WILL BE MADE TO OBTAIN WRITTEN INFORMED CONSENT DURING PRE-SURGICAL TESTING VISITS, IF POSSIBLE

CONSENT WILL BE OBTAINED ON THE DAY OF SURGERY, BUT PRIOR TO SEDATION

• OTHER CONSENT ISSUES/SAFEGUARDS: \_\_\_\_\_

N/A

51.) FOR RESEARCH INVOLVING PSYCHIATRIC PATIENTS:

IF THE PATIENT IS HOSPITALIZED DURING ENROLLMENT, I AGREE TO CONTACT THE SUBJECT'S PRIMARY PSYCHIATRIST OR OTHER ATTENDING PHYSICIAN BEFORE RECRUITING THE SUBJECT.

I AGREE TO TELL PATIENTS THAT A RESEARCH COORDINATOR OR OTHER INVESTIGATOR IN CONNECTION WITH THE RESEARCH WILL APPROACH THEM.

I AGREE TO HAVE A THIRD PARTY ASSESS THE SUBJECT'S CAPACITY TO CONSENT TO PARTICIPATE PRIOR TO ENROLLING SUBJECTS WITH PSYCHIATRIC ILLNESS AFFECTING COMPETENCY IN THE STUDY.

N/A

50A) WHO WILL DECIDE WHETHER AN INDIVIDUAL SUBJECT IS COMPETENT TO CONSENT?  
\_\_\_\_\_

52.)  HOW WILL THIS ASSESSMENT BE MADE? \_\_\_\_\_

## Recruitment

53.) HOW DO YOU INTEND TO RECRUIT RESEARCH SUBJECTS?

CHECK ALL THAT APPLY:

MY PRIVATE PATIENT POPULATION/DATABASE

Physician referrals

RESEARCH DATABASE

Advertising (attach)

FLYERS \*PLEASE ATTACH

Other (please specify): \_\_\_\_\_

CLINICAL PATIENT POPULATION AT MY INSTITUTION  
(IN ACCORDANCE WITH APPLICABLE LAW AND YOUR INSTITUTIONAL POLICIES ON PROTECTION OF PATIENT CONFIDENTIALITY)

CHECK ALL THAT APPLY:

I WILL BE ACCESSING RECORDS FOR **PATIENTS OTHER THAN MY OWN** NEED TO APPLY FOR **HIPAA WAIVER - PREPARATORY TO RESEARCH- OR WAIVER (AND DATA USE AGREEMENT IF LIMITED DATA SET IS INVOLVED)**

I WILL NOT BE ACCESSING RECORDS FOR **PATIENTS OTHER THAN MY OWN**

54) ARE YOU INVOLVED IN ANY RESEARCH PROJECTS THAT MAY INVOLVE THE SAME SUBJECT POPULATION AS THIS STUDY?

YES  NO

IF YES, HOW WILL YOU SELECT WHICH STUDY SUBJECTS ARE OFFERED PARTICIPATION IN? \_\_\_\_\_

55.) APPROXIMATE THE ETHNIC MAKEUP OF THE POPULATION TO BE RECRUITED FOR THIS RESEARCH:

\_\_\_\_\_ % AFRICAN-AMERICAN

\_\_\_\_\_ % middle eastern

\_\_\_\_\_ % native american/  
first nations

\_\_\_\_\_ % ASIAN

\_\_\_\_\_ % caucasian

\_\_\_\_\_ % other (specify):

\_\_\_\_\_ % PACIFIC ISLANDER

\_\_\_\_\_ % hispanic

\_\_\_\_\_

## PRIVACY AND CONFIDENTIALITY

56) WHAT PRECAUTIONS WILL BE USED TO MAINTAIN THE CONFIDENTIALITY OF IDENTIFIABLE HEALTH INFORMATION?

PAPER BASED RECORDS WILL BE KEPT IN A SECURED LOCATION AND ONLY ACCESSIBLE TO PERSONNEL INVOLVED IN THE STUDY

COMPUTER BASED FILES WILL ONLY BE MADE AVAILABLE TO PERSONNEL INVOLVED IN THE STUDY THROUGH THE USE OF ACCESS PRIVILEGES AND PASSWORDS.

PRIOR ACCESS TO ANY STUDY-RELATED INFORMATION, PERSONNEL WILL BE REQUIRED TO SIGN STATEMENTS AGREEING TO PROTECT THE SECURITY AND CONFIDENTIALITY OF IDENTIFIABLE HEALTH INFORMATION.

WHENEVER FEASIBLE, IDENTIFIERS WILL BE REMOVED FROM STUDY-RELATED INFORMATION.

