

# **BURRELL COLLEGE OF OSTEOPATHIC MEDICINE**

## **STANDARD OPERATING PROCEDURES**

<b>Informed Consent: Non-English Speaking Subjects</b>		<b>RSP.025.00</b>
Effective Date	May 2016	
Last Revision/Review	July 25, 2023	

### **1. Purpose**

This policy defines the requirements for informed consent to be presented in a language understandable to the subject.

Scope- All Burrell agents and students involved in human subjects research.

### **2. Related Policy/Authority**

Responsible Official(s)- Institutional Official for Research, Director of research, IRB Chairperson, IRB Members

45 CFR Part 46: Protection of Human Subjects

### **3. Faculty/Staff Responsibilities**

Responsible Official(s): Authorized Institutional Official for Research, Director of Research, IRB Chairperson, IRB Members.

### **4. Definitions/Abbreviations**

### **5. Procedural Steps**

- 5.1 **Written Presentation of Informed Consent:** Department of Health and Human Services regulations for the protection of human subjects require that informed consents information be presented “in language understandable to the subject” and, in most situations, that informed consent be documented in writing. The written consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. Subjects who do not speak English should be presented with a consent document written in a language understandable to them.
- 5.2 **Oral Alternative to Written Informed Consent:** 45 CFR 46.117(b)(2) permits oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. When this procedure is used with subjects who do not speak English, (i) the oral presentation and the short form written document should be in a language understandable to the subject; (ii) the IRB-approved English language informed consent document may serve as the summary; and (iii) the witness should be fluent in both English and the language of the subject. At the time of consent, (i) the short form document should be signed by the subject (or the subject’s legally authorized representative); (ii) the summary (i.e., the English language informed consent document) should be signed by the person obtaining consent as authorized under the protocol: and (iii) the short form document

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and the summary should be signed by the witness. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

- 5.3 **IRB Review and Approval of Informed Consent:** The IRB must receive all foreign language versions of the written presentation documents and/or the short form documents as a condition of approval under the provisions of 45 CFR 46.117(b)(2). Expedited review of these versions is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

### **6. Reports/Charts/Forms/Attachments/Cross References**

### **7. Maintenance**

Reviewed annually by the Office of Research.

### **8. Signature**

Approved by  
Assistant Dean for Research

8/9/2023  
Date

### **9. Distribution List**

Internal/External

### **10. Revision History**

Revision Date	Subsection #	Summary of Changes	New/Cancellation/Replacement Procedure? (if applicable)	Approval Date
7/25/2023		Converted from May 2016 policy		8/9/2023