Instructions:

1. Complete **all** sections of the protocol template. By clicking on headers in the Table of Contents below, the form will navigate you directly to that section.
2. If a section does not apply, list Not Applicable as advised.
3. Refer to documents, templates, checklists, SOPs, and worksheets as advised throughout the protocol in **Blue**. Each document referred to in blue contains a hyperlink to the RAP library to obtain the documents (CONTROL + CLICK)
4. Please ensure that your RAP Profile is up to date with your correct email address, phone number, and a current CV/Resume.
5. Upload this completed document into a New Study Submission in RAP (https://rap.irb.uc.edu/irb), on the Basic Information Page under "Protocol".

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STUDY SUMMARY:

PROTOCOL TITLE:	Determining the ease of utilizing 3D Printed Models to aide in Isolated Mandibular Fracture Repair
PRINCIPAL INVESTIGATOR:	Deepak G Krishnan, DDS, FACS Associate Professor of Surgery Chief, Oral & Maxillofacial Surgery
VERSION NUMBER/DATE:	Version 1.3- November 1st, 2022
SHORT TITLE:	3D Printed Models for Mandibular Fracture Repair
RESEARCH INTERVENTION(S)/ INVESTIGATIONAL AGENT(S):	N/A
IND/IDE #:	N/A

STUDY SPECIFIC ABBREVIATIONS/ DEFINITIONS:	UCMC is University of Cincinnati Medical Center HH is Holmes Hospital OMS is Oral and Maxillofacial Surgery OR Operating Room ORIF Open Reduction and Internal Fixation AMUPs Anatomic Model Utility Points MVCs motor vehicle collisions CPT The Current Procedural Terminology SSI Surgical site infection VTE Venous thromboembolism	
FUNDING SOURCE	N/A	
FUNDING LOCATION	☐	**Funds are held in Sponsored Research Services for a Grant or Contract (funds are held internally at UC)**
	☐	**Funds are from a department account (held internally at UC)**
	☐	**Funds held in a corporate account from a Contract (funds held externally from UC)**
	☒	**No funding**

PROTOCOL:

1.0 OBJECTIVES	**1.1 Describe the purpose, specific aims, or objectives.** The goal of treatment is to re-establish the patient's preinjury dental occlusion and facial harmony. Fractures that are nondisplaced and exhibit no occlusal changes may be amenable to nonsurgical management, but most mandible fractures will require stabilization for satisfactory healing and to restore pretraumatic maxillomandibular orientation. Various treatment strategies have been described and vary widely depending on the fracture location and surgeon's preference. The patient's demographics, comorbidities, dentition, and fracture characterization will all influence the choice of fixation by the treating surgeon. [4] There are very few randomized control trials that show outcomes when 3D printing is used for intervention planning and performing a procedure. These data are essential to establish value of 3D printing as a clinical service. There is also anecdotal evidence that a 3D printed model of a mandible fracture can be useful for pre-operative planning because the oral and maxillofacial surgeon can better assess the geometry of the bone lesions and can pre-bend fixation plates before the procedure. This hypothetically decreases the amount of time in the operating room. The investigators propose a parallel design randomized control trial to study the value of 3D printing for preoperative planning in patients with a fracture of the mandible who require open reduction, internal fixation. The study will be split into two arms: 1) Patients that will

	have a 3D model generated for the surgical procedure 2) The control group who will follow normal standards of care as outlined above and won't have the additional 3D model created pre-operatively.
	1.2 Describe the hypotheses to be tested.
	The investigators will test the hypothesis that patients randomized to the intervention (3D printing with pre-bent plate) arm have less operative room time and less time for the critical part of the procedure than patients in the control arm (no 3D printing, current standards of care). Personalized medicine and care for fracture treatment.
2.0 BACKGROUND	**2.1 Describe the relevant prior experience and gaps in the current knowledge.**
	Currently, several corporations are contracted with maxillofacial plating companies to provide 3D planning and printing of surgical models, stents, and guides to facilitate surgery. However, these services can be cost prohibitive and can require a considerable lead time. The typical minimum required time of 1 to 2 weeks for the planning and manufacturing process can be limiting when attempting to treat acute injuries in a timely fashion. On-site, or in-house, 3D model fabrication with preoperative plate bending is a cost- and time-effective option to provide predictable reconstructive solutions with an associated decrease in operative time and cost. An inexpensive on-site option mitigates the cost of an outside contracted biomedical engineering service, which has a typical per-case cost of $1,000 to $2,000, and decreases the time needed to deliver a patient-specific implant to the OR. [10] Numerous types of 3D printers are currently commercially available, ranging from industrial machines costing more than $100,000 to consumer-level products that yield nearly industrial-level results with start-up costs of under $3,000. [10] The purpose of this study is to evaluate the feasibility, accuracy, and compatibility with current surgical approaches to re-work the current standards of care to include the use of on-site 3D model creation and preoperative plate bending for mandibular fractures.
	2.2 Describe any relevant preliminary data.
	Recent advances in imaging modalities, software technology and 3D printing have allowed for increased accuracy, ability to troubleshoot prior to surgery, and decrease operative time. Virtual surgical planning (VSP) is routinely utilized in maxillofacial surgery for orthognathic surgery, complex craniomaxillofacial trauma, resection and free flap reconstruction of benign and malignant pathology. Typical input is radiographic imaging (CT, CT Angio, MRI, etc.), intraoral scans, 3D facial scans. With the end goal in sight, through virtual surgical planning, cutting guides can be fabricated for accurate osteotomies, intermediate and final dental splints can be created to ensure proper placement of osteotomized segments and custom plates can be fabricated to fixate the bony segments in a predictable fashion.
	2.3 Provide the scientific or scholarly background for, rationale for, and significance of the research based on the existing literature and how it will add to existing knowledge.

	3D printing is a technology that allows for physical creation of a 3D model (usually made of plastic) based on computer generated 3D images from CT scans. The 3D images of craniofacial skeleton using computer software are routinely generated and, in turn, these 3D images can be used to create a plastic 3D model using a 3D printer. Unstable or comminuted facial fractures need to be reduced and rigidly fixated using titanium plates and screws. Bending and shaping of the plates is usually performed by free hand based on the surgeon's estimation of what best fits the fracture. Often, bending the titanium plates to the shape of pre-injury skeletal contour is difficult when the bone is fractured into many pieces or is unstable, or when the patient is edentulous (missing several teeth). The process can increase the time spent in surgery and the bent plates may not snugly fit the fracture. For these difficult cases, one option is to use commercially manufactured 3D printed patient-specific models. The patient-specific models provide the benefit of correct shape/form for increased surgical accuracy and decreased intra-operative time. Thus, redefining standards of care increasing surgical satisfaction from the surgeon and patient, while decreasing the time in the OR.
3.0 RESOURCES AVAILABLE	**3.1 Describe the resources available to conduct the research. Justify the feasibility of recruiting the required number of suitable subjects within the agreed recruitment period, e.g. how many potential subjects do you have access to? What percentage of those potential subjects do you need to recruit?**
	The study will be conducted at University of Cincinnati Medical Center which is designated as the region's only Level I trauma center by the American College of Surgeons. This will be a joint study with the divisions of Oral and Maxillofacial surgery, Plastics and Reconstructive surgery and Otolaryngology who are designated as the primary teams for management of all facial trauma at the institution. Thousands of consults are requested annually through UCMC ED and neighboring hospital systems for these specific injuries.
	3.2 Describe the time that you will devote to conducting and completing the research, i.e. percent effort.
	The staff involved with conducting this research project have clinical and didactic responsibilities outside of their research work. The supervisors of this study tend to dedicate one academic day a week for research and other administrative needs, realistically yielding 10-15% of effort on the part of supervisors. However, the main research coordinator and main facilitator of the project has a full-time research position at the division of oral and maxillofacial surgery, where 100% of effort is dedicated towards the research effort.
	3.3 Describe the availability of medical of psychological resources that subjects might need as a result of an anticipated consequences of the human research.
	The study will be based out of Holmes Hospital Oral and Maxillofacial Surgery clinic and UCMC. In the event of an emergency (which would be extremely unlikely to be because of the medications used for this study), quick transportation to the emergency department can be arranged. Additionally, a crash cart and complete rescue airway carts are in the clinic,