OTHER (SPECIFY): \_\_\_\_\_

57) HOW WILL INFORMATION ABOUT RESEARCH PARTICIPANTS BE OBTAINED?

CHECK ALL THAT APPLY:

SURVEYS

direct observation

other (specify):

QUESTIONNAIRES

performance of tests and  
procedures

\_\_\_\_\_

INTERVIEW

58) HOW LONG WILL THE RESEARCH DATA BE STORED BY THE INVESTIGATOR?

\_\_\_\_\_ YEARS AFTER CLOSE OF STUDY (MINIMUM OF 3 YEARS AFTER CLOSE OR AS SPECIFIED BY THE SPONSOR, WHICHEVER IS LONGER)

## Data Safety Monitoring

59) ALL CLINICAL TRIALS REQUIRE SAFETY MONITORING, BUT NOT NECESSARILY BY A FORMAL COMMITTEE. DESCRIBE THE PROVISIONS FOR SAFETY MONITORING FOR THIS PROJECT.

CHECK ONE:

- A FORMAL DATA MONITORING COMMITTEE HAS BEEN ESTABLISHED:
- HOW OFTEN IS THE COMMITTEE EXPECTED TO MEET?
    - QUARTERLY
    - AFTER HALF OF THE ANTICIPATED ENROLLMENTS OCCUR
    - UPON RECOGNITION OF HARM
    - OTHER (PLEASE INDICATE): \_\_\_\_\_
  - WHEN WILL A REPORT BE AVAILABLE? \_\_\_\_\_
- A FORMAL DATA MONITORING COMMITTEE HAS NOT BEEN ESTABLISHED
- WHAT MECHANISM IS IN PLACE FOR SAFETY MONITORING? \_\_\_\_\_

**DO NOT LEAVE THIS ITEM BLANK – IT WILL DELAY THE REVIEW OF YOUR PROJECT!**

## PERSON COMPLETING THIS FORM

PRINTED / TYPED NAME OF PERSON COMPLETING THIS FORM:

Company and Title:

SIGNATURE OF PERSON COMPLETING THIS FORM:

date:

PHONE NUMBER: (       )

fax number: (       )

## BILLING

**PAYMENT IS DUE AT THE TIME THIS APPLICATION IS SUBMITTED.**

**Your Project will not be scheduled for review until payment is received.**

A PAYMENT CHECK (MADE PAYABLE TO FMC IRB)  
IS ENCLOSED IN THE AMOUNT OF: \_\_\_\_\_ [CHECK # \_\_\_\_\_]

Please submit your documents along with the IRB fee to the following address:

**Beth Cirillo  
Forsyth Medical Center IRB  
3333 Silas Creek Parkway Box 48  
Winston-Salem, NC 27103**

Submissions should be made in keeping with the IRB meeting/submissions deadline schedule found in the current Forsyth Medical Center IRB Investigator's Handbook.

The IRB will send all original correspondence to the Principal Investigator.

The Principal Investigator will be responsible for providing necessary documents to all other appropriate parties and regulatory agencies.

For questions in preparing submissions or other related topics, please contact the IRB office.

**Telephone (336) 718-5964, or Fax: (336) 277-9471,  
E-mail: [bjcirillo@novanthealth.org](mailto:bjcirillo@novanthealth.org) or [mdbeck@novanthealth.org](mailto:mdbeck@novanthealth.org)**

# Forsyth Medical Center IRB

## Investigator's Statement of Compliance

The proposed investigation involves the use of human subjects. I am submitting this form with a description of my project, prepared in accordance with institutional policy for the protection of human subjects participating in the research. I understand FMC IRB policies concerning research involving human subjects and:

1. I will not engage in any research involving human subjects without obtaining prior IRB approval.
2. I agree that the IRB approved consent form must be the only consent form in this study and must be used for every patient prior to enrollment;
3. I agree to report to the FMC IRB any unanticipated effects on subjects that become apparent during the course or as a result of experimentation and the actions taken as a result; all serious adverse events must be reported to the IRB within 24 hours of discovery, and a written report must be submitted to the IRB within two (2) business days, unless otherwise agreed to by IRB administration;
4. I agree to cooperate with members of the Committee charged with the continuing review of this project;
5. I agree to obtain prior approval from the Committee before amending or altering the scope of the project or implementing changes in the approved consent form;
6. I agree to maintain documentation of consent forms and progress reports (continuing review applications);
7. I agree that all advertising must be approved by the IRB prior to submission to any agencies and before posting;
8. I agree to submit continuing review applications in a timely fashion;
9. I agree to notify the IRB of study termination and/or any change in the status of the study;
10. I agree to notify the IRB of actions taken by any regulatory authority, including license suspension, medical board actions, or other
11. I agree to maintain records for a minimum of 3 years after closure, or as specified by the sponsor of the research, whichever is longer;
12. I will ensure that research subjects are given referrals for needed health care during the research or for follow-up after the research.
13. I familiar with the Forsyth Medical Center IRB Standard Operating Procedures
14. I certify that I have appropriate credentials to conduct study.
15. I agree that if I or my Sub-Investigator (s) have been suspended at another institution, or by another IRB, it is my responsibility to bring that action to the IRB's attention immediately.

