# **Consent Form Instructions and Template**

**Instructions**

* The consent form is **only one part** of the ongoing dialogue between researchers and participants. It is important to remember that obtaining the consent of each participant is a process that lasts throughout the study.
* Any text in the example form that is *italicized* is intended for direction only and should not be included in the final consent form.
* The consent process and recruitment should be described in the protocol in specific detail.
* The consent form should be written at an eighth-grade level and give the participant a clear understanding of the experience they can expect to have if they agree to participate. The form should be as easy as possible to read and understand. Grammar, sentence structure, spelling, and the format of the document combine with the content to accomplish this goal. Avoid complex or lengthy sentences, medical, scientific, and/or technical terms, and dense paragraphs. Use “bullets” or simple tables to explain topics or regimens clearly. Drawings or pictures might be necessary to help explain complex procedures or interventions.

* **The information in the consent document should be limited to the study question**.
* Avoid describing study visits, treatments, and procedures in lengthy narrative form. If the visits, treatments, and procedures are lengthy or complex, consider using a separate page that can be attached to the consent document, similar to the lay version of the schedule of events from the sponsor’s protocol, to describe the study visits, procedures, and treatments in detail for the participant. The body of the consent document should summarize the study visits, procedures, or treatments in a simple, concise format, using headers and bullets where possible.
* To help avoid unnecessary delay, please proofread the document before submitting it to the IRB/EC for review.
* For ease of reading, the consent document should be a single sided document, printed with a minimum of 1-inch margins, (leaving a 1.5 x 1.5 inch space in the lower right corner of each page for the IRB/EC approval stamp), using the same font type and size (13 or larger) throughout, double space between the paragraphs, and bold or underline the section headers.
* Suggested wording is contained in the consent template. The document should be written in the second person, using the present or future tense. Do not begin sentences with “You understand that”, “It has been explained to you that”, or similar assumptive phrases. To avoid confusion, use “study doctor” throughout the document, instead of “doctor” and “participant” instead of “patient” or “subject”.
* For studies with optional tissue or specimen banking, this information should not be included in the main consent document but added as an addendum, with a full signature block.
* For a sub-study, the additional information should not be contained in the body of the main consent document but added as an addendum, with a full signature block OR a completely separate consent document.
* Please review all language in the consent document to ensure that the correct information specific to your project is relayed to potential participants.
* A copy of the signed consent form must be filed in your study file and in the participant’s medical record (if appropriate), and a copy must be given to the participant.
* Absent extenuating circumstances, the investigator’s signature should be obtained within 72 hours of the participant’s signature.
* Each page of the consent document must be numbered and contain a header or footer with the study title and the name and title (Principal Investigator) of the Principal Investigator, version date, and, for studies with multiple consent documents, a short description of the document.
* HIPAA: The Health Insurance Portability and Accountability Act requires all consent documents to contain the following information:
	+ Description of health information to be gathered;
	+ Who may use or disclose the information;
	+ Who may receive the information;
	+ Description of the purpose of the use or disclosure;
	+ Expiration date of authorization (for example, end of study);
	+ Statement of right to revoke authorization;
	+ Statement of right to refuse to sign authorization;
	+ Statement regarding re-disclosure;
	+ Individual’s dated signature

Suggested language is included in the consent template.

CONSENT TO participate IN A CLINICAL RESEARCH STudy

and

AUTHORIZATION TO DISCLOSE HEALTH INFORMATION

**Study Title:**

**Funding Sponsor:** Apyx Medical Corporation

 5115 Ulmerton Road

 Clearwater, FL 33760

Principal Investigator:

Address:

Telephone: (xxx) xxx-xxxx

24-hour emergency telephone: (xxx) xxx-xxxx

**INTRODUCTION**

*<sample text>*

*You are being asked to join in a research study because* ***[****explain the specific reason(s) in lay language****].*** *Please ask us about anything in this document or that you do not understand. It is your choice to participate in this study, and you can change your mind later.*

**PURPOSE**

***(Briefly describe the purpose of the research study, including the device, treatment area, and expected effect on the treatment area.)***

*<sample text>*

*We are doing this study to learn about* ***[****explain in lay language the basic purpose(s) of the study****]****.*

**NUMBER OF PARTICIPANTS and DURATION of PARTICIPATION**

***(Update number of participants per site, total number of study sites and total number of participants.)***

*<sample text>*

*Approximately xx people will be in this study at this study site. Up to X study sites in the United States will be in this study. We expect that a combined total of up to x people will be in the study.*

*If you choose to be in this study, your participation will last x months following your study procedure. You will not be allowed to have any other cosmetic or plastic surgery procedures done on your xxxxxxx until after you finish your xx follow-up visit.*

**PROCEDURES**

***(Briefly explain in lay language the study visits, tasks, procedures, therapies, tests, etc. involved in this study.)***

