The Ohio State University Consent to Participate in Research
(Information provided verbally or in written form to the subjects that are recruited in the study)

Study title: BCRF: as a biomarker for joint disease progression
Principal investigators: Drs. David Flanigan, Thomas Best, Kevin Hackshaw, Sudha Agarwal.
Sponsor: The Ohio State University and National Institute of Health.

- **This is a consent form for research participation.** It contains important information about this study and what to expect if you decide to participate. Please consider the information carefully. If you decide to participate, feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to participate.

- **Your participation is voluntary.** You may refuse to participate in this study. If you decide to take part in the study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your usual benefits. Your decision will not affect your future relationship with The Ohio State University. If you are a student or employee at Ohio State, your decision will not affect your grades or employment status.

- **You may or may not benefit as a result of participating in this study.** You will be provided with any new information that develops during the study that may affect your decision whether or not to continue to participate. If you decide to participate, you will be asked to sign this form and will receive a copy of the form. You are being asked to consider participating in this study for the reasons explained below.

1. **Why is this study being done?** We have discovered that BRF is not produced in the body during arthritis in animal models. This protein is very important in bone function and healthy bone formation. Therefore, to find out if BRF is lower in patients with arthritis, we are recruiting participants for this study.

2. **How many people will take part in this study?** We anticipate recruiting 80 people for the study.

3. **What will happen if I take part in this study?** You will be asked to (i) give 1 CC of blood while your blood is being drawn for clinical tests, and (ii) the tissue that would be discarded during surgery will be saved and used for this study.

4. **How long will I be in the study?** You are not being recruited for any time period in the study. We are only asking permission to (i) use the diseased tissue that is discarded
during joint surgery, (ii) obtain 1 extra cc of blood, while the blood is being drawn for your clinical tests, necessary for your treatment.

5. *Your participation is voluntary.* You may leave the study at any time. If you decide to stop participating in the study, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with The Ohio State University.

6. *Will my study-related information be kept confidential?* Efforts will be made to keep your study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your participation in this study may be disclosed if required by state law.

7. *What are the costs of taking part in this study?* None.

8. *Will I be paid for taking part in this study?* No.

9. *What happens if I am injured because I took part in this study?* There are no extra procedures being performed just for this study. We are asking for: (i) One cc (half a tea spoon) of blood when you give blood for the diagnosis and treatment of your disease. (ii) A small piece of diseased or injured tissue that is discarded during surgery.

   If you suffer an injury from participating in this study, you should notify the researcher or study doctor immediately, who will determine if you should obtain medical treatment at The Ohio State University Medical Center. The cost for this treatment will be billed to you or your medical or hospital insurance. The Ohio State University has no funds set aside for the payment of health care expenses for this study.

10. *What are my rights if I take part in this study?* If you choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study. You may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled.

   An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable to carry out studies after a verbal consent of the subject. According to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

11. *Before researchers use or share any health information* about you as part of this study, The Ohio State University is required to obtain your authorization.

12. *The Ohio State University and its hospitals,* clinics, health-care providers and researchers are required to protect the privacy of your health information.
13. If you agree to take part in this study your health information will be used and shared with others involved in this study. Also, any new health information about you that comes from tests or other parts of this study will be shared with those involved in this study.

14. Health information about you that will be used or shared with others involved in this study may include your research record and any health care records at the Ohio State University. For example, this may include your medical records, x-ray or laboratory results.

15. Researchers and staff at The Ohio State University will use, share and receive your personal health information for this research study. Authorized Ohio State University staff not involved in the study may be aware that you are participating in a research study and have access to your information. This study is NOT related to your medical care.

16. Those who oversee the study will have access to your information, including: Members and staff of the Ohio State University’s Institutional Review Boards, including the Western Institutional Review Board, The Office for Responsible Research Practices, University data safety monitoring committees, The Ohio State University Research Foundation.

17. Your health information may also be shared with federal and state agencies that have oversight of the study or to whom access is required under the law. These may include: The Food and Drug Administration, The Office for Human Research Protections. The National Institutes of Health, The Ohio Department of Human Services. These researchers, companies and/or organization(s) outside of The Ohio State University may also use, share and receive your health information in connection with this study: Health care facilities, research site(s), researchers, health care providers, or study monitors involved in this study: [insert name of non-OSU co-investigator(s) and other research sites and organizations that will use and share information or delete]; Private laboratories and other persons and organizations that analyze your health information in connection with this study: [insert name(s) of organizations that analyze lab results or data or any collaborative groups that will have access to the data or delete]; The research sponsor and companies owned or connected with the sponsor: National Institute of Health and National Science Foundation.

18. Who can answer my questions about the study?
For questions, concerns, or complaints about the study you may contact Dr. Flanigan, Dr. Best or Dr. Hackshaw.
For questions about your rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you
may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251. If you are injured as a result of participating in this study or for questions about a study-related injury, you may contact Dr. Flanigan, Dr. Best or Dr. Hackshaw.

**Signing the consent form**

I have read (or someone has read to me) this form and I am aware that I am being asked to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

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**Investigator/Research Staff**

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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