I further understand that:

1. Failure to comply with any of the above, with the FMC IRB's Standard Operating Procedures, or with any applicable regulations may result in immediate closure of this study, which is reportable to my institution, FDA and/or OHRP.
2. This clinical research project will be subject to routine audits by FMC IRB, and at the discretion of the FMC Institutional Official, the results of such audits may be shared with appropriate Department Chairpersons and/or the Institutional Official.
3. Any disciplinary action by federal or state regulatory agencies or by the Medical Board that prohibit a physician from participating in research activities will be recognized by the IRB and the investigator will be considered ineligible. No action by the IRB can supersede the action by a regulatory agency that defines the scope of responsibility of the IRB.

NOTE: I have acknowledged [by signature] my awareness and agreement to comply with applicable federal, state and institutional policies and procedures pertinent to the research process and protection of human subjects. Investigators are referred to the Forsyth Medical Center Institutional Review Board Standard Operating Procedures for a complete statement of institutional policy and procedures regarding research and human subjects.

---

Principal Investigator (Print)

Signature of Principal Investigator

Date

FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

**Study Progress Report**

Principal Investigator: \_\_\_\_\_  
 Title: \_\_\_\_\_

Protocol Number: \_\_\_\_\_

**Request for IRB review for:**

Continuing Review (Request for renewal)    Closure to Accrual    Final Report

1.	Is this study:	<input type="checkbox"/> Active	<input type="checkbox"/> Enrollment Closed (follow up only)	<input type="checkbox"/> Closed
2.	If closed: Date formally closed by sponsor: ____/____/____			
3.	Please enclose copy of most recently signed consent form (with subject name blinded).			
4.	Signature date of most current FDA form 1572 ____/____/____. (If not previously submitted, provide copy)			
5.	Recruitment:	Total number of subjects screened _____		
		Enrolled (signed consent and met inclusion criteria) _____		
		Still participating _____		
		Completed _____		
		Withdrawn* _____		
6.	*Briefly state the reason each patient withdrew from the study: (attach list if necessary)			
	Subject #1 _____			
	Subject #2 _____			
	Subject #3 _____			
	Subject #4 _____			
7.	Please indicate if the following events have occurred at your site (not previously reported)*:			
	Serious and/or unexpected adverse events/deaths .....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Significant protocol deviations.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Protocol Amendments.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Changes to informed consent.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Changes in investigator's brochure.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Changes in advertising/recruitment material.....	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Has any subject sought compensation for injury associated with the study?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	Any new findings that may affect the subjects' willingness to continue in the trial?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
8.	Has the principal investigator ever been convicted of a crime or disciplined by a private medical organization or licensing authority?	Yes <input type="checkbox"/>	No <input type="checkbox"/>	
	<b>*If answer is "yes" provide explanation</b>			
9.	Has the FDA or Office of Human Research Protections (OHRP) audited your site since this study was started? <input type="checkbox"/> Yes <input type="checkbox"/> No			
	If yes, provide copy of audit report and any 483's issued.			

PRINCIPAL INVESTIGATOR'S STATEMENT AND SIGNATURE:  
*I certify that the information provided above is true and accurate.*

---

Investigator's Signature
Printed Name
Date

**Serious Adverse Event Report**

Protocol #: \_\_\_\_\_ Principal Investigator: \_\_\_\_\_

Protocol Title: \_\_\_\_\_

Initial Report  Follow – up

Subject Initials: \_\_\_\_\_ Subject #: \_\_\_\_\_

Date of Event: \_\_\_\_\_ Date Investigator Aware of Event: \_\_\_\_\_

Reason reported as SAE:

- Resulted in death  Hospitalization or prolongation of hospitalization
- Resulted in persistent or significant disability or incapacity
- Is a congenital anomaly/birth defect
- Is life threatening
- Required medical or surgical intervention to prevent one of the outcomes listed above.

Description of Event: (attach details if required)

Unexpected:  Yes  No

Principal Investigator's assessment of causality:

- Definitely related to study medication/device
- Possibly related to study medication/device
- Unlikely relationship to study medication/device
- Not related to study medication/device

In the Principal Investigator's opinion does this SAE warrant a revision in the informed consent document?  Y  N  
(If yes- attach explanation).