*Describe what will happen at each study visit from screening to exit.*

*When applicable, clearly describe:*

* *whether the devices are being used in ways that are not FDA approved;*
* *the use of placebo;*
* *whether all participants will receive the same therapy;*
* *the process of randomization, “by chance, like the flip of a coin”, if there are two study groups, or “like pulling numbers out of a hat”, if there are more than two study groups;*
* *if blood will be drawn, state the amount;*
* *what will occur at each study visit;*
* *identify any procedures, therapies, and/or tests that are considered experimental, and include a list of the tests/procedures being done for research purposes only. For example, “*If you enroll in this study the following additional tests or procedures will be performed*:”;*
* *the expected duration of study participation.*

Use tables and/or charts to simplify this section. If there are multiple study groups, explain this by listing the groups using the following:

<sample text>

*If you decide to join this research study you will be assigned by chance, like the flip of a coin, to one of the following groups:*

***Group A*** *– receives* ***[****insert treatment****]***

***Group B*** *– receives* ***[****insert treatment****]***

*Neither you nor your study doctor will know ahead of time what group you will be in, and you cannot choose which group you will be in.*

**POTENTIAL RISKS**

***(Update the risks based on treatment area, device, and any applicable medications.)***

*Identify all reasonably foreseeable side effects, risks, discomforts, or complications that could occur.*

*Whenever possible, risks should be grouped (either bulleted or in a chart) and identified by severity, likelihood and duration. For example, “common but not serious”, “unlikely but serious”, “occasionally” or “rare”, and “temporary” or “permanent” may be used. Avoid using specific numbers to describe a risk, e.g., “one person experienced”, which would necessitate a revision to the consent document each time an adverse event is reported or experienced. Whenever possible, using a table to summarize risk information should make the document easier to read and understand.*

*If applicable, include the risks of being in a placebo or observation group. If participants will be taken off medication they are currently receiving, either during a washout phase or because they will receive a different medication, you must include these risks, along with information describing how they will be monitored.*

*Include risk of loss of confidentiality or privacy.*

*Note: When the study involves therapy or procedures that would be recommended if the medical care were delivered outside the setting of a research protocol, it is appropriate to explain that the risks associated with such therapy will not be avoided by choosing not to participate in the study.*

<sample text>

*Use of the Renuvion APR device for improving the appearance of lax tissue in the neck and under the chin is considered investigational. The potential risks with the Renuvion APR device are similar to those seen with many routine procedures used by your doctor to improve the appearance of lax tissue. If you are in the study, you may experience none, some, or all of the potential risks or discomforts listed below. It is also possible that you may experience very uncommon or previously unknown problems or discomforts. Risks associated with the use of the Renuvion APR device may include:*

* *Unintended (not planned) burns. Early warning signs of burns include:*
* *Increased pain in any one particular area*
* *Discoloration of the tissue – it could present as waxy, white tissue or darkened tissue.  If the tissue is darkened, it could initially take on the appearance of a bruise.*
* *A sensation of heat or warmness in any one particular area*
* *Blisters*
* *Peeling skin*
* *Red skin*
* *Swelling*
* *Gas buildup causing temporary (not permanent) and transient (lasting only for a short time) crepitus (crackling sound or grating feeling under the skin) or pain*
* *Nerve injury (any symptoms of this), although anticipated to be temporary if they occur, could be permanent. Nerve injury symptoms include**unusual sensations such as pins-and-needles, pricks, tingling and numbness, burning pain or coldness, electric shock-like brief painful sensations, nerve weakness, muscle atrophy (wasting or loss of muscle tissue), twitching, and paralysis.*
* *Seroma formation (a pocket of fluid that sometimes develops in the body after surgery)*

*Patients using drugs that thin the blood (such as aspirin or NSAIDs, may experience increased bruising or bleeding at the procedure site.*

*Risks associated with tumescent anesthesia (lidocaine and epinephrine) include blurred vision, mental/mood changes, drowsiness, dizziness, unusually slow heartbeat, rash, itching, swelling, anxiety, apprehensiveness, restlessness, tremor, weakness, sweating, palpitations, pallor, nausea and vomiting, headache, and respiratory difficulties.*

*There might be side effects that are not known at this time. Please ask your doctor to explain other risks that may be associated with the procedure. You will be closely watched for side effects. You should tell the study staff about any unusual symptoms or signs you may notice during this study, even if you think these symptoms or signs are minor or not related to the study.*

*Being a part of this study while pregnant may expose the unborn child to significant risks. Therefore, pregnant women and women who are nursing their babies will be excluded from the study. If you are pregnant or will become pregnant during participating in the study, the study procedure may include risks to the embryo or fetus (unborn baby) that are currently unknown.*