	which always have direct UC always attending coverage. All residents and attendings are ACLS/BLS/PALS trained, and all staff at the clinic are BLS trained. Additionally, the clinic is located directly adjacent to the ambulatory operating rooms and facilities, which are staffed by anesthesiologists, various other surgical specialists, nurses, nurse anesthetists, anesthesia technologists, whose resources and help are readily available if needed. Psychological outcomes do not pertain to the study. However, standard psychological resources at UC are available to any patient who receives their care at UC
	3.4 Describe your process to ensure that all persons assisting with the research are adequately informed about the protocol, the research procedures, and their duties and functions.
	A formal orientation will be held for any member involved with this study conducted by the division's research coordinator. Given that this is a blinded study certain pieces of information will be withheld from certain individuals, particularly the surgical providers, for the integrity of the research. The orientation will include presentations, and one-on-one informative meetings, as well as question and answer sessions. All members involved in the research study will be carefully monitored by the principal investigator and research coordinator for appropriate conduct and compliance with the research protocol and specific responsibilities
	3.5 Describe the facilities you have access to that will allow you to conduct the research.
	As discussed earlier, the facility that will host the research study is Holmes Hospital Oral and Maxillofacial Surgery clinic affiliated with University of Cincinnati Medical Center and the Department of Surgery
4.0 INVESTIGATOR EXPERIENCE	**4.1 Detail the investigators' experience as it pertains to the study.**
	Dr. Krishnan has been a member of the UC Surgery faculty since 2008. He is currently associate professor of surgery and is serving as the chief of OMS at UC Medical Center and Cincinnati Children's Hospital. Dr. Krishnan obtained his dental degree from Bangalore University, India, and trained in Oral and Maxillofacial Surgery at Emory University's College of Medicine in Atlanta, Georgia. Upon completion of residency, Dr. Krishnan pursued further fellowship training in Oral & Maxillofacial Surgery focusing on orthognathic surgery at Dalhousie University, Halifax, Canada. He currently serves on the Committee of Education and Training (CET) of the AAOMS and is the chair of the special committee on Emerging leaders in OMS. He is also a consultant to the AAOMS Committee on Anesthesia (CAN) on Simulation in Anesthesia. Dr. Krishnan was in the first class of single degree oral and maxillofacial surgeons that were recognized as Fellows of the American College of Surgeons. Dr. Rybicki is Vice Chair of Operations & Quality at the University of Cincinnati Department of Radiology, and he is the clinical lead for the 3D printing section at UCH. HI is the past-Chair of the American College of Radiology Appropriateness Criteria, and the Founding Chair of the Radiological Society of North America 3D Printing Special Interest Group. He also is currently the Editor-in-Chief of the journal 3D Printing in Medicine. Dr. Rybicki obtained his medical

	degree through the physician scientist program at Harvard -MIT (Medicine and Medical Engineering), and he completed his residency in Diagnostic Radiology at the Brigham and Women's Hospital and Harvard Medical School, Boston, MA.
5.0 STUDY ENDPOINTS	**5.1 Describe any primary and secondary study endpoints.**
	Outcome 1: Noninferiority of the clinical outcome (defined by OMS on the post-op, follow up exam approx. 6 weeks out) Based on physical exam Outcome 2: a. Total time in the OR b. Time in the OR considered critical part of the procedure by the OMS Staff Outcome 3 a. Subjective outcome to surgeon Likert scale
	5.2 Describe any primary and secondary safety endpoints.
	Not Applicable.
6.0 PROCEDURES INVOLVED	**6.1 Thoroughly describe the study design.**
	We plan to conduct a randomized controlled trial on trauma patients brought to either UCMC or UC HH OMS for treatment of isolated mandibular fractures. This study plans to elucidate whether the utilization of 3D models during operations where effective in minimizing both OR time and operational costs. Subjects will be identified based off the initial physical assessments made by surgical specialists from OMS, Plastic Surgery, and otolaryngology. Once the subjects are identified the research coordinator will conduct a screening of the patient to ensure they meet the inclusion/ exclusion criteria for the study and then randomize the patient into either normal standard of care for surgical repair of the fractured mandible or normal standard of care for surgical repair of the fractured mandible aided by a 3D printed model of the patient's jaw. Any chart reviewing will be conducted from existing electronic medical records maintained by UC Health EPIC and OMS Vision. All the following data would be based on the patient's condition at the time of surgery. Following completion of the procedure, for the surgeons who received aide via the 3D model they will be asked to answer a brief Likert Scale survey outlining their thoughts how effectively or ineffectively the model assisted them. In addition to this information, if they feel the model increased efficiency saving time, they will be asked to state how much time they felt was saved. This time differential will be compared to current CPT codes for OR time to understand how much in operational costs were saved by utilizing the models.
	6.2 Detail the procedures being performed, specifically the interaction or intervention with human subjects and/or their identifiable information. Please be clear and concise and provide information relevant to the current study. For

example, please be sure that what will be done for this research is explained and differentiated from activities that have already taken place or will be submitted for future review. Please note that details about recruitment and consent are asked in later questions.

The primary goals in the management of mandibular fractures are restoration of functional occlusion and facial form. There are frequently several appropriate techniques available for the definitive management of a given mandible fracture. In general, mandible fractures are treated either closed (maxillomandibular fixation, splinting, modified diet) or open (plates and screws, interosseous wiring, lag screws). The technique chosen depends on several variables including, dental status, fracture characteristics (open, closed, favorable, unfavorable, comminution, bone lose, mechanism of injury, contamination, or frank infection etc.), fracture location, associated injuries, patient mental status and patient desires. The most important considerations are the dental status, fracture characteristics and fracture location.

