A. PURPOSE AND BACKGROUND:

Collagen is actually part of the natural support structure of your skin. Collagen can be injected into your skin to fill certain lines and facial furrows. Based on the results of a clinical study a pretreatment skin test for allergenicity is not required. As all medical and cosmetic procedures carry risks and may cause complications, the purpose of this document is to make you aware of the nature of the procedure and its risks in advance so that you can decide whether to go forward with the procedure.

B. PROCEDURE:

1. This product is injected into the areas of the face that might benefit from being filled with Collagen to eliminate or reduce the wrinkles and folds.

2. An anesthetic, a numbing medicine (lidocaine) is incorporated into the product to reduce the discomfort of the injection. Please let your doctor know if you are allergic to lidocaine before the treatment. Lidocaine makes the administration of the collagen and the procedure more comfortable.

3. Multiple injections may be required depending on the site, depth of the wrinkle(s) and its location(s).

4. If the treated area is swollen directly after the injection, ice may be applied to the site for a short period.

5. After the first treatment, additional Collagen injections may be necessary to achieve the desired level of correction.

6. Periodic touch-up injections help sustain the desired level of correction. How long the injection results last are variable to the individual but on average the human collagen correction lasts from 3-12 months.

C. RISKS AND DISCOMFORT:

1. Although a very thin needle is used, injection-related reactions may occur. These include: some initial swelling, pain, itching, discoloration, bruising, or tenderness at the injection site. These reactions may increase if you are using substances that reduce blood clotting, such as aspirin or other non-steroidal anti-inflammatory drugs, such as Advil, vitamin E or Ginkgo Biloba. These reactions generally lessen or disappear with a day or two.

2. As with all injections, this procedure carries the rare risk of infection.

3. Some temporary lumpiness may occur before absorption of the Collagen. Massaging the area by the administrator is beneficial to the overall results.

4. Some patients may experience additional swelling or tenderness at the implant site and rarely pustules may form. These reactions may last for 2 weeks, and in rare cases, may need to be treated with oral corticosteroids or other therapy.

5. Most patients are pleased with the results of Collagen use. However, like any cosmetic procedure, there is no guarantee that you will be completely satisfied. There is no guarantee that wrinkles and folds will disappear completely. You may
require additional treatments to achieve the results you seek. While the effect of Collagen use may last longer than other comparable treatments, the procedure is still temporary. Additional treatments will be required periodically, generally within 3-12 months, for the effect to continue.

6. Collagen must not be used in people with a history or serious allergic reactions or a know allergy to lidocaine.

7. Though unlikely, it is possible for an area of tissue death to occur that leads to a scab and/or scar formation. Local necrosis (tissue damage) is a very rare event.

8. The use of this product in patients who have collagen vascular diseases such as rheumatoid arthritis, systemic lupus erythematosus, polymyositis, dermatomyositis, or scleroderma may result in a greater chance of an allergic reaction or result in shorter durations of the collagen replacement.

9. Current recommendations limit the volume of Collagen to 30cc/year.

10. Injectable collagen should be used with caution in people who have asthma, hay fever, eczema, or a history or multiple allergies.

11. As with all procedures that involve an injection through the skin, this injection also runs the risk of infection and also activating or aggravating cases of latent facial herpes simplex at or near the site of injection. Please let your doctor know if you have a history of cold sores.

12. These injections should be avoided in areas of active skin infection.

13. Its use in pregnant women and nursing women has not been studied for safety.

D. POST TREATMENT CONSIDERATIONS:

1. In the first 24 hours you should avoid:
   - Strenuous exercise
   - Alcoholic beverages
   - Extensive sun or heat exposures

2. Exposure to the above may cause temporary redness, swelling, and/or itching at the injection sites.

3. Makeup may be applied a few hours post-treatment if no complications are present
   (e.g. open wounds, bleeding, and infection)

E. BENEFITS:

1. Collagen has been shown to be safe and effective, when compared to other approved filler materials. Its effect, once the optimal frequency, and areas to be corrected are established, can last 4-6 months or longer without the need for re-administration.