Should currently enrolled subjects be notified?  Y  N (If yes- explain)

Sponsor notified on \_\_\_\_/\_\_\_\_/\_\_\_\_ time: \_\_\_\_:\_\_\_\_

\_\_\_\_\_  
PI Name (Printed) PI Signature Date

\_\_\_\_\_  
Prepared by (Printed) Signature of Preparer Date

# FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

## Informed Consent to Participate in a Research Study (Template)

**Title:** Title of Protocol

**Principal Investigator:** Name and address of Principal Investigator

**Study Site:** List all addresses where study patients may be seen.

**This is a research study. You are being asked to read the following document as a part of the informed consent process. The informed consent process is to inform you of the risks and benefits involved in the study so you can make a free decision whether or not to participate. Informed consent includes having the study fully explained to you, an opportunity to ask questions, your questions answered to your satisfaction and a written informed consent to read and sign.**

### Description of Study

*The description of the study should be in layman's terms targeted at the 8th grade level. Begin with a statement that the study involves research; an explanation of the purposes of the research; the approximate number of patients involved nationally and locally; and the expected duration of the patient's participation.*

You are being asked to participate in this research study to be performed by [name of principal investigator] at [name of institution(s)]. The purpose of this study [short statement of purpose(s)-include any information about what is investigational.] You will be one of approximately [number of patients] involved in this research project at [name of institution] and of [number of people] enrolled nationally. Your participation will last for [approximate length of time.]

### Procedures

*This is a description of the procedures to be followed, in layman's terms, and specific identification of any procedures that are investigational. Be specific; avoid technical or exclusive medical terminology; the information on the consent form is intended for the patient's understanding and not to communicate with physicians and other health care professionals. Any technical language should be explained so that the patient understands the procedure. If subjects are randomized, adapt the following language to your specific study.*

It is not clear at the present time which [drug, treatment, device, etc.] is better. For this reason, the [drug, treatment, device, etc.] given to you will be assigned based on chance, using a method of selection called randomization. Randomization is like the flipping of a coin. Your chance of receiving [one of, either, etc] treatment is equal to [number in each group, etc.]

*If the study is blinded, add the following:*

Neither you nor your physician will know which treatment you are receiving, but this information is available in the event of an emergency.

### Risks

*This is a description of any reasonably foreseeable risks and discomforts, such as expected and possibly rare side effects. There should be clear detail of the type of adverse experiences, the relative severity, and the expected frequencies. Where possible, organize side effects in a listing format as follows:*

The most common side effects of \_\_\_\_\_ may include:

- 

Less common side effects of \_\_\_\_\_ may include:

- 

Rarely, side effects of \_\_\_\_\_ may include:

- 

*Include the following:*

The following risks exist, and side effects may happen. You should discuss these with your doctor. There also may be other side effects that we cannot predict.

*Where allergic reaction is potential, as in all drug studies, use the following language:*

As with all medications, side effects may include an allergic reaction. Allergic reactions may range from minor reactions, such as itching or rash, to major, life threatening reactions which can result in death.

# FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

*To cover blood drawing, use the following language:*

Risks associated with blood drawing may include pain, bruising, feeling faint and on rare occasion infection.

*If there is a risk posed by reproduction or sexual activity during treatment, include:*

Because the [drugs, device, treatment, etc.] in this study can affect an unborn baby, you should not become pregnant or father a baby while on this study. You should not nurse a baby while on this study. Ask about counseling and more information about preventing pregnancy. You may ask for a pregnancy test and birth control advice.

*To cover unforeseeable risks, insert the following paragraph:*

Any treatment has possible side effects. Treatments used in this program may cause some or none of the side effects listed. In addition, there is always the risk of uncommon or previously unknown side effects occurring. If you have any kind of unusual or unexpected symptoms, you should report them immediately to your doctor.

## **Benefits**

*If it is not known whether the study may benefit the subject, this should be stated using the following language:*

There may not be direct benefit to you for participating in this study. The possible benefit of the study is to learn about [the drug/intervention or type of cancer] that may help others in the future.

*If appropriate add:*

The possible benefits of taking part in this study are the same as receiving the treatments without being in the study.

*Describe any health benefits that may be reasonably expected from the research. However, avoid any suggestion or guarantee or assumption of success of the test article.*

*Payment to subjects for participating in research studies is considered a benefit, however exercise caution to avoid suggestion of coercion or undue influence.*

## **Alternative Treatments**

*This requires a disclosure of appropriate alternate procedures of courses of treatment, if any, that might be available to the patient, including those that are not experimental.*

Instead of being in this study, you have these options:

- 

Please talk to your doctor about these and other options.