The main surgical techniques that will be performed will be as follows:

Open reduction and internal fixation of mandible fractures is an evolving science. There are several different techniques used to internally fixate mandible fractures. Simple interosseous wiring to supplement intermaxillary fixation is a form of open reduction and internal fixation. There are a variety of plate and screw systems available for the repair of mandible fractures. Compression plating of mandibles has become popular over the last 10 years. Compression plate fixation allows direct bone healing and, in most cases, eliminates the need for 4 to 6 weeks of maxillomandibular fixation needed with closed reduction techniques. Compression plates used on the inferior cortex must always be used with some form of tension band as discussed above. A special type of compression plate called an eccentric dynamic compression plate can be used without a tension band. This plate has sliding ramp holes which allow compression of the fracture not only in the plate but also at the tension side of the mandible. In general, the application of compression plates requires that the angle of the fracture be no more than 30 degrees from a line perpendicular to the long axis of the plate. If an angle greater than this exists, the compression plate will cause the fragments to slide against one another rendering the reduction nonanatomic and not in compression.
If internal fixation is desired and compression plating cannot be performed due to an oblique fracture or significant comminution of fragments, several other options exist. Reconstruction plates are large plates which use at least three screws on each side of the fracture. They hold the bone in absolute stability and because of their large size and stability, they do not require a tension band. Reconstruction plates are useful in cases of severely comminuted mandible fractures such as those resulting from gunshot injuries. If correctly placed small, no compression plates (called adaptation plates) may be used to repair mandible fractures. The most well-known of these systems is the Champy system. One final method of internal fixation of mandible fractures is with lag screws. A lag screw can compress two bone fragments and therefore permits direct bone healing. The number of fracture cases suitable

	for lag screw repair is relatively small and this technique requires considerable experience and skill. Fractures of the mandible can be approached either trans orally or through the neck. In closed fractures one advantage of approaching the fracture through the neck is the absence of salivary contamination of the wound. The obvious drawback in an external approach is a scar. Most symphyseal and body fractures can be easily plated through the mouth. Angle and ramus fractures are difficult to approach through the mouth and if an intraoral approach is performed special instruments for the transcutaneous placement of screws must be available. Patients with open mandible fractures should be on antibiotics active against oral cavity organisms including anaerobes. Perioperative antibiotics have been shown to decrease the rate of wound infections.
	6.3 Describe procedures being performed to monitor subjects for safety or minimize risks.
	Several steps are taken to assure patient safety for surgical procedures. Prior to the procedure, their vitals are taken, including their blood pressure, heart rate, respiratory rate, and oxygen saturation. Depending on the patient, especially those with history of cardiopulmonary disease, monitors are kept cycling every five minutes during the procedure. A thorough history and physical is performed before any procedure to assure appropriate patient selection and to rule out more emergent issues. During the procedure, patients are continuously monitored with active physical examinations by the provider. There is always a certified oral and maxillofacial assistant with the patient in the room, especially during the procedure. For urgent-add on, a registered nurse is normally present as well to monitor the patient. The patient is treated via standard protocol of the oral and maxillofacial clinic at Holmes Hospital, which treats thousands of patients annually through safe, effective, and efficient measures. As explained earlier, emergency crash carts, including rescue airway carts, are present at the facility, as well as dozens of trained personnel promptly available if needed.
	6.5 Where applicable, list and describe the data collection tools such as surveys, data collection forms, etc. All tools described should be uploaded in the RAP Smart Form on the Local Site Documents page unless they are standardized, validated tools.
	Data collection will only be stored and collected on REDCap, which is a server software maintained by Cincinnati Children's Hospital Medical Center (CCHMC) informational technology team. The surgeon assigned to the case will fill out the questionnaire outlining the how effective using the 3D model was during the procedure. The outcome data will then be collected on the same secured software.
	6.6 Describe all data that will be accessed and collected during the study and how that data will be obtained (how it will be accessed).
	Description – Distinguish between data accessed and data collected if applicable.

	6.7 If there is a long-term follow-up plan (once all research related procedures are completed), what data will be collected during this period.
	No Long-Term Follow-Up
7.0 DATA AND SPECIMEN BANKING	**7.1 If data or specimens will be banked for future use, describe where the data or specimens will be stored, how the data or specimens will be accessed, and who will have access to the data or specimens.**
	Data collected from this study will be destroyed/deleted after the study's conclusion. No specimens will be collected.
	7.2 If specimens are being stored, list the data to be stored or associated with each specimen.
	Not Applicable
	7.3 Describe the procedures to release data or specimens, including: (the process to request a data/specimen release, approvals required for release, who can obtain data or specimens, and the data to be provided with the specimens.
	Not Applicable
8.0 SHARING OF RESULTS WITH SUBJECTS	**8.1 Describe whether results (study results or individual subject results, such as results of investigational diagnostic tests, genetic tests, or incidental findings) will be shared with subjects or others (e.g., the subject's primary care physician) and if so, describe the process for sharing. If you do not intend to share any results, please state that here.**
	The results of the study are obtained directly from the questionnaire and involvement. Thus, there is no process to share or release results with patients. Patients will not be sought to discuss the particulars of study results. Study results will be shared via peer-reviewed journals. This section is not pertinent to the study.
9.0 STUDY TIMELINES	**9.1 Describe the duration of an individual subject's participation in the study. List the number of study visits or frequency of study visits.**
	The subject's participation is limited to a one-time appointment.
	9.2 Describe the timeline allotted for the enrollment of subjects.
	Prospective subjects would be triaged during their admissions to UCHMC. If the subject meets the study criteria, the research coordinator would enter the evaluation room after the surgical provider has completed their history and physical, at which point involvement will be established and randomization will be conducted. Thus, based on study design, there is not specific timeline of enrollment since the decision is made same day.
	9.3 Describe the estimated date for the investigators to complete this study (complete primary analysis).
	Primary analysis is estimated to be complete in January 2024.

10.0 INCLUSION AND EXCLUSION CRITERIA & VULNERABLE POPULATIONS

10.1 Describe how subjects will be screened for eligibility.

The screening of potential participants will be performed by the providers of University of Cincinnati Medical Center's Department of Oral and Maxillofacial Surgery clinic located at Holmes Hospital (UCMC OMS HH clinic), or surgical providers from plastic surgery and otolaryngology located in UCMC including resident physicians, attending physicians, research staff, and clinic staff. Surgical team members from the division of plastic and otolaryngology will be consented and recruited to participate in this study by providing their feedback post operatively. The diagnosis and treatment planning will strictly be made by a resident or attending surgeon. However, an elected research coordinator will complete a standardized eligibility form on REDCap based on the study's inclusion/exclusion criteria to finalize participant selection

10.2 Describe/list the inclusion/exclusion criteria for the study.

Inclusion Criteria:
Patient ≥ 18 years of age
Patients who have received either a cone beam or conventional CT
Admitted through UCHMC emergency department
All isolated mandible fractures referred to UCH OMS
Surgical team members from the division of plastic and otolaryngology

Exclusion Criteria:
Patient < 18 years of age
Patients who have neither cone beam nor conventional CT
Patients requiring a repeat procedure
Unexpected exposure of hardware

10.3 Indicate specifically whether you will include each of the following vulnerable populations. Check all that apply. (You may not include members of the below populations as subjects in your research unless you indicate this in your inclusion criteria and are approved by the IRB to include them in your research) The member checklists are for reference only to ensure you provide appropriate safeguards and justification. The checklists do not need to be completed.