*The study will collect information about your health that could identify you. This means that it is possible that your confidentiality may be breached. This is a rare risk that can occur when someone who does not have permission to see your protected health information gains access to it. The study team has put measures in place to minimize the risk of this happening.*

**POTENTIAL BENEFITS**

***(Update potential benefits based on expected effect of treatment).***

<sample text>

*The potential benefit of a procedure with the Renuvion APR device may be an improvement in the appearance of lax tissue of the xxxxx. The information obtained from the study may help others.*

**ALTERNATIVES**

***(Explain alternatives in lay language****).*

*For treatment studies, identify and explain the alternative procedures or courses of treatment reasonably available to the participant (i.e., standard of care).*

*Explain whether the research therapy or treatment can be obtained off study.*

*<sample text>*

*Your doctor will tell you about other treatments for improving the appearance of lax tissue in the xxxx that are currently approved by the FDA. Ask your doctor about the risks and benefits of alternative treatments before you decide to be in this study.*

**PREGNANCY**

*<sample text>*

*If you are pregnant or breastfeeding, you will not be allowed to be in this study. If you become pregnant while in this study, you need to tell your doctor immediately.*

**COSTS AND COMPENSATION**

***(Clearly explain the costs that the participant will be responsible for, versus the charges that will be paid for by the sponsor and include any additional costs the participant may incur because of study participation or that may result from participation in the study. These costs DO NOT include Research Related Injuries.)***

*<sample text>*

*You should proceed with payment of your XXX surgery as you are doing (personal payment, insurance coverage, or a combination of both). There will be no cost for the Renuvion treatment.*

*You will be compensated for participating in this study. You are being asked to return to the clinic for follow-up visits that you would not normally have if you were not in this study. You will be compensated according to the following schedule:*

|  |  |
| --- | --- |
| ***Study Visit*** | ***Compensation Amount*** |
|  |  |
|  |  |
|  |  |
|  |  |
|  |  |

**RESEARCH FUNDING & CONFLICT OF INTEREST**

*<sample text>*

* ***Funding disclosure****: The practice(s) and investigator(s) are receiving a grant from Apyx Medical Corporation to support this research.*
* ***Conflict of Interest****: The study doctor has no conflict of interest.*

***OR***

*The study doctor owns stock in the sponsor company and receives additional honoraria from the study sponsor for activities unrelated to this study. If you have any concerns about this financial relationship, please ask the research staff.*

**PARTICIPATION IS VOLUNTARY**

*<sample text>*

*Your participation in this study is voluntary. You can decide not to be in the study at any time. If you decide not to be in the study or to stop being in the study, your decision will not result in any penalty or loss of benefits to which you are entitled. Your decision, either way, will not affect your relationship with your doctor or the care that you receive.*

*If you decide to stop being in the study, please tell your doctor in writing. Your doctor may also end your participation in the study at any time without your consent. An example of why your doctor may do this would be because he/she feels it is in your best medical care to no longer participate.*

*The funding sponsor of the study or the IRB/EC can also stop the study at any time. You can decide to see another doctor at any time if you want to.*

*We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.*

**NEW FINDINGS**

*<sample text>*

*Your doctor will tell you about any significant new findings that are learned during this research. This new information may affect your willingness to stay in the study. Your consent to continue to take part in this study may be obtained again.*

**CONFIDENTIALITY AND ACCESS AND USE OF HEALTH INFORMATION**

*<sample text>*

*Your research records that are reviewed, stored, and analyzed at [office location] will be kept in a secured area. For research records sent to the Study Sponsor, you will not be identified by name, social security number, address, or phone number. The records may include: a code number, date of birth, and initials. The list that matches your name with the code number will be kept in a locked file in the office of the Principal Investigator. The results of your procedure in this study, including tests and procedure notes, may be published for scientific purposes. Your identity will not be revealed by any reports or publications. You will not be identified by name.*

*Your study doctor and the funding sponsor of the study must follow the laws set forth by the Food and Drug Administration (FDA) for clinical trials and/or the European Union Medical Device Directive for clinical trials conducted in the European Union. It may be necessary for your health information to be reviewed by the FDA, Institutional Review Boards, Ethics Committees, and/or other government authorities that review the safety and welfare of patients and medical devices.*

*If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your procedure and does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has seen or will see your records. To request this information, please call [NAME (from IRB/EC)] at [PHONE NUMBER].*

*There is no limit to the length of time we will keep yourinformation for this research study because it may be analyzed for many years. We will keep it as long as it isuseful, unless you decide you no longer want to take part, orwe close the study. You are allowing access to this information indefinitely.*

*A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results and you can search this website at any time.*

**RELEASE OF PHOTOGRAPHIC DATA COLLECTED**

***(Update photographic area(s) and follow-up timepoints per study protocol.)***

*<sample text>*

*Photos will be taken of your xxxx before your procedure. Photos will also be taken of your xxxx at the following approximate times:*