If there are no alternative treatments this wording is acceptable:

*There are no alternative treatments (and/or procedures) to those offered in this research study.*

## **Confidentiality**

Efforts will be made to keep personal information in your research record private and confidential. Absolute confidentiality cannot be guaranteed. Personal information will be given out as required by law.

The following organizations may look at and/or copy your research records:

- FMC IRB
- Food and Drug Administration
- Study Sponsor: [sponsor name]
- Study research group: [study group name]

## **Cost**

*State whether or not there will be additional costs to the subject as a result of participation in the research study, and if so, state what the costs will be [i.e., professional fees, hospital charges, diagnostic studies, drugs, etc.]. State any drug, device, test, etc. that may be free of charge. If applicable, use the following language:*

## **Compensation for Injury**

If you are injured as a direct result of your participation in this research study, the Sponsor of the Study will cover the cost of medical care needed to treat this injury, to the extent not covered by your insurance company. The sponsor will reimburse you

## FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

for those medical expenses not covered by your insurance. You should notify the study doctor as soon as you believe you have experienced an injury. The Study Sponsor is not responsible for expenses that are due to pre-existing medical conditions or underlying disease. The Study Sponsor will not pay for expenses caused by negligence or misconduct of the Investigational site or Principal Investigator. For more information on medical treatment for a research related injury or to report a study related injury you should call Dr. \_\_\_\_ at \_\_\_\_\_. No other type of compensation, such as lost wages or payment for discomfort due to injury suffered as a result of your participation in this study, will be provided. You do not give up any legal rights as a research participant by signing this consent form.

### Compensation for Participation

*If appropriate:*

You will receive no payment for taking part in this study. You will not participate in any economic benefit derived from the research.

If during the study, the study drug becomes commercially available, you may have to pay for it to take part in the study.

*In the event of compensation from other sources [i.e., sponsor], include language to that affect.*

The Study Doctor:  (PI name) , MD will be paid by the study sponsor,  (sponsor name)  for your participation in this study or there may be other economic benefits to him or her. You are free to discuss this matter with him/her if you feel it may effect your willingness to participate in the study.

### Participant Rights

Your participation in this research study is voluntary. You may choose not to join or may leave the study at any time and this will not affect your medical care, nor will you be penalized or lose benefits to which you are otherwise entitled. If you decide to stop taking part in this study, at any time, you should talk to your doctor so that it can be done safely.

We will tell you about future findings that may affect your health, welfare, or willingness to stay on this study.

### Contact Information

During the study, if you experience any medical problems, suffer a research-related injury, or have questions about the study, please contact the study doctor, \_\_\_\_\_ at \_\_\_\_\_.

If you have any questions about your rights as a research subject, or questions regarding this research study, you should call or write:

Forsyth Medical Center Institutional Review Board  
Elms Allen, MD, IRB Chairperson  
3333 Silas Creek Parkway  
Winston-Salem, NC 27103  
(336) 718-5964

### Patient Consent

I am 18 years old or older and have the capacity to make and communicate my own health care decisions. I agree to participate in this study. I have read all of the above, or have heard it read to me. I have had the opportunity to ask questions about this study, and my questions have been answered to my satisfaction. I consent to release my medical records to the research staff. Such release will expire on \_\_\_\_\_.

You will get a copy of this form after you have signed it.

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\_\_\_\_\_  
Patient's Name

\_\_\_\_\_  
Medical Record #

\_\_\_\_\_  
Patient's Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness' Name

\_\_\_\_\_

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Date

**Surrogate (Representative) Statement:**

The patient is unable to consent because:

- he/she is a minor
- he/she is mentally incompetent
- other: \_\_\_\_\_

I am authorized to consent on behalf of the patient. I agree to participate in this study. I have read all of the above, or have heard it read to me. I have had the opportunity to ask questions about this study, and my questions have been answered to my satisfaction

\_\_\_\_\_  
Patient Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship to patient.

**Investigator Statement**

I have participated in the informed consent process with this patient and have offered an opportunity for further explanation of the procedure, study, and /or drugs to the individual whose signature appears above.

\_\_\_\_\_  
Investigator's Name

\_\_\_\_\_

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date

**REMEMBER To:**

- **Add page X of Y in the header or footer**
- **Subject Initials in the header and footer**
- **Date the consent form**

# FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

## Expedited Review Application Guidelines

### **CATEGORIES OF RESEARCH THAT MAY BE REVIEWED BY THE INSTITUTIONAL REVIEW BOARD (IRB) THROUGH AN EXPEDITED REVIEW PROCEDURE 1** (Source: 63 FR 60364-60367; effective November 9, 1998)

#### **Applicability**

- (A) 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 the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. 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.
- (B) The categories in this list apply regardless of the age of subjects, except as noted.
- (C) 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 subject's 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 confidentiality are no greater than minimal.
- (D) The expedited review procedure may not be used for classified research involving human subjects.
- (E) The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- (G) Categories one (1) through seven (7) pertain to both initial and continuing IRB review.
- (H) 1 An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110 and 21 CFR 56.110.