☐ **Adults unable to consent (cognitively impaired individuals)** (**HRP-417 – MEMBER CHECKLIST Cognitively Impaired**)

☐ **Individuals who are not yet adults (infants, children, teenagers)** (**HRP-416 – MEMBER CHECKLIST Children**)

- ☐ **Individuals who are not yet adults and are, or may become, wards of the state.**

☐ **Pregnant women (a woman shall be assumed pregnant if she exhibits and of the presumptive signs of pregnancy, such as a missed menses, until the results**

		of a pregnancy test are negative or until delivery.) (HRP-412 MEMBER CHECKLIST Pregnant Women)
	☐	**Non-Viable Neonates (HRP-413 – MEMBER CHECKLIST Non-Viable Neonates)**
	☐	**Uncertain Viability Neonates (HRP-414 – MEMBER CHECKLIST Uncertain Viability Neonates)**
	☐	**Prisoners** (HRP-415 – MEMBER CHECKLIST Prisoners)
	10.4 If the research involves individuals listed in 10.3 or other individuals who are vulnerable to coercion or undue influence, please justify based on the applicable checklist and describe additional safeguards included to protect their rights and welfare.	
	N/A	
	10.5 If the research involves or may involve individuals who are students or employees where the research is taking place, please describe additional safeguards included to protect their rights and welfare.	
	Not Applicable	
11.0 NUMBER OF SUBJECTS	**11.1 Indicate the total number of subjects to be accrued.**	
	We aim to obtain 50 procedures for each arm of the study (100 in total) 50: standard surgical procedures aided by use of 3D Printed model 50: procedures carried out by standard surgical repair for isolated mandibular fractures (No model)	
	11.2 If applicable, distinguish between the number of subjects who are expected to be enrolled and screened, and the number of subjects needed to complete the research procedures.	
	N/A	
12.0 RECRUITMENT METHODS	**12.1 Describe when, where, and how potential subjects will be recruited.**	
	Subjects of this study are those that require emergent medical attention and are referred to either UCHMS Emergency Department or to UC OMS for treatment. Subjects will be triaged by the clinical providers, and the research coordinator will then complete a standardized informative process. Regardless of involvement, the subject will undergo the same treatment course as any other patient presenting with an isolated mandibular fracture. For the consenting of the surgical team members, they will undergo a research presentation given by the research coordinator in which they have an adequate amount of time to ask any questions or concerns before deciding to be a part of the study.	
	12.2 Describe the source of the subjects.	
	Subjects for the study are any patient are referred to HH OMS for treatment of isolated mandibular fracture. The referral arrives will need emergent medical treatment arriving from the emergency department. No subject will be sought after for the purposes of the study since the population will be emergent cases admit to UCHMC. Surgical team members will be	

	identified by both the PI and research coordinator for recruitment based off of past surgical collaboration on routine procedures at UCMC.
	12.3 Describe the materials that will be used to recruit subjects. (Attach copies of these documents in the Recruitment section on the local site documents page in RAP. For advertisements, attach the final copy of printed advertisements (avoid making copies until approved in case modifications are required). When advertisements are taped for broadcast, attach the final audio/video tape. You may submit the wording of the advertisement prior to taping to preclude re-taping because of inappropriate wording, provided the IRB reviews the final audio/video tape)
	N/A
13.0 COMPENSATION FOR SUBJECTS	**13.1 Describe the amount, method, and timing of payments to subjects.**
	N/A
14.0 WITHDRAWAL OF SUBJECTS	**14.1 Describe the anticipated circumstances under which subjects will be withdrawn by the study team from the research without their consent.**
	Given the strict inclusion and exclusion criteria of the study, we anticipate very few circumstances in which patients will need to withdraw by the study team without their consent.
	14.2 Describe any procedures for orderly termination.
	Patients will be withdrawn from the study if they unfortunately succumb to their injuries related to any polytrauma that caused the underlying mandibular fracture before any procedures can be completed. Surgeons who no longer wish to provide feedback via the Likert scale questions will also no longer be associated with the study.
	14.3 Describe procedures that will be followed when subjects withdraw from the research, including partial withdrawal from procedures with continued data collection, withdrawal of previously collected data upon request, etc.
	Patients and surgeons who are withdrawn from the study for the purposes listed earlier will be excluded from all study results.
15.0 RISKS TO SUBJECTS	**15.1 Describe the reasonably foreseeable risks, discomforts, hazards, or inconveniences to the subjects related to the subjects' participation in the research. It may be useful to include: a description of the probability, magnitude, duration, and reversibility of the risks. Consider the physical, psychological, social, legal, and economic risks.**
	There are no risks related to the 3D printing. The physical model is generated from the CT images that have already been acquired, and the addition of the 3D printed model for those patients randomized to the 3D printing arm will be completely transparent.

	The following risks as described are general risks that the patient would assume with the study. Confidentiality of the data Electronic data will contain a de-identified patient ID number, which will be used to link back to the identifier. The key linking identifier to subject number will not be stored with the electronic data. Electronic data will be managed using an excel sheet stored on a secure computer. Analytical datasets will be stored on secure servers that also limit access to the investigator team. Should results of the study be published or reported, individual names or other identifying information will not be used.
	15.2 If applicable, indicate which procedures may have risks to the subjects that are currently unforeseeable.
	All procedures and medications used have known risks and are discussed above. Thus, there are no unforeseeable risks to discuss.
	15.3 If applicable, indicate which procedures may have risks to an embryo or fetus should the subject or the subject's partner be or become pregnant.
	Not Applicable
	15.4 If applicable, describe risks to those who are not subjects.
	Not Applicable
	15.5 Describe the procedures and actions taken to mitigate the risks to subjects and others.
	See section 15.1. Each specific risk listed includes a description on mitigation. Since risk and mitigation are synonymous, they have been discussed in the same section.
16.0 POTENTIAL BENEFITS TO SUBJECTS	**16.1 Describe the potential benefits that individual subjects may experience from taking part in the research. It may be useful to include: the probability, magnitude, and duration of the potential benefits. Indicate if there is no direct benefit to subjects. Do not include benefits to society or to others.**
	N/A

17.0 DATA MANAGEMENT AND CONFIDENTIALITY	**17.1 Describe the data analysis plan, including any statistical procedures or power analyses.**
	We are going to use the Likert questions to develop a numerical scoring system and report that data as "raw" Likert scores. Likert questions and conversion of specialists' responses to Anatomic Model Utility Points (AMUPs). Responses of "strongly disagree", "disagree", and "neutral" were assigned 0 AMUP points. Responses to preprocedural confidence are assigned negative points, to effectively subtract the impact of the anatomic model post- versus pre-procedure. The maximum AMUP for each patient was 500.
	17.2 Describe the steps that will be taken to secure the data.
	All data will be stored on REDCap. During data collection, the research coordinator will record the data directly into REDCap. REDCap which is a server software maintained by Cincinnati Children's Hospital Medical Center (CCHMC) informational technology team. REDCap must be installed on a local web server by CCHMC's internal IT staff. CCHMC's server environment is physical/on-premises. CCHMC's internal IT staff must handle all aspects of REDCap installation, maintenance, and support. The REDCap license is required to install the software. Note, it must be pointed out that much of the security surrounding REDCap has nothing to do with the REDCap software itself but rather is dependent upon the IT infrastructure and environment in which REDCap has been installed. This includes the webserver and database server, the communication between those two servers, and the communication of the web server with the REDCap end-user. REDCap is easily configurable for use and requires minimal infrastructure and setup. REDCap can run on several different operating systems (Linux, Unix, Windows, Mac). To ensure that REDCap users have access only to data and information that they are supposed to have access to within the application, user privileges are utilized within the software. REDCap implements authentication to validate the identity of end-users that log in to the system. CCHMC's utilizes Shibboleth authentication to provide a single sign-on, external method of authentication. User's username and password are controlled in CCHMC's OIM. Users in REDCap are redirected to another webpage to log in, and then are redirected back to REDCap if they authenticated successfully. REDCap contains an auto-logout setting, which is customizable (default auto-logout time is 30 minutes) and will automatically log a user out of the system if they have not had any activity (e.g., clicking, typing, moving the mouse) on their current web page for the set amount of time. This prevents someone else from accessing their account and their project data if they leave a workstation without properly logging out or closing their browser window. CCHMC's REDCap will store all data captured in REDCap on its own servers. Therefore, all project data is stored and hosted at CCHMC, and no project data is ever transmitted at any time by REDCap from CCHMC to another institution or organization. REDCap does not employ any kind of

encryption of data (i.e., encryption "at rest") on its database server. (This is not to be confused with encryption of data "in transit" (i.e., via SSL) to the database, which should always be done.) The encryption of database data is not necessary if the database server is properly secured. All documents that are uploaded and/or stored in REDCap will be stored on the local REDCap web server in a secure directory. To help protect and secure the data stored in Redcap's back-end database, the software application employs various methods to protect against malicious users who may attempt to identify and exploit any security vulnerabilities in the system. Such methods will be described here in technical detail:

