	WORKSHEET: Recruitment Materials			IRB #
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The purpose of this worksheet is to provide support for the convened IRB or Designated Reviewers when evaluating recruitment and advertising materials meant to be seen or heard by subjects. This worksheet is to be used. It does not have to be completed or retained.

1 Recruitment or Advertisements (All must be “Yes”)


<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Is the activity considered recruitment and/or advertising materials? There are some activities that do not constitute recruitment and/or advertising materials for human subject’s research, including, but not limited to:</p> <ul style="list-style-type: none"> • Communications intended only to be seen or heard by healthcare professionals, such as “dear doctor” letters and doctor-to-doctor letters; • News stories, so long as they are not intended for recruitment purposes (e.g., a phone number at the end to contact for more information to participate in a particular study, full details of inclusion/exclusion criteria of a particular study, etc.); and • Publicity intended for other audiences (e.g., media releases regarding types of services available or offered by a particular clinic, institute, or physician).
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2 Context (All must be “Yes” or N/A)

<input type="checkbox"/> Yes <input type="checkbox"/> No	The application describes the mode of communication (e.g. in person, “cold calling”, email, etc..)
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For printed advertisements, the final copy is being reviewed
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For audio/video tape, the tape is the final version
<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	For website/social media advertisements/posts the screenshots provided represent the final versions and if multiple platforms are being used, they should be identified
<input type="checkbox"/> Yes <input type="checkbox"/> No	For studies using “cold calling”, the study does NOT include the collection of sensitive information (e.g. substance abuse, sexual health, mental health) nor is the study high risk
<input type="checkbox"/> Yes <input type="checkbox"/> No	For Mychart recruitment, the study does NOT include Adults with Diminished Decision-Making Capacity, or Children (see policy)

3 The Recruitment Material: (All must be “Yes”)

<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT state or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT promise “free treatment,” when the intent is only to say subjects will not be charged for taking part in the research
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT include exculpatory language
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT emphasize the payment or the amount to be paid, by such means as larger or bold type
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The advertisement is limited to the information prospective subjects need to determine their eligibility and interest, such as:</p> <ul style="list-style-type: none"> • The name and address of the investigator or research facility • The condition under study or the purpose of the research • In summary form, the criteria that will be used to determine eligibility for the study • Brief list of what study participation entails (study procedures, number of visits, time or other commitment required of the subjects) • A brief list of participation benefits if any (per FDA guidance)

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	<ul style="list-style-type: none"> The location of the research and the person or office to contact for further information
<input type="checkbox"/> Yes <input type="checkbox"/> No	The recruitment material or advertisements include reimbursement information, the information is not coercive to potential subjects and the \$ amount is NOT overemphasized.

4 For Social Media Advertising and Recruitment Materials: (All must be “Yes”)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>The investigator provided the following: (see Corewell advertising policy for more detailed information):</p> <ul style="list-style-type: none"> The name of all sites/applications/platforms that will be utilized; The content of the post that will be published; If applicable, how the social media is governed; The name an owner of the account from which the recruitment will be posted and how the team will present themselves; Confirmation that the frequency of each post is kept to the minimum number of posts necessary to achieve exposure
<input type="checkbox"/> Yes <input type="checkbox"/> No	The study team provided the plan for monitoring comments, sharing, and “likes” of recruitment posts and filtering/hiding/reporting inappropriate comments or comments that are against the Terms of Use for the application/platform. This includes any plans to delete comments or replies to interactive posts.
<input type="checkbox"/> Yes <input type="checkbox"/> No	The study team explained how any monitoring to posts and the lines of authority for any editing will occur.

5 For FDA-Regulated Research, The Advertisement: (All must be “Yes”)	
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT make claims, either explicitly or implicitly, that the test article is known to be equivalent or superior to any other drug, biologic or device
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.
<input type="checkbox"/> Yes <input type="checkbox"/> No	Does NOT include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.