*The photos will not include your name or other identifying information about you. Identifiable features (such as eyes, nose, or mouth) will not be de-identified (masked) on the photos. The photos will be used as visual documentation of the status of the laxity of your neck tissue and tissue under your chin and may be used in scientific publications. By signing this consent form, you authorize disclosure of this information to the sponsor and other authorized people described in this consent form.*

**RESEARCH RELATED INJURY**

***(Describe your practice injury policy)***

*<sample text>*

*Every effort to prevent injury as a result of your participation will be taken. It is possible, however, that you could develop complications or injuries as a result of participating in this research study. In the case of injury or illness resulting from your participation in this study, medical treatment is available to you at xxxx. You will [or will not] be charged the usual and customary charges for any such treatment you receive. You will [or will not] be responsible for charges associated with research-related injury that are not paid by your insurer or other third-party.*

**CONTACTS FOR QUESTIONS**

***(Update Investigator and IRB/EC name and contact information.)***

*<sample text>*

*While participating in this study, you have the right to have any questions you answered. You may contact the Principal Investigator at any time in case you have further questions about the research or to report a research-related injury or with questions about participant rights and privacy issues.*

 *[INVESTIGATOR NAME]*

*[PHONE NUMBER]*

*For more information about participation in a research study and about the Institutional Review Board (IRB) [or Ethics Committee (EC)], a group of people who review the research to protect your rights, you should contact [NAME (from IRB/EC)] at [PHONE NUMBER].*

*If you decide to be in the study, you will be given a copy of the consent document. It is suggested that you keep a copy of this document for your later reference and personal records.*

**SUMMATION/SIGNATURE**

*<sample text>*

*I have read and understand the above description of this research study. I have been informed of the risks and benefits involved, and all of my questions have been answered to my satisfaction. A member of the research team will answer any future questions I may have. I voluntarily agree to join this study and know that I can withdraw from the study at any time without penalty. I also grant permission to my study doctor to use my study data and photographs for medical education and scientific purposes such as presented at medical industry meetings or published in medical journals. I understand that these images may be used by my study doctor as stated above without further notifying me and that my name will not be used. By signing this form, I have not given up any of my legal rights and I indicate that I am voluntarily choosing to take part in this research.*

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Signature of Participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed Name of Participant

**Person Obtaining Consent Statement**

*<sample text>*

*In addition to advising the above participant of other forms of treatment and therapy which are appropriate, I have offered an opportunity for further explanation of the risks and discomforts which are or may be associated with this study and to answer any further questions relating to it.*

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_**
**Person Obtaining Consent Signature                   Date**

**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**
**Person Obtaining Consent Printed Name**

**Health Insurance Portability & Accountability Act (HIPAA) Authorization Agreement: Permission to Review, Use, and Release Information about You**

*<sample text>*

*If you decide to be in this study, the study doctor and research team will use and share health data about you within the group to conduct the study. Health data may include:*

* *Your name*
* *Address*
* *Phone number*
* *Date of birth*
* *Medical history*
* *Information from your study visits, including all test results.*

*Health data may come from your study records or from existing records kept by your doctor or other health care workers.*

*For this study, the research team may share health data about you with authorized users. Authorized users may include:*

* *Representatives of XXX IRB/EC (a Research Ethics Review Board that reviews this study)*
* *The Food and Drug Administration (FDA)*
* *International Regulatory Agencies (if audited by such)*
* *Laboratories working with the sponsor on this study*

*Authorized users are subject to and are obliged to follow the same HIPAA and federal privacy laws.*

*Your permission to use and share health data about you expires in 50 years. You may take back your permission to use and share health data about you at any time by writing to the study doctor. If you do this, you will not be able to stay in this study. No new health data that identifies you will be gathered after your written request is received. However, health data about you that have already been gathered may still be used and given to others as described in this form.*

*Your right to access your health data in the study records will be suspended during the study to keep from changing the study results. When the study is over, you may access your study health data.*

*If you decide not to sign this form, you will not be able to participate in the study.*

STATEMENT of authorization

*<sample text>*

*I have read this form and its contents were explained. My questions have been answered. I voluntarily agree to allow study staff to collect, use, and share my health data as specified in this form. I will receive a signed and dated copy of this form for my records. I am not giving up any of my legal rights by signing this form.*

 \_\_\_\_/\_\_\_\_/\_\_\_\_

Signature of Research Subject Date

Printed Name of Research Subject

STATEMENT OF PERSON EXPLAINING Authorization

*<sample text>*

*I have carefully explained to the subject the nature and purpose of this form. I have been available to answer any questions that the subject has about this form.*

 \_\_\_\_/\_\_\_\_/\_\_\_\_

**Signature of Person Explaining Authorization** Date

**Printed Name Person Explaining Authorization**