In REDCap, all incoming data gets intentionally filtered, sanitized, and escaped. This includes all data submitted in an HTTP Post request and all query string data found in every URL when users access REDCap, among other modes through which user-defined data gets submitted in the application. Server environment variables that are vulnerable to forgery by end-users are also checked and sanitized. All user-submitted data is properly filtered for any possibly harmful markup tags (e.g., <script>) and is then escaped before ever being displayed on a web page within the application. SQL queries sent to the database server from REDCap are all properly escaped before being sent. If any values used in an SQL query originated from user-defined values, they would also have already been sanitized beforehand, as described above. User-defined data used within SQL queries have their data type-checked to prevent any mismatching of data types (e.g., making sure a number is really a number). These processes of sanitization, filtering, data type checking, and escaping all help to protect against methods of attack, such as Cross-Site Scripting (XSS) and SQL Injection. To specifically protect against Cross-Site Request Forgery (CSRF), which is another method of attack, REDCap utilizes a "nonce" (a secret, user-specific token) on every web form used in the application. The nonce is generated as a unique value for each new HTTP request in every REDCap session.

Additionally, REDCap employs "rate-limiting" on its web pages, in which there is a set maximum number of web requests per minute that are allowed from a single IP address, and after that maximum is hit, the IP address of that user is permanently banned from REDCap. The rate-limiting value of requests per minute per IP is customizable and can be modified within Redcap's Control Center. Rate limiting prevents denial of service attacks by bots as well as preventing other types of hacker attacks that require making many requests to the server in a short amount of time, such as with a BREACH attack. Regarding the prevention of BREACH attacks specifically, in addition to using rate limiting, REDCap always outputs an invisible string of random text of random length on every web page (to conceal the page's true length) as an effective technique for mitigating such an attack. Redcap's use of a unique nonce token on every web form also greatly diminishes the possibility of a BREACH attack.

About the security of cookies used by REDCap, all session cookies and other cookies related to authentication that are created by REDCap will automatically have the "HTTP Only" attribute set to TRUE. By default, the "Secure" cookie flag will be set to FALSE. while this is slightly more insecure, setting its value as TRUE can sometimes cause login issues with certain server configurations, such as reverse proxies. So, for compatibility reasons, it is set as FALSE by default. However, CCHMC administrators can enable the "Secure" flag of session cookies to improve security by setting session. cookie secure=On in the REDCap web server's PHP.INI configuration file.

Administrative controls

University of Cincinnati Medical Center Division of Oral and Maxillofacial Surgery Research Coordinator, Reese Triana, has complete administrative control over the individuals involved with the research project. Any research members involved must formally apply to University of Cincinnati Health Office of Clinical Research. This application entails a confidentiality and data security agreement which must be signed and approved, which holds the employee liable for violating HIPAA policies and patient confidentially. Otherwise, the process of gaining access to the UC charting systems is rigorous and extensive, including drug screening, badge identification application, IT registration, etc. The research member has an orientation overseen by the Research Coordinator, to adjust them to the project, including the rules and regulation of maintaining patient confidentiality. CITI training is required of all participants, including annual confidentially agreements.

On REDCap, the Research Coordinator is given full rights to everything within the project, after which they may grant other users access to the project and limit those users' privileges as desired. Within each project, there are user controls to limit access to various functionality and modules, such as being able to export data, to enter data, to add or modify database fields or survey questions, to build or run reports, to modify user privileges, to view the logging records, and so on.

17.3 Describe any procedures that will be used for quality control of data collection.

REDCap has a built-in audit trail that automatically logs all user activity and logs all pages viewed by every user, including contextual information (e.g., the project or record being accessed). Whether the activity be entering data, exporting data, modifying a field, running a report, or add/modifying a user, among a plethora of other activities, REDCap logs all actions. The logging record can itself be viewed within a project by users that have been given privileges to view the Logging page. The Logging page allows such users to view or export the entire audit trail for that project, and to filter the audit trail in various ways based upon the type of activity and/or user. The built-in audit trail in REDCap allows administrators to be able to determine all the activity and all the data viewed or modified by any given user. This structural aspect

	of REDCap allows for close monitoring of data from the study supervisors. Additionally, only the research coordinator will have capability to add or remove data. REDCap allows the coordinator to designate or prevent specific rights to be assigned from team members.
	17.4 Describe how data or specimens will be handled study wide as outlined below.
	17.5 What information will be included in the data or associated with the specimens?
	No specimens will be collected. The information collected will be as follows: Procedural Time Cost differential via model utilization 3D Printing Likert scale Questions answered by specialist post operatively

	17.6 Who will have access to the data or specimens?
	No specimens will be collected. Data access will be restricted to the research coordinator, the principal investigator, and co-investigators
	17.7 Where and how data or specimens will be stored?
	No specimens will be collected. As discussed earlier, all the data will be stored on REDCap.
	17.8 How long the data or specimens will be stored?
	No specimens will be collected. The data will be stored for the duration of the study, which is expected to take approximately two years, and for the duration of data analysis and peer-reviewed publication, which is expected to take another year. Realistically, the data will be stored for three years.
	17.9 If applicable, how data or specimens will be transported?
	Not Applicable.
	17.10 Who is responsible for receipt or transmission of the data or specimens?
	Not Applicable.
18.0 PROVISIONS TO MONITOR THE DATA TO ENSURE THE SAFETY OF SUBJECTS	**18.1 For more than minimal risk research, describe the plan to periodically evaluate the data collected regarding both harms and benefits to determine whether the subjects remain safe.**
	The participants will be undergoing surgical repair at UCMC for a mandible fracture. The participants participation in the study only lasts for the duration of the procedure. The evaluation of the data will be assessed following the completion of the procedure by the surgeon consented for participation in answering the Likert Scale questions. Routine surgical monitoring associated with current standards of care will be conducted by the surgical staff in the procedure room as assigned on the patients care team.
	18.2 What data are reviewed, including safety data, untoward events, and efficacy data?

