Procedure for Use of Synovetin OA®

[*Note: Licensee to modify to match specific facility operations.*]

Scope

This procedure is designed to be used in conjunction with the veterinary hospital's normal operating procedures and addresses those aspects which are unique to Synovetin OA®.

A primary objective of this procedure is to ensure that pet owners understand and can comply with any post-treatment restrictions and instructions before treatment is initiated, and again before the dog is released. In this procedure, there are three interactions with veterinary personnel specifically trained in the use of unsealed sources. If, during any of these interactions compliance with instructions and restrictions cannot be confirmed, then treatment will not be administered, or the dog will not be released.

The following process is summarized in a flow chart in Appendix A

Procedure A: Identification of Dogs for Treatment with Synovetin OA®.

The purpose of Procedure A is to:

1. Determine the common behavior patterns of the owner(s) with the dog,
2. Determine if those behavior patterns create any risk for any household member to exceed the public dose limits and,
3. If necessary, examine whether or not the owner(s) can modify certain behaviors necessary to comply with the public dose limits.

If the licensee concludes the owner is not willing or able to comply with any limitations necessary to preserve the public dose limits, then treatment will not be offered.

A1. The veterinarian will examine the dog and determine if Synovetin OA is medically appropriate.

A2. If so, the veterinarian will discuss Synovetin OA with the owner.

A3. The licensee will conduct the Pre-Screening Questionnaire (Appendix B) with the owner to determine the behavior patterns of the dog and owner(s). The owner will have full knowledge of household member's interaction with the proposed dog.

A3.1. The Pre-Screening Questionnaire is contained in Appendix B. Follow each prompt in the Pre-Screening Questionnaire with assistance from the content included in this Procedure (A3.2.-A3.9.).

A3.2. Collect information regarding the dog(s) and household members (anyone that shares the residence where the dog lives).

A3.3. Ask the owner to describe the behavior of their dog. Use leading questions that need more than a yes/no answer. Suggested questions include:

- What does your dog typically do during the day?
- Where does it sleep?
- Who primarily interacts with the dog?

A3.3.4. How does the dog interact with family members on a daily basis? For each activity, determine:

- What is the interaction?
- Which person?
- For how long?
- At what distance? [Note the owner will typically think of the distance from the dog's body to the closest portion of the owner's anatomy. Attempt to discern the distance from the dog's elbow to the center of the owner's torso and categorize as <1 foot, 1 foot, 3 feet, or more than 3 feet. Round down for added conservatism.]

A3.3.5. Are there any other behaviors or interactions we have not discussed yet?

A3.4. Compile the answers to determine the amount of time each person spends at distances of <1 foot, 1 foot, or 3 feet on a daily basis. The time at more than 3 feet does not need to be considered.

A3.5. Complete the questions on the remainder of the questionnaire.

A3.5.1 The "Additional Items" section of the Pre-Screening Questionnaire is the opportunity for licensee to provide a focused discussion on applicable items to that household. Examples may include the general ALARA principle, strategies to minimize public dose with attention to kids and potentially pregnant members of the household, clarifying dialogue about the distances associated with direct, close, and intermediate contact (anytime less than 1ft falls into the direct category", how to carry a treated dog to minimize dose, reminders that the duration of Release Instructions apply to the behaviors that the owner(s) provide, what to do if their pet is injured or expires, when boarding the treated animal would be appropriate, what to do if the owner thinks any of the limits have been exceeded (e.g., travel across State or National borders).

A3.6. Flag any asterisked questions where the answer was yes. Review those in detail and discuss with the owner whether the identified behavior can be changed and if so how. Note any specific behavior modifications on the Pre-Screening Questionnaire and also on the Release Instructions. [Note: The objective is to eliminate or reduce duration of identified behaviors such that the daily interactions with the dog are for no more than 1 minute a day at less than a foot, 15 minutes a day at 1 foot, and 4 hours a day at 3 feet]

A3.6.1 The asterisked questions on the Pre-Screening Questionnaire reflect those conditions which may contraindicate the therapy. If the owner(s) are not able to modify their behaviors to comply with the Release Instructions, the Authorized User may make an informed decision to contraindicate the therapy. There may be other clinical factors which may influence the decision of the AU such as unique time and distance behaviors exhibited by the dog/owner, split time caring for the dog by multiple owners, or other conditions that are not expressly covered in the Questionnaire. The AU has the ultimate responsibility to ensure regulatory limits are met.

A3.7. Determine which of the four categories of dog/owner distance behaviors is applicable and explain to owner. Determination should be conservatively based on each household member's interactions. This table will aid in the determination of the duration of the Release Instructions. Note that only category will apply for the entire household.

Common Contact
Up to 5 min/day direct contact (e.g., joint to torso) 15 min/day @ 1 ft 4 h/day @ 3 ft e.g., feeding, grooming, petting, dog walking
Extended Duration Intermediate Contact
Up to 5 min/day direct contact (e.g., joint to torso) 15 min/day @ 1 ft 12 h/day @ 3 ft e.g., dog rests at the feet of the owner etc.
Extended Duration Close Contact
Up to 5 min/day direct contact (e.g., joint to torso) 3 h/day @ 1 ft e.g., holding dog in lap or on the couch, extended grooming, etc. 4 h/day @ 3 ft
Prolonged Close and Intermediate Contact
Up to 5 min/day direct contact (e.g., joint to torso) 11 h/day @ 1ft e.g., dog sleeps in the owner's bed etc. 9 h/day @ 3 ft e.g., dog rests at the feet of the owner etc.