#### **Categories of Research That May Be Reviewed Through an Expedited Review Procedure**

- (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 (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability if the risks associated with the use of the product is not eligible for expedited review.)
  - (b) Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- (2) Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
  - (a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - (b) from other adults and children 2 , considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight week period and collection may not occur more frequently than 2 times per week.
- (3) Prospective collection of biological specimens for research purposes by noninvasive means.

#### **Examples:**

- (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) excreta and external secretions (including sweat);
  - (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax 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 scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques;
  - (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;
  - (j) sputum collected after saline mist nebulization.
- (4) 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:**

- (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;
  - (c) weighing or testing sensory acuity;
  - (d) magnetic resonance imaging;
  - (e) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;
  - (f) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.
- (5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects, 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
  - (6) Collection of data from voice, video, digital, or image recordings made for research purposes.
  - (7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, 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 HHS regulations for the protection of human subjects. 45 CFR 56.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)
  - (8) **Continuing review of research previously approved by the convened IRB as follows:**
    - a) **Where**
      - (1) *the research is permanently closed to the enrollment of new subjects*
      - (2) *all subjects have completed all research-related interventions and*
      - (3) *the research remains active only for long-term follow-up of subjects; or*
    - b) **Where no subjects have been enrolled and no additional risks have been identified; or**
    - c) **Where the remaining research activities are limited to data analysis.**

# FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

## Expedited Review Request

<b>Principal Investigator:</b>	Study Number
<b>Study Title:</b>	
<b>Materials submitted:</b>	
<b>Date Submitted:</b>	
<b>Submitted By:</b>	<b>Name and Phone Number</b>

### Expedited Review Category

	Research Category	Description
<input type="checkbox"/>	(1)	No NDA or IND required per FDA regulations
<input type="checkbox"/>	(2)	Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows: from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week.  Or from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
<input type="checkbox"/>	(3)	Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (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) excreta and external secretions (including sweat); (e) uncanalulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax 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 invasivethan routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.
<input type="checkbox"/>	(4)	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: (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.
<input type="checkbox"/>	(5)	Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for <b>nonresearch</b> purposes (such as medical treatment or diagnosis).
<input type="checkbox"/>	(6)	Collection of data from voice, video, digital, or image recordings made for research purposes.
<input type="checkbox"/>	(7)	Behavioral studies Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, 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
	<b>(8)</b>	<b>Continuing review of research previously approved by the convened IRB:</b>
<input type="checkbox"/>	(a)(i)	Research is permanently closed to the enrollment of new subjects
<input type="checkbox"/>	(a)(ii)	All subjects have completed all research-related interventions
<input type="checkbox"/>	(a)(iii)	Research is active only for long-term follow-up of subjects, or
<input type="checkbox"/>	(b)	No subjects have been enrolled and no additional risks have been identified or
<input type="checkbox"/>	(c)	The remaining research activities are limited to data analysis

<input type="checkbox"/>		Minor changes in previously approved research (during the period covered by the original approval) 45 CFR 46 110 (b)(2)
<input type="checkbox"/>	Other	Patient recruitment/education materials

**Submit To:**  
**Forsyth Medical Center IRB**  
**Attention: Beth Cirillo Box 48**  
**3333 Silas Creek Parkway**  
**Winston-Salem, NC 27103 Fax: 336-277-9471**  
**E-mail: [bjcirillo@novanthealth.org](mailto:bjcirillo@novanthealth.org)**

# FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

## Guidelines for Completing the HIPAA Authorization Form

Federal regulations have been issued to protect the privacy rights of patients. These regulations were issued under a law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This law is designed to protect the confidentiality of a patient's protected health information ("PHI"). PHI is information about the patient that could be used to determine the patient's identity.

The purpose of the HIPAA authorization form is to:

- inform the patient of his or her privacy rights regarding participating in research; and
- obtain the patient's consent to use and disclose PHI for the research study.

PHI, as defined by HIPAA, includes the following:

- names;
- all geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, and their equivalent geocodes;
- all elements of date for dates directly related to an individual, including birth date, admission date, discharge date, date of death, ages, elements of dates (including year) that are indicative of age;
- telephone numbers;
- fax numbers;
- electronic mail addresses;
- social security numbers;
- medical record numbers;
- health plan beneficiary numbers;
- account numbers;
- certificate/license numbers;
- vehicle identifiers and serial numbers, including license plate numbers;
- device identifiers and serial numbers;
- web universal resource locators (URLs);
- internet protocol address numbers;
- biometric identifiers, including finger and voice prints;
- full face photographic images and any comparable images; and
- any other unique identifying number, characteristic or code.