	Clinician Monitoring and Respiratory System Monitoring typically conducted by various surgical team members assigned for the patient's surgical procedure.
	18.3 How will the safety information will be collected?
	Safety information will be collected by the patient's surgical team in the charting conducted both pre and post operatively to coincide with UCMC's current standards of care for surgical procedures.
	18.4 The frequency or periodicity of review of cumulative data.
	The review will follow the duration of the surgical procedure and standard six-week follow-up provided by the patients care team.
	18.5 Who will review the data?
	Data will be reviewed by the surgical team members.
	18.6 The statistical tests for analyzing the safety data to determine whether harm is occurring.
	Statistical testing will follow the outlined analysis for this current study as stated in the protocol.
	18.7 Any conditions that trigger an immediate suspension of research.
	The standard procedure is to not use a model, and thus we believe that looking at the model before the procedure is genuinely minimal risk. The surgeon will have already performed the review of the imaging (that forms the basis of the physical model), and therefore there is no risk of increased OR time for any patient. As we stated in the second to last paragraph of Page 3 in the initial submission, we are looking at potentially less time in the OR, as there will not be more time spent in the OR for any patient. This is looking to redefine the current standards of care minimizing the OR time already expected under the normal standards of care. No conditions would trigger immediate suspension as current standards of care will be utilized throughout surgery.
19.0 PARTICIPANT PRIVACY	**19.1 Describe the provisions to protect participants' privacy and to minimize the intrusiveness of the study questions or procedures.**
	Subject confidentiality will be protected to the extent permitted by law. Electronic databases with subject identifier will also be user-access protected. Subject identifiers will not be used, since medical record numbers will be replaced by de-identified patient ID numbers. The research data will be periodically reviewed by study team members to ensure that patient information and privacy is not at risk of being compromised. Patient privacy during evaluations and procedures will be maintained via standard-of-care HIPAA protocols.

20.0 COMPENSATION FOR RESEARCH RELATED INJURY	**20.1 For more than minimal risk research, describe the available compensation in the event of research-related injury.**
	Not Applicable- even though the research is labeled as more than minimal risk, the same standard surgical procedure will be carried out regardless of the use of the 3D model. Any complications that arise unexpectedly will be covered under UCMC surgical consent the patient signs before surgery that is routine for all surgical procedures conducted in the hospital.
	20.2 Provide a copy of contract language relevant to compensation for research-related injury.
	Not Applicable- even though the research is labeled as more than minimal risk, the standard surgical procedure will be carried out regardless of the use of the 3D model. Any complications that arise unexpectedly will be covered under UCMC surgical consent the patient signs before surgery that is routine for all surgical procedures conducted in the hospital.
21.0 ECONOMIC BURDEN TO SUBJECTS	**21.1 Describe any costs that subjects may be responsible for because of participation in the research.**
	There is no additional cost for the subjects for participation in the study

22.0 CONSENT	**22.1 Obtaining consent – Check applicable and complete the corresponding section(s). Please note, sections 23-28 each apply under different circumstances. Please complete the correct sections as checked in this section (e.g. if you do not request a waiver of documentation of consent, do not complete section 24)**	
	☒	**The research team will obtain written consent from all subjects. (Complete section 23) (HRP-502M TEMPLATE Medical Informed Consent or HRP-502S TEMPLATE SBER Informed Consent or HRP-502V TEMPLATE VA Informed Consent)**
	☐	**The research team will obtain consent from all subjects but is requesting a waiver of documentation (signature) of consent. (Complete sections 23 and 24) (HRP-502I TEMPLATE Information Sheet)**
	☒	**The research team is requesting a waiver or alteration of the consent process. (Complete section 25)**
	☐	**The research team is requesting Exception from Informed Consent for emergency research. (Please complete the EFIC supplement document and upload under number 3 on the local site documents page in RAP)**
	☐	**The research team will enroll Non-English-speaking subjects and obtain consent (written or otherwise). (Complete sections 23 and 26)**
	☐	**The research team will enroll subjects who are not yet adults (infants, children, teenagers) and will obtain written consent from the subject's parent(s) or guardian(s). (Complete sections 22 and 27) (Parent Permission Template)**
	☐	**The research team will enroll adult subjects unable to provide consent (cognitively impaired individuals) and will obtain written consent from the subject's Legally Authorized Representative. (Complete sections 23 and 28)**

23.0 CONSENT PROCESS	**23.1 Where will the consent process take place?**
	For patients: A research team member will go over the consent form with potential subjects in a private area and will answer any questions subject may have. Subject will be given a copy of the consent and time as needed to consider enrolling in the study. A phone number will be given in case the subject has additional questions. All subjects are to receive copies of their signed consent form. The date the subject signs the consent form is to be recorded on CRF. For surgeons: The research coordinator will go over the consent form with the surgical team members in a private area and will answer any questions subject may have. The surgeons will be given a copy of the consent and time as needed to consider enrolling in the study. A phone number will be given in case the subject has additional questions. All subjects are to receive copies of their signed consent form. The date the subject signs the consent form is to be recorded on CRF.
	23.2 Is there a waiting period available between informing the prospective subject and obtaining the consent?
	There will be a minimal waiting period, (< 60 minutes) between informing prospective patients of interest in study involvement and obtaining consent.
	23.3 Describe: • **The role of the individuals listed in the application as being involved in the consent process.** • **The time that will be devoted to the consent discussion.** • **Steps that will be taken to ensure the subjects' understanding.** • **Steps that will be taken to minimize the possibility of coercion or undue influence.**

For patients:
A research team member will accompany a surgical team member to the pre-operative consultation appointment for a prospective study patient about to undergo treatment for a mandible fracture. The team member will bring the necessary consent forms.

During this appointment the surgeon will introduce the research team member first so they can introduce the study to determine patients' willingness to participate. That way if the patient isn't interested in participating minimum time out of the visit has been spent discussing study. If subject agrees, the study team member will begin the consenting process.

During the consenting process the research team member will go over all the details and timelines for the study. Contact information will also be provided so if any questions or concerns arise, they can contact the study team.

The study team will ensure that the patient is by no way obligated to participate in this study. The procedure and normal post operative standards of care will be provided if the patient participates or not. There will be adequate time for the patient to ask any question or discuss any concerns.

Participants will be provided a consent for both to review and take with them during their appointment visit. The one copy the research team will obtain the signature of the participant and the research team member that obtained the consent. This form will be kept in the regulatory binder in the research coordinators office in a locked filing cabinet in a personal office where only the study team members have access to.

For surgeons:
The research coordinator will establish a private meeting with each surgical team member involved in the study who will be preforming the surgical repair for a mandible fracture. The research coordinator will bring the necessary consent forms for the surgeon's review.

During this appointment the study coordinator will introduce the Likert scale questions that the surgeon will be responsible for answering post- operatively if they are selected to use the 3D model for that procedure. That way if the surgeon elects to remove themselves from the study, they may do so at that present time. If the surgeon agrees to the Likert scale questions, the study coordinator will begin the consenting process.

During the consenting process the research team member will go over all the details and timelines for the study. Contact information will also be provided so if any questions or concerns arise, they can contact the study team.

The study team will ensure that the surgeon is by no way obligated to participate in this study. The procedure and normal post operative standards of care will be provided if the

	patient participates or not. There will be adequate time for the surgeon to ask any question or discuss any concerns. Participants will be provided a consent for both to review and take with them during the meeting. The one copy the research team will obtain the signature of the participant and the research team member that obtained the consent. This form will be kept in the regulatory binder in the research coordinators office in a locked filing cabinet in a personal office where only the study team members have access to.
	23.4 Describe how consent of the subject will be documented in writing.
	Both the patients and surgeons will be provided a consent for both to review and take with them. The one copy the research team will obtain the signature of the participant and the research team member that obtained the consent. This form will be kept in the regulatory binder in the research coordinators office in a locked filing cabinet in a personal office where only the study team members have access to.
	23.5 Describe the conditions under which you believe it would be appropriate to obtain ongoing consent from the subjects.
	Ongoing consent and communication will be important throughout the study. The subject has the right to be removed from the study at any point in time. It is crucial that the subject's recovery and well-being be placed above determining effectiveness of the device. Subjects will be provided the research coordinators phone number and IRB contact information so they can report any issues if need be or any issues directly to the IRB if worried about notifying the study team directly.