A3.8. If the licensee is confident the owner understands the need to comply with public dose limits and the household can comply with the Release Instructions, then proceed with scheduling the procedure, ordering Synovetin OA® and then continue with the following procedures. If the licensee is not confident the owner and other household members can comply with the Release Instructions as needed, exit this procedure and do not offer treatment with Synovetin OA®.

A3.9. If the procedure moves forward, the licensee will retain the signed copy of the Pre- Screening Questionnaire.

Procedure B: Review Release Instructions, Scheduling Treatment

The purpose of this procedure is to ensure that owners appreciate and understand the Release Instructions they would receive immediately after treatment (including any specific behavior limitations that may have been identified in Procedure A). The licensee will explain that dogs cannot be released without a signed copy of the Release Instructions specific to each dog, so care is taken to ensure owners understand those Release Instructions and confirm their ability to comply before treatment is planned. Only if the owner gives that confirmation, will treatment be scheduled and Synovetin OA ordered.

B1. Review the Release Instructions with the owner. Confirm that the owner understands and will comply with all of the applicable instructions.

B2. Schedule treatment and then order Synovetin OA in accordance with manufacturer requirements and schedule treatment.

B3. When the Synovetin OA arrives, receive and handle the package in accordance with site shipping and receiving procedure and radiation safety program precautions.

Procedure C: Treatment and Release

In this procedure, the owners are reminded of the Release Instructions prior to treatment. After the dog is treated and the release measurements taken, the licensee completes the Release Instructions with the appropriate duration, and presents them to the owner for signature. The dog will not be released until the owner signs the Release Instructions. Upon release, the owner is given a copy of the signed Release Instructions for ongoing reference. The licensee will retain a copy of the signed Release Instructions. Additionally, the licensee should review the Release Instructions with the owner(s) should any follow up care be provided to ensure public dose limits are met.

C1. Treatment

C1.1. On the day of treatment, re-review the Release Instructions with the owner, discuss any behavior modifications that are required.

C1.2. Follow standard site personnel safety requirements.

C1.3. Prepare the injection in accordance with the directions on the package insert.

C1.4. The dog shall be injected by trained staff under the supervision of the AU.

C1.4.1. If the injection site is missed, the owner must be informed that re-treatment can be scheduled 1 year from the initial treatment date.

C1.5. After the procedure, perform contamination surveys in accordance with the site procedures. Check the treatment site for removable contamination and decontaminate as needed.

C2. Release

C2.1 Once the dog is recovered and medically stable for release, perform exposure rate surveys of the dog at a distance of 1 meter from the nearest treated elbow. Surveys should be performed at the dog's elbow height anteriorly and left and right laterally. Record the highest reading.

C2.2 If the highest reading is greater than 0.45 mR/h, the dog must be held at the facility until such time as the highest reading is 0.45 mR/h or less. A decrease in the exposure rate reading of approximately 5% per day can be expected.

C2.2.1 If the dog must be held, kennel the dog in the kennel(s) identified for holding dogs treated with Synovetin OA.

C2.2.2 Resurvey the dog periodically (typically daily) until the release exposure rate criteria is met.

C2.2.3 Fill in the duration of time on the Release Instructions and present to the owner for signature.

C2.2.4 After the owner signs the Release Instructions, releasethe dog and provide the owner with a copy of the signed Release Instructions. The licensee will retain a copy of the signed Release Instructions.

C2.2.5 Reinforce to the owner that they may return to their normal interactions with the dog after expiration of the written instruction but that they should continue to practice ALARA (time and distance moderation) for the next two weeks afterwards.

C2.2.6 Instruct owner that if the dog dies within 20 weeks to contact you. In the event that the dog dies, burial may proceed without restriction. Delay cremation until less than 10 uCi is present (e.g., approximately 20 weeks for largest dog from date of being treated with both elbows).

C3. Post-Release

C3.1 Retain in the files a copy of the completed and signed Pre-Screening Questionnaire.

C3.2 Retain in the files a copy of the signed Release Instructions with the recorded release exposure rate.

C3.3 Follow up with the patient's owner approximately one week after the procedure. Remind the owner on how to keep doses ALARA and review compliance with the Release Instructions. Document in the files if follow up contact was successful or not and the date of follow up. If the owner indicates that the household has not complied with the written instructions, perform a dose assessment to determine the dose to date of the individual household members and formulate corrective actions for the household members to follow as necessary.

C3.4 Investigate any instances where public dose limits may have been exceeded including instances when owners have self-reported exceeding the limitations prescribed in the Release Instructions. If at any point, it is determined that the dose to a member of the public has exceeded 100 mrem, send the NRC a written report within 30 days as required by 10 CFR 20.2203.

Appendix A

Process Flow Chart