### What information will be used?

Include in this section any specific information as it relates to your study. **How will my information be disclosed?**

Indicate how the information will be disclosed. This must be specific to the research study. It may include, but is not limited to, in-person review, paper copies mailed or picked up, fax, copy of angiogram film, use of computer database through the internet with protected user names and passwords.

### May I cancel my permission?

Add the name and address of the principal investigator. If a principal investigator receives a revocation of authorization, a copy must be forwarded to the facility's Institutional Review Board.

### PLEASE NOTE:

A copy of the HIPAA authorization must be placed in the patient's medical record and a copy must be given to the patient. The original may be kept in the patient's research file.

# FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

## Authorization for Use and Disclosure of Protected Health Information for Research Purposes

Study Title: [redacted]  
Protocol #: [redacted]  
Sponsor: [redacted]

You have agreed to participate in a research study that has been described to you in the research consent form. To do this research, we need to collect health information that identifies you. This form is called an "Authorization" and explains how your health information will be used and disclosed for this study. It also explains your rights, including the right to see your protected health information.

There is a federal law called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). This law protects the confidentiality of your protected health information. Protected health information is information about you that could be used to find out who you are.

### What information will be used?

The study doctor is working with the sponsor to conduct a research study. By signing this form, you allow the study doctor to use and share Protected Health Information about you to carry out this study. Protected health information includes all information about you collected during the research study for research purposes and information about you in medical records that is related to the research study. For example, this may include laboratory tests, x-rays, physical examinations, scans, medical history, medications you currently take and the following health information and tests:

*(Add any specific health information related to your research study, for example: if the study requires HIV testing explain that positive results have to be reported)*

### How will my information be disclosed?

<input type="checkbox"/> In-person review	<input type="checkbox"/> Paper copies picked up	<input type="checkbox"/> Paper copies mailed
<input type="checkbox"/> Fax		
<input type="checkbox"/> Other		

Generally, the study data sent by the Researchers to the sponsor does not include your name, address, social security number or other information that directly identifies you. Instead, the Researchers assign a code number to the study data and may use your initials. Some study data sent to the sponsor may contain information that could be used to identify you. Your medical records and study data may be held and processed on computers.

### How will my information be used?

The researchers may use your information in making decisions about your medical care and to carry out the study. Both the researchers and the sponsor may use your health information to analyze and evaluate the results of the study. The sponsor may also reanalyze the results of the study at a later date and combine them with results of other studies.

You agree to permit *(insert name of principal investigator)* and his/her staff ("Researchers") conducting the research study to use and disclose protected health information about you to the sponsor of the research and representatives of the sponsor assisting in the research. You agree to permit other health care providers to disclose health information in your medical records to the Researchers for the purposes of the research study.

The information may be given to the Food and Drug Administration (FDA) or other government agencies as part of applications to gain approval of new medicines or devices or to meet other reporting requirements such as side effects.

Your original medical records and study records, which contain information that directly identifies you, may be reviewed by the following organizations:

- Forsyth Medical Center Institutional Review Board
- Food and Drug Administration (FDA)
- Office for Human Research Protections (OHRP)
- Possibly representatives of other government or regulatory agencies in the United States and around the world.
- Study sponsor: [sponsor name and CRO]
- Study research group: [study group name]



## IND Safety Report Submission

**PLEASE USE THIS FORMAT AS YOUR COVER TO YOUR IND SAFETY REPORTS-**

Date:

Protocol #:

Protocol Title:

**Example:**

MFR #	Type of Report	Event Description	Investigator Causality (per report)
A1099011	(2)	Report of Atrial Fibrillation	Possibly related
A899988	(Initial)	Report of CVA – hemorrhagic	Investigator Causality Not Reported

I have reviewed the above referenced IND Safety Reports, and request review at the next meeting of the Institutional Review Board.

Principal Investigator:

\_\_\_\_\_  
(signature)

Submitted By:

\_\_\_\_\_  
(signature)

FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD



Researcher Assurances regarding Access to PHI  
"Preparatory to Research"

DATE:

The HIPAA privacy rule allows researchers to review protected health information ("PHI") that is "preparatory to research." 45 C.F.R. 164.512(i)(1)(ii). This includes access to PHI for the development of protocols, as well as for screening purposes to determine if a patient meets the criteria to participate in a particular study. In order to review this information without an authorization from the patient, researchers must provide the facility IRB with certain assurances.