24.0 WAIVER OF DOCUMENTATION OF CONSENT	**24.1 Justification for waiver of consent documentation. Check all that apply and provide rationale for all checked items. Please note that certain combinations of the selections below may justify a waiver of documentation. Please refer to HRP-411 – MEMBER CHECKLIST Waiver of IC Documentation to determine if your study qualifies for a waiver of documentation, and which boxes to check to justify the waiver.**	
	☒	**N/A not requesting a waiver of documentation of consent.**
	☐	**The research presents no more than minimal risk to subjects.** Rationale/Explanation
	☐	**Written information describing the research is to be provided to the subject, subject parent(s) or guardian(s), or subject Legally Authorized Representative.** Rationale/Explanation
	☐	**Written information describing the research does not need to be provided to the subject, subject parent(s) or guardian(s), or subject Legally Authorized Representative.** Rationale/Explanation
	☐	**The research involves no procedures for which written consent is normally required outside of the research context.** Rationale/Explanation
	☐	**The only record linking the subject and the research would be the consent documentation.** Rationale/Explanation
	☐	**The principal risk of a signed consent document would be the potential harm resulting from a breach of confidentiality.** Rationale/Explanation
	☐	**The subjects are members of a distinct cultural group or community in which signing forms is not the norm.** Rationale/Explanation
	☐	**There is an appropriate alternative mechanism for documenting that informed consent was obtained.** Rationale/Explanation
	☐	**The research is not FDA-Regulated.** Rationale/Explanation
	☐	**The written script of the information to be provided orally, electronically, or on paper (information sheet) includes all required and appropriate additional elements of consent disclosure. When requesting a waiver of documentation, an information sheet is required. This box should always be checked for a waiver of documentation. (Follow HRP-502I TEMPLATE Information Sheet)** Rationale/Explanation
	☐	**Other Describe** any other reasons/explanations for request of waiver/alteration

25.0 WAIVER OR ALTERATION OF CONSENT PROCESS	**25.1 Justification for waiver or alteration of the consent process. Check all that apply and provide a rationale/explanation for all checked statements. Please note that certain combinations of the selections below may justify a waiver of or alteration of consent. Refer to HRP-410 – MEMBER CHECKLIST Waiver of IC Process to determine if your study qualifies for a waiver or alteration of consent, and which boxes to check to justify the waiver or alteration.**	
	☒	**N/A Not requesting a waiver or alteration of consent process.** Rationale/Explanation
	☐	**The research does NOT involve non-viable neonates.** Rationale/Explanation.
	☐	**The research involves no more than Minimal Risk to subjects.** Rationale/Explanation.
	☐	**The research could NOT practicably be carried out without the waiver or alteration.** Rationale/Explanation
	☐	**The waiver or alteration will NOT adversely affect the rights and welfare of the subjects.** Rationale/Explanation
	☐	**Whenever appropriate, the subjects will be provided with additional pertinent information after participation.** Rationale/Explanation
	☐	**The research is NOT FDA regulated.** Rationale/Explanation
	☐	**Other** Describe any other reasons/explanations for request of waiver/alteration
26.0 CONSENT OF NON-ENGLISH-SPEAKING SUBJECTS	**26.1 Indicate what language(s) other than English are understood by prospective subjects or representatives. (Please note that if non-English speaking subjects will be consented, translated consent forms must be uploaded into the consent section of the RAP Smart Form. For Greater than minimal risk studies, a third-party translation certificate is also required. For minimal risk studies, the consent must be translated by someone independent of the study team and their credentials should be provided.)**	
	Not Applicable	
	26.2 If subjects who do not speak English will be enrolled, describe the process to ensure that the oral and written information provided to those subjects will be in that language. Indicate that language that will be used by those obtaining consent.	
	Not Applicable	

27.0 CONSENT OF SUBJECTS WHO ARE NOT YET ADULTS (infants, children, adolescents)	**27.1 Describe the criteria that will be used to determine whether a prospective subject has not attained the legal age for consent to treatments or procedures involved in the research under the applicable law of the jurisdiction in which the research will be conducted (e.g. individuals under the age of 18 years (Ohio))**
	Subjects will receive an ID check during the screening process, to ensure no patients under the age of 18 are included in the study.
	27.2 Describe whether parental permission will be obtained. (Parent Permission Template)
	• Parental permission for inclusion in this study will be determined by the parents and/or legal guardians that accompany the patient to the surgical consult. A research team member will go over the consent form with potential subjects and accompanying parents and/or guardians in a private area and will answer any questions subject may have. Subject will be given a copy of the consent and time as needed to consider enrolling in the study. A phone number will be given in case the subject has additional questions. All subjects are to receive copies of their signed consent form. The date the subject signs the consent form is to be recorded on CRF
	27.3 Describe whether permission will be obtained from individuals other than parents, and if so, who will be allowed to provide permission. Describe the process used to determine these individuals' authority to consent to each child's general medical care.
	Not Applicable
	27.4 Indicate whether assent will be obtained from all, some, or none of the children. If assent will be obtained from some children, indicate which children will be required to assent. (HRP-502Y Youth Assent or Medical Assent Template)
	N/A
	27.5 When assent is obtained, describe whether, and how, it will be documented.
	N/A

28.0 CONSENT/ASSENT OF COGNITIVELY IMPAIRED ADULTS	**28.1 For potentially cognitively impaired adults, describe the process to determine whether an individual is capable of consent.**		
	N/A		
	28.2 List the individuals from whom permission will be obtained in order of priority. (Please note that the consent form will require revision to add a signature line for LAR and authority of LAR).		
	(N/A		
	28.3 Describe the process for assent of the subjects. Indicate whether assent will be required for all, some, or none of the subjects. If some, indicate which subjects will be required to assent and which will not.		
	N/A		
	28.4 If assent will not be obtained from some or all subjects, explain why.		
	N/A		
	28.5 Describe whether assent of the subjects will be documented and the process to document assent.		
	N/A		
29.0 HIPAA	**29.1 If you will use hospital or other healthcare provider records, data from a research data repository or any other information maintained by a hospital, academic medical center, or another healthcare entity, how will you gain access to the information? (check all that apply, i.e. if you will request a waiver for screening and obtain a signed authorization upon enrollment, check both).**		
	☐	**Not using HIPAA-protected information for any research activities**	
	☒	**Through a HIPAA Authorization signed by the participant (or their legally authorized representative).**	
	☐	**Requesting that the IRB approve a waiver of authorization in this application. Submit HRP-209 – FORM – UC Waiver of HIPAA Authorization**	
	☐	**As a limited data set under a data use agreement.**	
30.0 STUDY INTERVENTION/ INVESTIGATIONAL AGENT	**30.1 FDA – Select all that apply.**		
	☐	**Drugs/Biologics**	**The proposed research involves the administration of an article (e.g. drug, biologic, herbal preparation, dietary supplement, etc.) to a human where the article is intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease or is intended to affect the structure or any function of the body. For both FDA and non-FDA approved article. Include HRP-306 – WORKSHEET Drugs and Biologics in the submission in RAP.**
	☐	**Devices**	**Any research that involves the use of a device (medical or other devices, approved or investigational) to test the safety or**

