

FROM: SGHG

21 December 1971

SUBJECT: Research Protocol

TO: SGS

1. TITLE: The Radioimmunoassay of Serum Human Follicle-Stimulating Hormone (FSH) and Luteinizing Hormone (LH)

2. PURPOSE: The development of the radioimmunoassay for serum FSH and LH is proposed to:

- a. Establish this procedure as the first stage in a series of clinical investigations in reproductive physiology.
- b. Support future clinical studies of hypopituitarism and hypoovarianism, and amenorrheas of adrenal and ovarian origin.
- c. Determine responsiveness of pituitary to ovulation stimulating drugs (clomiphene citrate, glucocorticosteroids, and gonadotropin releasing factors).

3. BACKGROUND: Since the development of radioimmunoassay techniques, precise measurement of serum FSH and LH has been sensitive enough to detect the daily fluctuations in the normal ovulatory menstrual cycle (4,5,6,7,8,21,22,23,26,27,28,34). In the normal cycle serum FSH and LH gradually rise early during the follicular phase followed by a mid-cycle surge of both; serum LH having a greater peak than FSH, with return of both, during the luteal phase, to levels lower than those found in the follicular phase.

Postmenopausally, both serum FSH and LH are markedly elevated and decrease following appropriate estrogen therapy (14). In hypopituitarism, as would be expected, serum FSH and LH are low or undetectable (13). In the differential diagnosis of amenorrhea, serum gonadotropins are most helpful and far more accurate than urinary gonadotropins by bioassay. Various etiologies may be distinguishable, such as hypopituitarism (low), anorexia nervosa (normal) gonadal dysgenesis (high), and primary ovarian failure (high) (4,13,14,19).

Daily serum gonadotropins done in women with Stein-Leventhal syndrome indicated low mean serum FSH values when compared to follicular levels in normal women (12,36,37). Although the fluctuations of serum LH were wider than normal, ranging from low to elevated, the majority of patients had mean serum LH values that were within the range of the follicular phase of the ovulatory cycle (12,14). Others have reported that mean serum LH values in the Stein-Leventhal syndrome were consistently and significantly elevated when compared to normal ovulatory women (36,37). Some patients with the amenorrhea-galactorrhea syndromes (Post-Pill amenorrhea-galactorrhea,