Principal Investigator: \_\_\_\_\_

Clinical Research Team Member / Title: \_\_\_\_\_

Protocol Number and Title: \_\_\_\_\_

I certify that the following are true:

- (1) **use or disclosure is sought solely to review protected health information as necessary to prepare a research protocol or for similar purposes preparatory to research;**
- (2) **no protected health information is to be removed from the covered entity by the researcher in the course of the review; and**
- (3) **the protected health information for which use or access is sought is necessary for research purposes.**

My signature below indicates that I have read and will fulfill my responsibilities concerning access to PHI that is "Preparatory to Research" 45 C.F.R. 164.512(i)(1)(ii)., and will inform the IRB of any changes in my proposal, as well as any additional requirements imposed upon me by the facility IRB.

Requested by:

Accepted by:

\_\_\_\_\_  
Clinical Research Team Member / Title      Date

\_\_\_\_\_  
Elms Allen, MD      Date

Chairman,  
Forsyth Medical Center  
Institutional Review Board

\_\_\_\_\_  
Principal Investigator      Date

NOTE: the granting of this request does not allow **actual research to occur** – to do that you must get either a patient’s authorization (Informed Consent) or an IRB waiver of authorization. **This only allows access to information as needed to prepare for research.**

FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD



**Forsyth Medical Center Institutional Review Board**

**Request for Waiver or Alteration of HIPAA Authorization [45CFR164.512 (i)]**

1.	Investigator Name:		
2.	Company Name:		
3.	Mailing Address: (street, city, state/province, zip, country)		
4.	Phone Number: ( )	Fax: ( )	E-mail:

1.	Describe the identifiable health information that will be accessed under this waiver:		
2.	Who will have access to the information?		
3.	Are the persons who have access to the information required to sign confidentiality statements?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
4.	What identifiers are included on the information you plan to use and/or disclose?		
5.	In what form will the information be maintained? <input type="checkbox"/> Paper <input type="checkbox"/> Electronic <input type="checkbox"/> Both		
6.	If the information is in paper format, describe the precautions you are taking to protect the identifiers from improper use and disclosure:	NA <input type="checkbox"/>	
7.	If information is in an electronic medium, are passwords required?	NA <input type="checkbox"/>	Yes <input type="checkbox"/>
8.	Is access to the information restricted to only those who have a need to know for performance of their job?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
9.	Is this electronic system used to transmit data outside of your site?	Yes <input type="checkbox"/>	No <input type="checkbox"/>
10.	If information is transmitted, what safeguards does your system have to prevent inadvertent access to this data?		

FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

11.	When do you plan to destroy the identifiers? ( <b>Identifiers must be destroyed at the earliest opportunity.</b> ) <input type="checkbox"/> End of Study <input type="checkbox"/> _____ years after the end of the study. <input type="checkbox"/> Other (please specify): _____
12.	Other than you and your research staff, who else will have access to this information?
13.	Please explain how your research meets the following criteria for a waiver: 1. This research cannot be practicably carried out without the Waiver of Authorization. _____  2. This research cannot practicably be conducted without the participants' PHI. _____

Waiver criteria: I certify the following to be true:

- the use or disclosure of protected health information involves no more than a minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
    - there is an adequate plan to protect the identifiers from improper use and disclosure (included above);
    - there is an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law (included above); and
    - the protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of protected health information would be permitted by the HIPAA privacy regulations.
  - the research could not practicably be conducted without the waiver or alteration;
- and
- the research could not practicably be conducted without access to and use of the protected health information.

\_\_\_\_\_  
Signature of Principal Investigator

\_\_\_\_\_  
Date

Review and approval procedures: Based on the above written assurances, the alteration or waiver of authorization has been reviewed and approved by:

- normal IRB review procedures; or
- expedited review procedures.

\_\_\_\_\_  
IRB Chair or designee

\_\_\_\_\_  
Date

FORSYTH MEDICAL CENTER - INSTITUTIONAL REVIEW BOARD

**Fee Schedule**

**(Effective January 1, 2007)**

Service Requested	Fee
Initial Full Board Review (all materials).....	2,000.00
Full Board Review of Expired Protocol.....	2,000.00
Expedited Review (new study- if eligible).....	1,000.00
Expedited Review of Expired Protocol (if eligible)	1,000.00
Expedited Review (from previously approved research).....	250.00
Annual review (1st annual renewal- no charge).....	500.00
Suspension/Reinstatement fee.....	500.00
Preparation of Consent Form (per page).....	100.00
Consultation for Submission Preparation (per page after 1st 1/2 hour).....	100.00

IRB fees can be waived at the Boards discretion for Federally funded and other non-commercial research. Contact the IRB to discuss such consideration.

The IRB Chair reserves the right to determine what materials can be expedited according to GCP's and FDA guidelines.