			effectiveness of the device or the device is the focus of the research. Note: This includes research that will use human samples to test the safety or effectiveness of a device. Include HRP-307 – WORKSHEET Devices in the submission in RAP.
	☐	**Data Collection**	**Any research that involves the collection of data or other results from individuals that will be submitted to, OR held for inspection by, the FDA. In general, this would include research that involves any data that will be provided (in any form) to a pharmaceutical, medical device or biotech company.**
	☐	**Specimens**	**Any research activity where specimens (of any type) from individuals, regardless of whether the specimens are identifiable, are used to test the safety or effectiveness of any device (medical or other devices, approved or investigational) and the information will be submitted to, or held for inspection by, the FDA.**
	☒	**Not Applicable**	**None of the above describes my research.**
	30.2 Describe the study intervention and/or investigational agent (e.g. drug, device) that is being evaluated.		
	Not Applicable		
	30.3 Drug/Device Handling: Describe plans to store, handle, and administer those drugs or devices so that they will be used only on subjects and be used only by authorized investigators.		
	Not Applicable		
	30.4 If the drug is investigational and has an IND or if the device has an IDE, or claim of an abbreviated IDE (non-significant risk device) include the information below: • **Identify the holder of the IND/IDE/Abbreviated IDE** • **Explain the procedures followed to comply with the sponsor requirements for FDA regulated research (as applicable, 21 CFR 11, 21 CFR 54, 21 CFR 210, 21 CFR 211, 21 CFR 312, 21 CFR 812, 21 CFR 820)** • **If the PI holds the IND/IDE, please include the FDA Application and the FDA Letter of Acknowledgement on the Drugs/Devices page of the RAP Smart Form. Please also note that a Safety Monitoring Plan will be required if the PI holds the IND/IDE.**	
	Not Applicable		
31.0 ADDITIONAL REVIEWS AND CONSIDERATIONS	**31.1 Check all that apply.**		
	☐	**The proposed research meets the definition of a clinical trial, is regulated by HHS, and requires that the consent form is posted to a federal website within 60 days of completion** **Clinical Trial: A research study in which one or more human participants are prospectively assigned to one or more interventions (which may include**	

		placebo or control) to evaluate the effects of those interventions on health-related or behavioral outcomes.
	☐	**The proposed research involves embryonic stem cells or xenotransplantation.**
	☐	**The PI is responsible for registration of this study on www.clinicaltrials.gov. (Please contact the Human Research Protection Program with questions about clinicaltrials.gov)**
	☐	**The proposed research requires review by the Institutional Biosafety Committee (IBC). IBC review is required for research that will utilize infectious agents, select agents, recombinant DNA or viral gene transfer vectors, toxins for human gene transfer or genetically modified agent.**
	☐	**The proposed research requires Radiation Safety Committee (RSC) review. RSC review is required if the research involves participants being exposed to radiation for research purposes or an increase in frequency or duration of radiological imaging procedures.**
	☐	**UC Student is serving as Principal Investigator (Add the Faculty Advisor to the Study Team Members page in the RAP Smart Form and ensure that their CV is included in their RAP profile.)**
	☐	**UC study team members will be conducting research activities at international location(s).**
		If the research involves international locations, describe additional safeguards included to protect the rights and welfare of subjects recruited in these locations. Refer to HRP-399 – MEMBER WORKSHEET International Research for more information on the information required for review for international studies.
		Description, e.g. information about local research oversight, local context, etc.
	☐	**Collection of information that may include incriminating activities (e.g. illicit drug use, illicit sexual behaviors, fraudulent behaviors, theft, abortion or other related activities that may be illegal in some states, assault)**
	☐	**Review of UC Student records without obtaining consent. If so, a FERPA waiver is required. (Please reach out to Lorre Ratley with UC Office of General Counsel.)**
	☐	**Sharing of genomic information generated from NIH-funded research**
	☐	**UC Health services will be utilized (check applicable).**
		☐ **Investigational Drug Services** ☐ **Imaging Services** ☐ **Lab Services**
	☐	**CCHMC Services will be utilized (check applicable).**
		☐ **CICRL** ☐ **IRC** ☐ **SRC**

	☐	**Acute Care Research (Research that occurs within 24 hours of a visit to an emergency department or unscheduled admission, or within 24 hours of identification of a new or worsening condition – characterized by sudden onset requiring immediate care)**
	☐	**The research team will send data FROM the United States TO another country:** if so, list the country or countries here
	☐	**The research team will send data FROM another country TO the United States:** if so, list the country or countries here

32.0 REGULATORY OVERSIGHT	**32.1 Check the applicable federal oversite and/or funding.**			
	☐	**Environmental Protections Agency**	☐	**Department of Energy**
	☐	**Tribal Law**	☐	**Department of Defense**
	☐	**Department of Justice**	☐	**Department of Education**
	☐	**Food and Drug Administration**	☐	**Health and Human Services (NIH)**
	☐	**Office of Civil Rights**	☐	**National Science Foundation**
	☐	**Veterans Affairs *See Below**	☐	**Other Federal Agency**
	☐	***Check if you will enroll non-veterans**	☐	**ICH-GCP (E6)**
	☐	**Specify other federal agency/oversight** Name		

33.0 SETTING	**33.1 Where will research activities take place, including where data will be stored/accessed (check all that apply).**			
	☐	**Barrett Cancer Center**	☐	**Infectious Disease Clinic (Holmes-UC Health)**
	☐	**Blue Ash Campus**	☐	**Kettering Laboratory**
	☐	**Cincinnati State Technical and Community College**	☐	**Linder Center of Hope**
	☐	**Clermont College**	☐	**Liver Transplant Clinic (Medical Arts Building)**
	☐	**College of Allied Health Sciences**	☒	**Medical Sciences Building**
	☐	**College of Arts & Sciences**	☐	**Shriners Hospital**
	☐	**College of Business**	☐	**Talbert House**
	☐	**College Conservatory of Music**	☐	**UC Gardner Neuroscience Institute**
	☐	**College of Design, Art, Architecture & Planning**	☒	**UCMC (Emergency Department, Inpatient and Outpatient Units)**

	☐	**College of Education**	☐	**UCMC NICU**
	☐	**College of Nursing**	☐	**University of Cincinnati Physicians (UCP)**
	☐	**College of Pharmacy**	☐	**University Pointe Surgical Hospital**
	☐	**Crossroads Center**	☐	**VA – Cincinnati Medical Center**
	☐	**Drake Center**	☐	**VA – Chillicothe Medical Center**
	☐	**Genome Research Institute (Reading Campus)**	☐	**VA – Columbus Medical Center**
	☐	**Hoxworth: Inpatient Unit**	☐	**West Chester Hospital**
	☐	**Hoxworth: Outpatient Clinics**	☒	**Other UC/UC Health Affiliated location/clinic:** Holmes Hospital Oral and Maxillofacial Surgery Outpatient Clinic

34.0 EXTERNAL LOCATIONS	**34.1 List any external locations to UC or its affiliates.**
	N/A

	35.1 List any references sited throughout the protocol below.

35.0 REFERENCE LIST

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